HOW COULD SHARED PATIENT EXPERIENCE SUPPORT THE PROCESS OF DECISION-MAKING IN STARTING INSULIN THERAPY IN NON-INSULIN-TREATED ADULTS WITH TYPE 2 DIABETES IN THE UK?

Thesis submitted for the degree of Doctor of Philosophy

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Abstract

How could shared patient experience support the process of decision-making in starting insulin therapy in non-insulin-treated adults with type 2 diabetes in the UK?

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Background: Many individuals with type 2 diabetes are reluctant to accept insulin treatment. As a complementary resource to formal support, an intervention based on shared patient experience might be able to facilitate such a process. Presently, however, there are many uncertainties about the evidence to support the pragmatic use of shared patient experience.

Methods: Several research techniques were used to examine these issues. A review of existing systematic reviews was conducted to clarify the idea of shared patient experience in a context of type 2 diabetes management in general. Second, a systematic review explored the impact of shared patient experience on health in adults with type 2 diabetes. Third and fourth, two linked studies, a narrative literature review of qualitative studies and a secondary analysis of an existing collection of qualitative interviews examined patients' attitudes, experiences, information/support needs in relation to the initiation of insulin therapy. Fifth, a primary qualitative study investigated patients' views and preferences toward the use of shared patient experience to support the process of decision-making in starting insulin. Finally, a proposed intervention design was developed based on all the evidence provided by the previous studies.

Results: More new knowledge was contributed to the field of shared patient experience in diabetes care by identifying a working definition of shared patient experience, some common components of shared patient experience and some studies highlighting the evidence of the effects of shared patient experience on disease-related health in type 2 diabetes. It also revealed the patients' reluctance about moving onto insulin, concerns about the lack of communication about insulin with their healthcare providers prior to insulin, a range of valuable potential shared patient

experience has to help patients in the decision-making process, and the patients' preferences about different formats of shared patient experience. This evidence suggested that shared patient experience, delivered though a face-to-face one-to-one discussion and/or an online curated collection of the filmed narrative interview material conveying certain key elements of peers' stories, could be an appropriate, efficient and acceptable way to deliver such an intervention in the context of insulin decision-making in type 2 diabetes.

Conclusion: There are still many patients being left with psychological concerns about insulin and without sufficient support to overcome such concerns, suggesting a need for additional support which can be delivered as a supplement to formal support provided by healthcare professionals. Shared patient experience could be one of the potential strategies to help ease the process of insulin decision-making.

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Acronyms used in this thesis

UK	United Kingdom
RCTs	Randomized Controlled Trials
IDF	International Diabetes Federation
UKPDS	United Kingdom Prospective Diabetes Study
HbA1c	Haemoglobin A1c
DESMOND	Diabetes Education and Self-Management for Ongoing and Newly Diagnosed
USA	United States of America
CDSMP	Chronic Disease Self-Management Programme
RCT	Randomized Controlled Trial
HIV	Human Immunodeficiency Virus
MND	Motor Neurone Disease
MRC	Medical Research Council
PS	Peer Support
SS	Social Support
SR	Systematic Review
DSME	Diabetes Self-Management Education
CHW	Community Healthcare Worker
SMA	Shared Medical Appointment
SDP	Socially Disadvantaged Populations
LHL	Low Health Literacy
QOF	Quality And Outcomes Framework
BMI	Body Mass Index
SD	Standard Deviation
HCP	Healthcare Professional
SPE	Shared Patient Experience

DCP	Diabetes Care Profile
CdR	problem solving ability scale (Condotte di Riferimento)
DKN	Diabetes Knowledge assessment scales
DKQ	Diabetes Knowledge Questionnaire
WHOQOL	World Health Organization Quality of Life abbreviated version scale
SKILL-D	Spoken Knowledge in Low Literacy in Diabetes scale
GISED	Education Study Group of the Italian Society for Diabetes
SF36	Medical Outcomes Study - Short Form-36
DQOL	Diabetes Quality of Life questionnaire
VR-36	SF-36 for Veterans
WHOQOL-BREF	WHOQOL abbreviated version scale
DRP	Diabetes-related Problems questionnaire
SF-12	Short-Form General Health survey
DHBM	Diabetes Health Belief Measure
DSEQ	Diabetes Self-Efficacy Questionnaire
C-DMSES	Diabetes Management Self-Efficacy Scale
DES	Diabetes Empowerment Scale
DESSF	Diabetes Empowerment Scale Short-Form
PEI	Patient Enablement Instrument
PAID	Problem Areas in Diabetes scale
CES-D	Centre for Epidemiologic Studies Depression scale
PAID-2	Revised Problem Areas in Diabetes 2 scale
ATT 39	Psychological Integration scale
STAI	State Trait Anxiety Inventory
PHQ-9	Patient Health Questionnaire
WHO-5	5-item World Health Organization well-being index
WBQ-22	22-item Well-Being Questionnaire

DSS	Diabetes Support Scale
ISEL	Interpersonal Support Evaluation List
MHCCQ	Health Care Climate Questionnaires
C-PTES	Perceived Therapeutic Efficacy Scale
MHLC	Multidimensional Health Locus of Control Scale
DTSQ	Diabetes Treatment Satisfaction Questionnaire
SDSCA	Summary of Diabetes Self-care Activities Assessment tool
FFB	Kristal Fat and Fibre Behaviour
FHQ	Food Habits Questionnaire
FFQ	Fred Hutchinson 12-page Food Frequency Questionnaire
PASE	Physical Activity Scale for the Elderly questionnaire
GLTEQ	Godin Leisure-Time Exercise Questionnaire
BRFSS	Behavioural Risk Factor Surveillance System
DSMT	Diabetes Self-Management Training
HE	Health Education
HB	Health Behaviour
IG	Intervention Group
CG	Control Group
N/R	Not Reported
GPs	General Practitioners
DSM	Diabetes Self-Management
HDL	High-Density Cholesterol
HPLC	High Performance Liquid Chromatography
RIAIM	Roche Integra Automated Immunoturbidimetric Method
NGSPS	National Glycohemoglobin Standardization Program Standards
AC	Affinity Chromatography
MSER	Mono Sion-Exchange Resin

AIGHA	Abbott IMX Glycosylated Hemoglobin Assay
ACOPM	Adaptation of the Cholesterol Oxidase/Peroxidase Method
CEHOPM	Cholesterol Ester Hydrolase Oxidase/Peroxidase Method
NZ	New Zealand
IPA	Interpretative Phenomenological Approach
NIDDM	Non-Insulin Dependent Diabetes
T2DM	Type 2 Diabetes Mellitus
GP	General Practitioner
NHS	National Health Service
DSN	Diabetes Specialist Nurse
RE-AIM	Reach, Efficacy, Adoption, Implementation and Maintenance
BMQ-Specific	Beliefs about Medicines Questionnaire - Specific
ITAS	Insulin Treatment Appraisal Scale
IMDSES	Insulin Management Diabetes Self-Efficacy Scale
DKT2	revised Diabetes Knowledge Test
ISEL	Interpersonal Support Evaluation List
HIN	Health Innovation Network
PPI	Patient and Public Involvement

Chapter 1. Introduction

1.1 Overview

The prevalence of type 2 diabetes is increasing rapidly across the world. In 2015, the number of people with diabetes was estimated at 415 million, and this is expected to rise to 642 million by 2040[1], with type 2 diabetes accounting for the majority (>85%) of total diabetes prevalence[2]. The United Kingdom (UK) is not exceptional, where incidence of the disease has nearly doubled over the past 10 years[3]. In 2015 in the UK, about 3.3 million people were reported to suffer from diabetes[4], with type 2 accounting for 85–90% of cases[5], and its prevalence is expected to rise to over 5.6 million by 2035[5].

Insulin therapy is currently thought the most effective diabetes medication in lowering glycaemia[6], and many individuals with type 2 diabetes ultimately require insulin treatment[6,7]. However, delay in starting insulin is still a major issue in type 2 diabetes care[8]. One of the factors that may explain this delay is patients' concerns toward insulin therapy[8,9]. Previous studies and reviews have reported various psychological factors involved in reluctance toward starting insulin as experienced by non-insulin treated patients, suggesting that decision-making in starting insulin treatment is not an easy process for many patients. To mitigate such psychological barriers and ease the decision-making process, the International Diabetes Federation (IDF) emphasises the importance of healthcare providers proactively explaining to patients the potential need for insulin treatment and eliciting and discussing concerns raised by patients from the early course of the disease[10,11]. Decision-making in insulin can be an intense and time-consuming process[12,13] especially for patients who have serious reservations. As such, it is important for healthcare providers to start discussions about insulin earlier rather than later in the disease process.

Previously, several sets of materials and toolkits have been developed to fulfil this need, many of which are developed for the use of healthcare professionals as a diagnostic tool to assess, and/or

problem-solving tool to address, patients' concerns about insulin[10]. In the UK such an approach as suggested by the IDF is also included as part of structured education programmes for type 2 diabetes[14]. Yet, these strategies may not sufficiently address the existing issues around the decision-making process, suggesting that additional strategies may be needed to address patients' concerns[10,15]. Delivering such strategies is also affected by severe resource constraints in public health systems[16-18]. Failure to address patients' concerns, however, is a major obstacle to optimal health for the millions with type 2 diabetes. There is an urgent need to develop interventions that support patients in the process of decision-making in starting insulin therapy.

One potential approach, not previously examined in detail, is a patient-focussed intervention based on shared patient experience. Patients frequently choose to seek information and support from each other. Evidence also suggests that some patients have positive views relating to the use of shared patient experience in a healthcare context[19-21]. If designed properly as a complementary resource to formal support, shared patient experience might be able to support the process of decision-making in starting insulin by helping patients alleviate their concerns toward insulin and build confidence in starting insulin, which in turn, may prevent unnecessary delay in starting insulin. Shared patient experience may also support public health systems by providing a potentially low-cost, flexible means of supplementing formal support for the decision-making process. Presently, however, research into shared patient experience in diabetes is still in its infancy[22]. There are many uncertainties about the evidence to support the pragmatic use of shared patient experience to ease the decision-making process. This research project aims to contribute to this area. By addressing gaps in the literature on shared patient experience in diabetes care, the project explores how shared patient experience could support the process of decision-making to commence insulin therapy in non-insulin-treated adults with type 2 diabetes in the UK. As a result, this thesis provides empirical evidence to design an intervention based on shared patient experience aiming to support the process of decision-making in starting insulin.

1.2 Motivations for the research

My research focus has been on the social, psychological, and cultural aspects of health and chronic illnesses, and especially on type 2 diabetes. This stems from my own experience with my father who has had type 2 diabetes for nearly 30 years. In the past, I observed his constant psychological battle with food and exercise to maintain good haemoglobin A1c (HbA1c) and yet his condition is still getting worse year by year. I also was shocked by the absence of effective psychosocial strategies available for patients for supporting such needs in Japanese clinical fields at that time. These experiences lead me to think psychology could be one of the crucial factors for helping patients manage the disease successfully. My psychology studies in the United States of America (USA) strengthened my research interest in such areas, and also made me realise that the UK was advanced in this field of research at that time.

Following my research interests, I took a master's degree course in health psychology in the UK, where I conducted a project on the influence of family relationships on diabetes self-management in Japanese adults with type 2 diabetes. The project showed that patients with better family relationships tended to have better clinical (e.g. HbA1c), psychosocial (e.g. quality of life), and health behavioural (e.g. exercise) outcomes. I conducted this DPhil project in order to further pursue my interest in research and to help contribute to the advancement of research in this field by filling in the gaps in the literature on shared patient experience in insulin decision-making in type 2 diabetes (discussed further in chapter 2).

1.3 Objectives of thesis

In order to do this, this thesis sets out to meet the following objectives:

- to clarify the idea of shared patient experience by examining explicit or implicit components of shared patient experience in the context of type 2 diabetes

- to find evidence of the impact of shared patient experience in adults living with type 2 diabetes

- to understand patients' attitudes and beliefs toward the initiation of insulin therapy

- to understand patients' attitudes and experiences in relation to information/support needs (in particular, support through shared patient experience) in the context of the decision-making process to commence insulin therapy

- to understand patients' views and preferences specifically toward the use of shared patient experience to support the process of decision-making in starting insulin therapy

- to design a possible future intervention based on the Medical Research Council (MRC) framework and a causal modelling approach

1.4 Structure of thesis

Chapter 2. Background

Chapter 2 outlines the background to the literature on the experiences of people with type 2 diabetes making the decision to commence insulin treatment. It describes why insulin treatment is important for type 2 diabetes, why decision-making to initiate insulin can be a problem for patients, how such a problem has been addressed in a current health care context, and why there is potential for using shared patient experience as a new intervention tool to support the decision-

making process in starting insulin. It concludes with summary points and the rationale for the thesis.

Chapter 3. Review of existing systematic reviews - A definition and systematic approach to components of shared patient experience in adults with type 2 diabetes

Chapter 3 reports on a review of existing systematic reviews on shared patient experience in adults with type 2 diabetes. This chapter sets out the introduction, aim, methods, results of the descriptive analysis, and concludes with a summary of the main findings and implications for the next study.

Chapter 4. Systematic review of randomized controlled trials on effects of shared patient experience on health in adults with type 2 diabetes

Chapter 4 reports on a systematic review of randomized controlled trials (RCTs) on the effects of shared patient experience in adults with type 2 diabetes. This chapter sets out the introduction, aim, methods, results of the descriptive analysis, and concludes with a summary of the main findings and implications for developing a future intervention.

Chapter 5. Analysis of existing sources of qualitative evidence exploring patients' attitudes, experiences, information/support needs in relation to the initiation of insulin therapy

Chapter 5 consists of two linked pieces of work, namely a narrative literature review of qualitative studies (chapter 5- part 1), and a secondary analysis of an existing collection of qualitative interviews (chapter 5- part 2). These two pieces of work are complementary and combine to assess the same aims and research questions. The chapter draws together results from these two pieces of work, and concludes with a discussion, implications for the next study, and conclusion.

Chapter 6. Primary qualitative study exploring patients' views and preferences toward the use of shared patient experience to support the process of decision-making in starting insulin therapy

Chapter 6 pursues a particular question in more depth, and assesses patients' views and preferences toward the use of shared patient experience to support the process of decision-making in starting insulin therapy. It describes the introduction, aim, methods, results, and concludes with a discussion, reflexivity, and conclusion.

Chapter 7. Discussion, Proposed intervention design, and Conclusion

Chapter 7 summarises the findings of the strands of research that make up this thesis, addressing gaps in the existing literature. All the findings of each of the individual components and their collective implications for a future intervention based on shared patient experience are explored in terms of what might be the most appropriate, efficient, and acceptable way to deliver a shared patient experience intervention. Finally, the conclusions that can be drawn from this thesis are described in full.

1.5 References

1. International Diabetes Federation. *IDF Diabetes Atlas.* Brussels, Belgium,2015.
2. Forouhi NG, Wareham NJ. Epidemiology of diabetes. *Medicine (Abingdon).* 2014;42(12):698-702.
3. Sharma M, Nazareth I, Petersent I. Trends in incidence, prevalence and prescribing in type 2 diabetes mellitus between 2000 and 2013 in primary care: a retrospective cohort study. *BMJ Open.* 2016;6(1).
4. Diabetes UK. Facts and stats. 2016. Accessed 10/11/2016.
5. Hex N, Bartlett C, Wright D, Taylor M, Varley D. Estimating the current and future costs of Type 1 and Type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs. *Diabet Med.* 2012;29(7):855-862.
6. Nathan DM, Buse JB, Davidson MB, et al. Medical Management of Hyperglycemia in

Type 2 Diabetes: A Consensus Algorithm for the Initiation and Adjustment of Therapy: A consensus statement of the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes Care.* 2009;32(1):193-203.

7. Swinnen SG, Hoekstra JB, DeVries JH. Insulin therapy for type 2 diabetes. *Diabetes Care.* 2009;32(Suppl 2):S253-S259.
8. Peyrot M, Rubin RR, Lauritzen T, et al. Resistance to Insulin Therapy Among Patients and Providers: Results of the cross-national Diabetes Attitudes, Wishes, and Needs (DAWN) study. *Diabetes Care.* 2005;28(11):2673-2679.
9. Prospective Diabetes Study Group UK. Prospective Diabetes Study 16. Overview of six years' therapy of type 2 diabetes - a progressive disease. *Diabetes.* 1995;44:1249-1258.
10. Brod M, Alolga SL, Meneghini L. Barriers to initiating insulin in type 2 diabetes patients: development of a new patient education tool to address myths, misconceptions and clinical realities. *Patient.* 2014;7(4):437-450.
11. International Diabetes Federation. Global Guideline for Type 2 Diabetes. International Diabetes Federation; 2012: http://www.idf.org/global-guideline-type-2-diabetes-2012. Accessed October 2013.
12. Minze MG, Dalal K, Irons BK. Removing barriers to insulin use. *J Fam Pract.* 2011;60(10):577-580.
13. Funnell MM, Kruger DF, Spencer M. Self-management support for insulin therapy in type 2 diabetes. *Diabetes Educ.* 2004;30(2):274-280.
14. Health Innovation Network. Structured education for people with type 2 diabetes: A toolkit for optimal delivery. 2014; http://www.hin-southlondon.org/system/resources/resources/000/000/047/original/Structured_Education_Toolkit_%28Final%29.pdf?1412668611. Accessed 10/02/2016.
15. Meneghini L, Artola S, Caputo S, et al. Practical guidance to insulin management. *Prim Care Diabetes.* 2010;4 Suppl 1:S43-56.
16. Kunt T, Snoek FJ. Barriers to insulin initiation and intensification and how to overcome

them. *Int J Clin Pract.* 2009;63:6-10.

17. Tang TS, Ayala GX, Cherrington A, Rana G. A review of volunteer-based peer support interventions in diabetes. *Diabetes Spectr.* 2011;24(2):85-98.

18. Winkley K, Evwierhoma C, Amiel SA, Lempp HK, Ismail K, Forbes A. Patient explanations for non-attendance at structured diabetes education sessions for newly diagnosed Type 2 diabetes: a qualitative study. *Diabet Med.* 2015;32(1):120-128.

19. Entwistle VA, France EF, Wyke S, et al. How information about other people's personal experiences can help with healthcare decision-making: a qualitative study. *Patient Educ Couns.* 2011;85(3):e291-298.

20. Gray R, Fitch M, Davis C, Phillips C. A qualitative study of breast cancer self-help groups. *Psychooncology.* 1997;6(4):279-289.

21. Ussher J, Kirsten L, Butow P, Sandoval M. What do cancer support groups provide which other supportive relationships do not? The experience of peer support groups for people with cancer. *Soc Sci Med.* 2006;62(10):2565-2576.

22. Simmons D, Bunn C, Cohn S, Graffy J. What is the idea behind peer-to-peer support in diabetes? *Diabetes Management.* 2013;3(1):61-70.

Chapter 2. Background

2.1 Overview

This chapter summarises the literature that provides a background to experiences of people with type 2 diabetes making the decision about whether or not to start insulin treatment. It describes why insulin treatment is important for type 2 diabetes, why decision-making about insulin can be a problem for patients, how this problem has been addressed in a current health care context, and why there is potential for using shared patient experience as a new intervention to support decision-making in starting insulin therapy. It concludes with summary points and the rationale for the thesis.

2.2 Diabetes and insulin therapy

2.2.1 Type 2 diabetes and progression to insulin treatment

Diabetes refers to a group of diseases characterized by abnormally high glucose levels[1]. Type 2 diabetes more commonly occurs later in life[2] and is sometimes known as late-onset diabetes or non-insulin-dependent diabetes mellitus. Due to the progression and underlying pathophysiology of the disease, patients with type 2 diabetes may produce too little insulin (loss of β-cell function resulting in gradual loss of insulin secretion) or may display insulin resistance, resulting in a build-up of glucose in the bloodstream. Left untreated, high levels of blood glucose can cause serious long-term health problems including diabetes complications (e.g. stroke, neuropathy)[3,4].

For patients with type 2 diabetes, reducing high levels of glycaemia (blood glucose levels) helps to delay progression of the disease and potentially prevents complications associated with diabetes. The United Kingdom Prospective Diabetes Study (UKPDS), for instance, has shown the importance of lower levels of blood glucose, reporting that each 1% reduction in mean haemoglobin A1c (HbA1c) was associated with a 37% reduction in risk of microvascular

complications such as diabetic nephropathy, neuropathy, and retinopathy and a 14% reduction in risk of macrovascular complications such as coronary artery disease, peripheral arterial disease, and stroke ($p < 0.0001$ for both), after taking into account confounding factors such as age, sex and duration of diabetes[5,6].

Patients newly diagnosed with the disease may initially achieve and maintain acceptable glycaemia through meal planning and physical activity. However, glycaemic control cannot normally be maintained indefinitely by these non-pharmacological methods, and many individuals with type 2 diabetes eventually need to use pharmacologic therapy[7]. While pharmacologic therapy initially starts with oral anti-diabetic drug treatment, the treatment eventually fails to maintain glycaemia target levels with disease progression. Thus, many patients ultimately require insulin treatment[8,9]. Insulin cannot be taken in pill form, and is usually administered into the layer of fat under the skin using a syringe, insulin pen or insulin pump. The insulin regimen to be prescribed also depends greatly on an individual patient's needs and lifestyle. Currently, insulin therapy is considered to be the most effective of diabetes medications in lowering glycaemia[8], and delaying progression of the disease by potentially preventing diabetes complications.

2.2.2 Patients' concerns about initiating insulin treatment

Despite the potential of insulin therapy to deliver a significant contribution to the health and well-being of persons with type 2 diabetes, many patients with type 2 diabetes who could benefit from insulin therapy currently do not receive it or do not receive it in a timely manner[10,11]. In fact, the initiation of insulin therapy is often delayed by between 1.8 and 5 years[12]. According to a recent study by Khunti et al. (2013), insulin had been initiated in just 1 in 5 people who had HbA1c levels of 7.5% or higher, despite their taking 3 anti-diabetic drugs[13].

Several factors are raised as contributing to a delay in commencing insulin therapy including behaviours and attitudes of healthcare professionals toward insulin, and patients' concerns about starting insulin therapy[14]. Studies have identified reluctance by patients to accept insulin treatment. In the United kingdom (UK), the UKPDS reported that 27% of patients initially refused insulin therapy[15]. A survey conducted in 13 countries in Asia, Australia, Europe, and North America, including a total of 2,061 non-insulin treated patients with type 2 diabetes, reported that over half of patients expressed negative attitudes toward insulin therapy[11]. In the United States of America (USA), a survey of 708 non-insulin treated patients with type 2 diabetes found that 28% showed unwillingness to initiate insulin therapy when advised to do so[16]. Similar findings were also reported in a prospective study of 100 non-insulin treated patients with type 2 diabetes conducted in the USA, where more than 30% were not willing or only partially willing to take insulin if advised[17]. Furthermore, Khan et al[18] investigated this problem longitudinally, and found that 42.5% of 212 patients who were prescribed insulin initially refused it, and that half of these continued to refuse insulin treatment even after repeated counselling.

Previous studies and reviews have highlighted psychological factors involved in reluctance toward and refusal of starting insulin therapy as experienced by non-insulin treated patients. These factors include perceptions that a requirement for insulin was an indicator of a more serious stage of their condition; the belief that insulin causes blindness, renal failure, or leads to amputations; low self-efficacy (lack of confidence to handle the day-to-day demands of treatment); and the belief that maintaining a more strict regime of non-pharmacological methods (e.g. exercise, diet) will control diabetes[17,19-22]. This may indicate that the decision-making in starting insulin therapy is not an easy process for many patients. A more in-depth understanding about patients' attitudes and experiences in relation to insulin therapy, including the views of those who have already begun insulin therapy, will be explored in chapters 5 and 6.

2.2.3 Proactive approach to mitigate concerns

In order to assist patients in overcoming such psychological barriers toward insulin therapy and to ease the decision-making process, in recent years, the International Diabetes Federation (IDF) has emphasised the importance of early information on insulin therapy, where healthcare providers proactively explain to patients the potential need for insulin treatment and elicit and discuss concerns raised by patients at an early stage of the disease[23,24]. The decision about the initiation of insulin is made through an active process of assessing the expected benefits and risks of taking insulin, and hence this can be an intense and time-consuming process requiring repeated follow-ups[7,25] especially when patients have serious reservations. It is thus crucial to understand and address their concerns toward insulin therapy as early as possible in the disease process.

Previously, various materials and toolkits have been developed to support this need. Many of them are developed for the use of healthcare professionals as a diagnostic tool to assess and/or problem-solving tool to address patients' concerns about insulin, and they include

- an insulin treatment appraisal scale (a 20-item self-report measure to help healthcare professionals identify patients' barriers toward and concerns about insulin therapy)[26];
- practical guidance on insulin management (a guide designed to help primary care physicians address the challenges of insulin management with their patients)[27];
- strategies for insulin injection therapy in diabetes self-management[28];
- right insulin, right time, right dose, for type 2 diabetes - a toolkit for optimal delivery[29];
- confrontation persistence and reality[7];
- the 5A programme[30]

  (the last four materials are guidelines or tools aimed at helping healthcare professionals identify patients' obstacles to effective initiation of insulin such

as fears and barriers around insulin, and address such obstacles through the use of specific strategies).

Yet, a recent study reported that most type 2 diabetic patients still chose not to start insulin regardless of whether they had discussed it with their healthcare professionals, and trusted them[24]. Such resources have also been criticised for not being used in a timely manner, where they have often only been considered at the time of actual initiation subsequent to the decision being made[27].

In the UK, such a proactive approach as suggested by the IDF is also included as part of structured education programmes for Type 2 diabetes run by healthcare professionals, to which clinicians are recommended to refer patients in the course of disease management[31]. A number of structured education models are available, with variations in the length of programme and follow-up, target audience (e.g. those who are newly diagnosed and/or with established type 2 diabetes), mode of delivery (e.g. group-based versus individual-based, online versus offline, type of facilitators), and theoretical models underpinning the programmes[31]. The most commonly provided include:

- Diabetes X-PERT (six weekly 2-hour offline group sessions based on the theories of empowerment and discovery learning, delivered by a diabetes research dietician, and developed for anyone with diabetes or at risk of developing it)[32];
- Diabetes Education for Ongoing and Newly Diagnosed Diabetes – DESMOND (one-day or two half-day 6-hour offline group sessions based on theories of learning, Leventhal's common sense theory, the dual process theory, and the social learning theory, delivered by two registered healthcare professionals, and developed for newly diagnosed or established diabetes)[33]; and
- Diabetes Manual (12-week one-to-one offline/online structured education programme based on self-efficacy theory, delivered by practice nurses, and developed for people with type 2 diabetes with an HbA1c over 7%)[34].

However, the topics on insulin that are covered in the programmes are often limited to physiological aspects of insulin (e.g. how insulin works in the body; when insulin treatment is required). Such information is important for helping people acknowledge the potential need for insulin treatment and build insulin-related knowledge, but it is unclear whether such programmes support patients to overcome concerns around and build confidence in starting insulin.

Moreover, while current strategies to support insulin decision-making (individually during a consultation or through structured education programmes) are often developed from the perspective of equipping healthcare providers to assess patients' concerns about insulin, barriers also exist to deliver such strategies. Several factors have been identified as contributing to such barriers including time, cost, and healthcare providers' perceptions that patients would always reject insulin[14,35]. Assessing patients' concerns individually during a consultation or through education programmes requires considerable time for healthcare providers. The cost of delivering current strategies using structured education programmes amounts to approximately £65 – 100 per patient[36]. In addition, there is the problem of low attendance rates at structured education programmes among patients with type 2 diabetes[37]. Recent studies have reported that uptake of programmes is low, particularly among those newly diagnosed[36]. As such, even if healthcare providers are equipped (in terms of time and cost) and motivated to provide support, patients may not attend to receive their support to mitigate whatever concerns toward insulin they may have.

This may suggest that the current organisation of health care may not be well suited to resolve the existing issues surrounding the decision-making process. Yet, such a gap in service is expected to worsen with the predicted future increase in patients with type 2 diabetes as well as growing demands on healthcare providers to address patients' concerns earlier in the disease process. There may be a need to look beyond formal education and interactions between an individual patient and healthcare provider to help ease the decision-making process. One possible response is an intervention based on shared patient experience. Patients themselves might be able to

mitigate psychological barriers toward insulin therapy, which in turn may improve the timing of the initiation of insulin therapy. The potential role of shared patient experience is explored in the next section.

2.3 Shared patient experience

2.3.1 Shared patient experience

Historically, sharing experiences with other patients is not new, and has long been available for people living with diseases such as through support groups and self-help groups[38], where people attempt to overcome disease-related issues, discuss new treatments, or share fears about the possible progression of disease. The format of shared patient experience varies considerably, ranging from talking to friends or other individual patients with the condition in everyday encounters, an unstructured support group where patients can share each other's experiences on any topic, to a more structured education programme where healthcare professionals or a patient lay leader facilitate sessions involving shared patient experience. The advent of social media and information technologies (e.g. Web sites, blogs, forums, Facebook, and Twitter) also extends the reach of the shared patient experience from the clinic/community buildings to the patient's home[39,40]. Such support delivered online could come at little or no financial cost to its recipients, and could be a highly cost-effective support tool for patients.

Since the development of the chronic disease self-management programme (CDSMP)[i] by Lorig and colleagues in the early 1970s in the USA, the idea of shared patient experience has often been

[i] The CDSMP is a community-based patient self-management education course led by trained lay persons with chronic conditions[41]. The programme is based on self-efficacy theory and incorporates skills mastery, reinterpretation of symptoms, modelling, and social persuasion to enhance a sense of personal efficacy (i.e., confidence in one's ability to manage different aspects of one's health functioning)[42].

discussed in relation to the concept of empowerment[ii], as one of the effective strategies to support patients in disease self-management[38,43-45]. Such a concept has been adapted to various self-management programmes for long term conditions[46], including structured education programmes for type 2 diabetes (as noted above)[47,48]. However, the empowerment-based self-management programmes have been criticised for not genuinely incorporating the idea of shared patient experience as a strategy to empower patients[38,49]. While in theory such programmes provide the ideal arena for patients sharing their own experiences with peers[49-52], they still tend to be heavily reliant on the medical model (e.g. emphasis on imparting factual clinical information)[49,52,53], where sharing disease experiences is treated as an 'unintended outcome of the programmes' rather than as an effective strategy to achieving empowerment[49].

Yet, several studies show that patients frequently choose to seek information and support from each other. According to a national, internet-based survey of 3,000 respondents in the USA, one in four adult Internet users living with a chronic condition reported going online to find others with similar health concerns and share information and personal health experience[54]. A survey conducted to explore patterns of participation in support groups for 20 disease categories in 4 metropolitan areas of the USA (New York, Chicago, Los Angeles, and Dallas) and 2 online forums, including a total of 12,596 support groups, reported that the highest rates of support groups seeking activity on the Internet were for chronic fatigue syndrome, followed by diabetes and then by breast cancer. Diabetes also ranked 8th highest among those seeking participation in face-to-face support groups[39]. Experiencing illness can elicit intense emotions and hence patients may have a desire to talk to others with a similar condition[39].

[ii] The concept of empowerment assumes that 'patients can accrue sufficient skills and information not only to be able to take greater control of their own health, but also to offer a significant resource for others'[38].

As a complementary resource to formal support for the process of decision-making in starting insulin, an intervention based on shared patient experience might be able to facilitate the decision-making process by maximising the potential benefits of the empowerment approach.

2.3.2 Research into attitudes toward/impact of shared patient experience (both online and offline) in healthcare

Research that has examined the use of sharing narratives has provided mixed results on patients' views toward the use of shared patient experience. Some studies have highlighted positive views. A study on women's experience of breast cancer self-help groups reported that the women who joined the group benefited from feeling that they were understood, provided hope for others, and were connected with others[55]. Another study conducted into people with various types of illness conditions suggested that hearing and/or reading stories of other patients' personal experiences could be an important part of the evidence that patients use when making decisions about health care[56]. A study conducted on nine Australian cancer peer support groups found that participants who joined the groups felt increased confidence, a sense of control in relation to the self, a sense of community, and unconditional acceptance, in contrast to the isolation and rejection frequently experienced outside the group[57].

By contrast, some studies have reported negative views amongst patients toward the use of shared patient experience. A study that examined non-participation in support groups among human immunodeficiency virus (HIV) positive men reported that patients often felt frightened of disclosing their HIV status due to resulting stigma and social rejection[58]. In research on non-participation and withdrawal from online support groups for women with breast cancer, Sandaunet et al. (2008) suggested that online support group communities could instil anxiety, expose patients to frightening illness trajectories, and produce emotional overload[59].

On the other hand, Locock and Brown (2010) argued that individuals' experiences of using shared patient experience may not be categorized simply as either positive or negative[60]. In their study on the attitudes to interactions with fellow patients with motor neurone disease - MND (both online and offline), they found that seeing the potential variability of symptoms from contact with fellow patients could create confidence, reassurance, and hope such as by witnessing a slower than sometimes expected deterioration process experienced by fellow patients, or positive examples of other patients coping well. But it could also lead to feelings of shock, fear and uncertainty by considering what different symptoms one might later encounter. Regardless of whether the individuals are currently using, have subsequently withdrawn from, or have never used shared patient experience, people's views toward shared patient experience may be a complex mixture of positive and negative feelings. Indeed, as Locock and Brown (2010) have shown, 'most people occupy a sliding space on the continuum and identify simultaneously encouraging and distressing elements of meeting others with the condition'[60].

These studies suggest mixed results on patients' views relating to the use of shared patient experience (online and offline). Such views can be positive and/or negative, and the two may not be mutually exclusive. While much has been studied regarding the benefits and drawbacks of shared patient experience, especially in HIV[58] and cancer[60], there has been little research into patients' views of shared patient experience in the decision-making process to start insulin in type 2 diabetes. This will be explored further in chapter 5 and particularly in chapter 6.

Research into the effects of shared patient experience in diabetes care has most commonly been conducted in the field of health behaviour research, which examines psychosocial factors (e.g. beliefs, attitudes) that affect people's health behaviour including behaviours beneficial to health (e.g. exercise), behaviours compromising health (e.g. alcohol, smoking), behaviours taken to identify and treat illness at an early stage (e.g. screening), decisions to seek medical treatment, adherence to treatment provided, and interpretations of symptoms[61,62]. In the research, the idea

of shared patient experience has most often been grouped under the term 'peer support'[38]. However, there are some notable problems and gaps in the literature. Use of the term 'peer support' does not always reflect the idea of peers as patients encountering each other in a mutual and non-hierarchical relationship, sharing experiences of illness. For instance, one study used the term 'peer support' to describe support from networks of family and friends, and not other diabetic patients[63]. In another study, while peer educators were people with diabetes, their only function was to give a lecture to the group of patients rather than mutually sharing experiences of how to manage the disease[64]. In fact, there is still disagreement between researchers about what peer support really means[38]. Uncertainties about the relevance of studies based on 'peer support' may suggest that there is currently no common understanding of the idea of shared patient experience as a concept in the field of diabetes research. Yet, the lack of common understanding creates challenges when attempting to synthesize shared patient experience studies, and to examine the impact of shared patient experience in diabetes care, specifically in relation to the process of making the decision to commence insulin in type 2 diabetes. These issues will be explored in chapters 3 and 4.

Overall, these studies show that empirical evidence is promising but as yet inconclusive in terms of whether the development of an intervention based on shared patient experience might support the process of decision-making in starting insulin in type 2 diabetes.

2.3.3 Theory

Despite these gaps in the literature on shared patient experience, health behaviour research may offer some theoretical perspectives that potentially explain why it may be an effective intervention tool to support patients in the decision-making process. Health behaviour of interest in this section and this project is the decision-making about starting insulin therapy. Four potential health behaviour theories that explain how shared patient experience influences health behaviour (e.g.

decision-making in starting insulin treatment) through psychosocial (social cognitive) factors are later discussed in more detail following the overview of the health behaviour theories.

Theories that explain health behaviour change are typically categorised into two main groups: 1) social cognition models (also called continuum models); and 2) stage models[65,66]. Social cognition models refer to 'a group of similar theories each of which specifies a small number of cognitive and affective factors (e.g. intentions, beliefs and attitudes) as the proximal determinants of behaviour'[65]. Social cognition models include the theory of reasoned action[67], the theory of planned behaviour[68], the protection motivation theory[69], the self-efficacy theory[70], and the health belief model[71]. On the other hand, stage models use 'similar concepts but organize them differently'[65]. These models assume that behaviour change takes place in several discrete stages. Depending on the stage an individual belongs to, different social cognitive factors are assumed to be more important than others[72]. As a result, people at different stages are assumed to require stage-specific interventions to support them in their move to the next stage in the sequence[65,72]. Stage models include the health action process approach[73], the trans-theoretical model[74], the precaution adoption process model[75], the health action process approach[73], and the health behaviour goal model[76]. Other than social cognition models and stage models, another theory that explains health behaviour change is the self-regulation model[77,78].

According to Hinyard and Kreuter, who developed overarching theoretical explanations for the use of narratives (e.g. first-hand experiential stories, second hand stories of others that we retell) in health behaviour change[79], health behaviour theories provide three possible mechanisms through which narratives might influence health behaviour change: two from social cognition models, namely the theory of reasoned action and the self-efficacy theory; and one from stage models, namely the precaution adoption process model. Since shared patient experience is a type of narrative that makes use of first-hand and/or second-hand experiential stories, these theories may be considered as potential theoretical models to explain the mechanism of shared patient

experience in health behaviour (e.g. decision-making in starting insulin treatment). Other than these theories as suggested by Hinyard and Kreuter, another theoretical perspective from health behaviour research that may explain possible links between shared patient experience and health behaviours is the self-regulation model. The applicability of each of the theories to explain the mechanism of how shared patient experience may support psychosocial and health behavioural well-being is examined below.

Theory of reasoned action

The theory of reasoned action[67] assumes that people will have strong intentions to perform a given action (behaviour) if they evaluate it positively (attitude towards behaviour) and if they believe that important others think they should perform it (subjective norm)[65]. Hinyard and Kreuter suggest that narratives (e.g. shared patient experience) can be used to promote subjective norms, which in turn may improve intention and health behaviours[79]. That is, shared patient experience works only when fellow patients are important to a patient, and when the patient recognises expectations from 'important others' with regard to his/her performing the behaviour in question.

Precaution adoption process model

Second, the precaution adoption process model[75] is a cognitive-stage model of preventive behaviour, which was 'originally developed to describe and explain the process by which people adopt precautions against a new risk, i.e. one that they have recently learned about rather than one they have been aware of for some time'[80]. The theory assumes two measures of peer influence, namely 'number of testers known' (frequency of the number of fellow patients who have performed a target behaviour)[75] and 'perceived community concern' (perception about the degree of reservation that fellow patients in the community hold toward the behaviour in question) as the factors that may directly move people closer to taking action for a certain behaviour. Hinyard and Kreuter suggest that narratives (e.g. shared patient experience) can be used to promote these factors, which in turn may influence health behaviours[79]. That is, shared patient experience is

likely to work only when fellow patients are from the same community as the patient and/or have performed the behaviour in question[75]. The impact of shared patient experience also depends on the perceived degree of reservation that fellow patients in the community hold toward the behaviour in question and the perceived frequency of the number of fellow patients who have performed a target behaviour[75].

Self-efficacy theory

Third, self-efficacy theory[70] asserts that an individual's behaviour is predicted by perceived self-efficacy (beliefs or confidence in one's ability to perform a particular behaviour that leads to the outcome in question) and outcome expectancies (beliefs concerning the probability that this specified course of action will lead to certain outcomes or consequences), which are enhanced by observational learning/modelling (observing the behaviour of others). In particular, if the model is perceived by the audience to be similar to themselves, or if the audience sees the model reinforcing the behaviour in ways that appeal to them (e.g. watching the model tell stories of successful behavioural strategies), they are more likely to enhance self-efficacy and positive outcome expectancies, and perform the behaviour themselves[70,81]. Hinyard and Kreuter suggest that narratives (e.g. shared patient experience) can be used to promote observational learning/modelling, which in turn may improve perceived self-efficacy and health behaviours[79]. That is, shared patient experience works only when fellow patients are similar to a patient and/or have performed appealing behavioural strategies.

Self-regulation model

Fourth, the self-regulation model assumes that health behaviour is the result of an iterative process by which the person integrates social, emotional, and cognitive factors to give meaning to the person's experience[81]. It consists of three main interrelated constructs, namely interpretation (making sense of the problem through parallel cognitive processing of 'illness/treatment

representations' and 'emotional response'[iii], which are shaped by 'social messages'[iv]), coping (dealing with the problem), and appraisal (assessing whether the coping strategy has been effective). These constructs continue the integration until the coping strategies are deemed to be successful[82,84v]. The model (in particular, the concept of 'treatment representations') has also been extended with several new beliefs about treatment. Research by Horne et al. (1999)[86] has provided support for this extension, by demonstrating patients' specific beliefs about medication including 'beliefs about the necessity of the medicines for maintaining health' and 'concerns about medication', and how they relate to coping[82,87]. It is suggested by the author that shared patient experience can be used to promote 'social messages', which in turn may improve 'treatment representations' and health behaviours.

Shared patient experience is a complex intervention (interventions comprising of multiple components which interact to produce change[88,89]). Guidance on developing complex interventions stresses the importance of theory to optimise its design and implementation. Guidance by the Medical Research Council (MRC), for instance, has been used as a general approach to designing and developing complex interventions informed by theory[90]. As discussed above, each of the four theories from health behaviour research appears to have the potential to explain the mechanism of how shared patient experience may work for health behaviour changes (e.g. decision-making in starting insulin treatment), and inform the possible techniques/components that might be used to change health behaviours[91]. Yet, each on its own may be limited in its ability to explain the scope of the whole mechanism. It may be that

[iii] 'Illness/treatment representations' refer to how people perceive illness and treatment. Both concepts (illness and treatment representations) consist of five components, namely, *identity*, *cause*, *timeline*, *consequence*, and *cure*[82,83]. 'Emotional response' refers to how people emotionally react to such perceptions (illness and treatment representations).

[iv] 'Social messages' refer to information acquired from a range of sources such as friends, family, and peers.

[v] The model features a cyclical process (also called a feedback loop) since 'the feedback from prior performance is used to make adjustments during current efforts'. The model suggests that personal, behavioural and environmental factors are constantly changing over the course of performance[85].

interventions based on shared patient experience can build in a complementary way on all four health behaviour theories. Theories drawn from other disciplinary perspectives may also be able to contribute some useful explanatory insights for understanding shared patient experience interventions[92,93]. The applicability of theories underpinning shared patient experience interventions aiming to support the process of decision-making in starting insulin as well as a design of the intervention will be explored further in chapters 6 and 7.

2.3.4 Shared patient experience programmes to support the process of decision-making in starting insulin

Appropriately designed based on theories, shared patient experience programmes may work directly for patients by mitigating their concerns about insulin therapy, which may in turn promote beneficial health behaviours (e.g. decision-making in favour of the initiation of insulin), and thus increase the likelihood of patients beginning insulin therapy without delay. Such a programme may also support public health systems that face resource constraints (e.g. time, money) by providing a potentially low-cost, flexible means of supplementing formal support for the decision-making process. This research project aims to contribute to this area. By addressing the gaps in the literature on shared patient experience in diabetes care, the project explores how shared patient experience could support the process of decision-making in starting insulin therapy in non-insulin-treated adults with type 2 diabetes in the UK.

2.4 Summary points

- The prevalence of type 2 diabetes is increasing rapidly across the world
- While insulin therapy is considered to be the most effective of diabetes medications in lowering glycaemia, studies have shown that many patients with type 2 diabetes, who

might benefit from insulin therapy, currently do not receive it or do not receive it in a timely manner

- One of the factors that may explain the delay in the commencement of insulin is patients' psychological barriers toward insulin therapy. Studies have identified that patients are often reluctant to accept insulin treatment

- To mitigate such barriers and ease the decision-making process to commence insulin therapy, the IDF has emphasised the importance of using a proactive approach in the early course of the disease. Previously, several materials and toolkits have been developed to fulfil this need (often developed from the perspective of helping healthcare providers assess and/or address patients' concerns). In the UK such an approach is also included as part of structured education programmes for type 2 diabetes

- The current strategies, however, may not sufficiently address the existing issues around the decision-making process. There are also some issues in delivering such strategies due to severe resource constraints in public health systems. This may suggest a need to develop an additional support that appropriately influences patients to make the decision about insulin and initiate it without delay

- One possible response to this need is an intervention based on shared patient experience. As a complementary resource to the current strategies, an intervention based on shared patient experience might be able to support patients in the process of decision-making in starting insulin therapy by maximising the potential benefits of the empowerment approach

- However, there are still many uncertainties about the evidence to support the pragmatic use of shared patient experience in the decision-making process to commence insulin therapy in type 2 diabetes. Some gaps in the literature include: the lack of common

understanding of shared patient experience as a concept; uncertainties about the impact of shared patient experience in the decision-making process in type 2 diabetes; a need for more in-depth understanding about patients' attitudes and beliefs toward the initiation of insulin therapy as well as their attitudes and experiences in relation to information/support needs (in particular, support through shared patient experience) in the context of the decision-making process to commence insulin therapy; and uncertainties about patients' views and preferences toward the use of shared patient experience to support the process of decision-making in starting insulin therapy

- Four complementary theoretical perspectives from health behaviour research offer some potential explanations for why shared patient experience may be an effective intervention tool

- If designed properly based on theories, a shared patient experience programme has significant potential to support the process of decision-making in starting insulin therapy in non-insulin-dependent patients in type 2 diabetes

2.5 Rationale of thesis

This thesis aims to answer the following five research questions:

1. How had shared patient experience (or had not) been incorporated/defined in previous interventions?

2. Could shared patient experience interventions improve health in the context of type 2 diabetes care in general? And what methods have been used to evaluate such interventions (e.g. components of shared patient experience)?

3. What does a non-systematic narrative review of the existing literature say and what is known about patients' attitudes and beliefs toward the initiation of insulin therapy as well as their attitudes and experiences in relation to information/support needs (in particular, support through shared patient experience) in the context of the decision-making process to commence insulin therapy?

4. How do patients feel about the use of shared patient experience to support the process of decision-making in starting insulin therapy?

5. What do these findings suggest would be a possible shared patient experience intervention design to support patients in the process of decision-making in starting insulin therapy?

This thesis answers the above questions through the following studies:

- A review of existing systematic reviews to assess research question 1
- A systematic review of randomised controlled trials (RCTs) to assess research question 2
- A narrative literature review of qualitative studies and a secondary analysis of an existing collection of qualitative interviews to explore research question 3
- A new primary qualitative study to investigate research questions 3 and particularly 4
- Development of a proposed intervention design to address research question 5

2.6 References

1. American Diabetes Association. Diagnosis and Classification of Diabetes Mellitus. *Diabetes Care.* 2009;32(Suppl 1):S62-S67.
2. Hex N, Bartlett C, Wright D, Taylor M, Varley D. Estimating the current and future costs of Type 1 and Type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs. *Diabet Med.* 2012;29(7):855-862.
3. Khunti K, Davies M. Glycaemic goals in patients with type 2 diabetes: current status, challenges and recent advances. *Diabetes, Obesity and Metabolism.* 2010;12(6):474-484.
4. Arner P. Insulin resistance in type 2 diabetes - Role of the adipokines. *Curr Mol Med.* 2005;5(3):333-339.
5. Dailey G. Optimum management of type 2 diabetes--timely introduction, optimization and intensification of basal insulin. *Diabetes Obes Metab.* 2008;10 Suppl 2:5-13.
6. Stratton IM, Adler AI, Neil HA, et al. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. *BMJ.* 2000;321(7258):405-412.
7. Funnell MM, Kruger DF, Spencer M. Self-management support for insulin therapy in type 2 diabetes. *Diabetes Educ.* 2004;30(2):274-280.
8. Nathan DM, Buse JB, Davidson MB, et al. Medical Management of Hyperglycemia in Type 2 Diabetes: A Consensus Algorithm for the Initiation and Adjustment of Therapy: A consensus statement of the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes Care.* 2009;32(1):193-203.
9. Swinnen SG, Hoekstra JB, DeVries JH. Insulin Therapy for Type 2 Diabetes. *Diabetes Care.* 2009;32(Suppl 2):S253-S259.
10. Khunti K, Damci T, Meneghini L, Pan CY, Yale JF. Study of Once Daily Levemir (SOLVE): insights into the timing of insulin initiation in people with poorly controlled type 2 diabetes in routine clinical practice. *Diabetes Obes Metab.* 2012;14(7):654-661.

11. Peyrot M, Rubin RR, Lauritzen T, et al. Resistance to Insulin Therapy Among Patients and Providers: Results of the cross-national Diabetes Attitudes, Wishes, and Needs (DAWN) study. *Diabetes Care.* 2005;28(11):2673-2679.

12. Rubino A, McQuay LJ, Gough SC, Kvasz M, Tennis P. Delayed initiation of subcutaneous insulin therapy after failure of oral glucose-lowering agents in patients with Type 2 diabetes: a population-based analysis in the UK. *Diabet Med.* 2007;24(12):1412-1418.

13. Khunti K, Wolden ML, Thorsted BL, Andersen M, Davies MJ. Clinical inertia in people with type 2 diabetes: a retrospective cohort study of more than 80,000 people. *Diabetes Care.* 2013;36(11):3411-3417.

14. Kunt T, Snoek FJ. Barriers to insulin initiation and intensification and how to overcome them. *Int J Clin Pract.* 2009;63:6-10.

15. Prospective Diabetes Study Group UK. Prospective Diabetes Study 16. Overview of six years' therapy of type 2 diabetes - a progressive disease. *Diabetes.* 1995;44:1249-1258.

16. Polonsky WH, Fisher L, Guzman S, Villa-Caballero L, Edelman SV. Psychological insulin resistance in patients with type 2 diabetes: the scope of the problem. *Diabetes Care.* 2005;28(10):2543-2545.

17. Larkin ME, Capasso VA, Chen CL, et al. Measuring psychological insulin resistance: barriers to insulin use. *Diabetes Educ.* 2008;34(3):511-517.

18. Khan H, Lasker SS, Chowdhury TA. Prevalence and reasons for insulin refusal in Bangladeshi patients with poorly controlled Type 2 diabetes in East London. *Diabet Med.* 2008;25(9):1108-1111.

19. Blonde L. Easing the transition to insulin therapy in people with type 2 diabetes. *Diabetes Educ.* 2007;33 Suppl 7:232S-240S.

20. Sharma SK, Yeo JP, Garber A. Lessons in initiating insulin in clinical practice. *Diabetes Res Clin Pract.* 2008;81 Suppl 1:S16-22.

21. Karter AJ, Subramanian U, Saha C, et al. Barriers to insulin initiation: the translating research into action for diabetes insulin starts project. *Diabetes Care.* 2010;33(4):733-735.

22. Campbell RK. Recommendations for improving adherence to type 2 diabetes mellitus therapy--focus on optimizing insulin-based therapy. *Am J Manag Care.* 2012;18(3 Suppl):S55-61.

23. International Diabetes Federation. Global Guideline for Type 2 Diabetes. International Diabetes Federation; 2012: http://www.idf.org/global-guideline-type-2-diabetes-2012. Accessed October 2013.

24. Brod M, Alolga SL, Meneghini L. Barriers to initiating insulin in type 2 diabetes patients: development of a new patient education tool to address myths, misconceptions and clinical realities. *Patient.* 2014;7(4):437-450.

25. Minze MG, Dalal K, Irons BK. Removing barriers to insulin use. *J Fam Pract.* 2011;60(10):577-580.

26. Snoek FJ, Skovlund SE, Pouwer F. Development and validation of the insulin treatment appraisal scale (ITAS) in patients with type 2 diabetes. *Health and Quality of Life Outcomes.* 2007;5:69-69.

27. Meneghini L, Artola S, Caputo S, et al. Practical guidance to insulin management. *Primary care diabetes.* 2010;4 Suppl 1:S43-56.

28. American Association of Diabetes Educators (AADE). Strategies for insulin injection therapy in diabetes self-management. https://www.diabeteseducator.org/docs/default-source/legacy-docs/_resources/pdf/research/aade_meded.pdf?sfvrsn=2. Accessed 02.10, 2016.

29. Health Innovative Network. Right insulin, Right time, Right dose, for type 2 diabetes - A toolkit for optimal delivery. 2014; http://www.hin-southlondon.org/system/resources/resources/000/000/139/original/Right_Insulin_Right_Time_Toolkit_210316.pdf. Accessed 10/02/2016.

30. Peyrot M, Rubin RR, Khunti K. Addressing barriers to initiation of insulin in patients with type 2 diabetes. *Primary care diabetes.* 2010;4 Suppl 1:S11-18.

31. Health Innovation Network. Structured education for people with type 2 diabetes: A toolkit for optimal delivery. 2014; http://www.hin-southlondon.org/system/resources/resources/000/000/047/original/Structured_Education_Toolkit_%28Final%29.pdf?1412668611. Accessed 10/02/2016.

32. Deakin TA, Cade JE, Williams R, Greenwood DC. Structured patient education: the diabetes X-PERT Programme makes a difference. *Diabet Med.* 2006;23(9):944-954.

33. Davies MJ, Heller S, Skinner TC, et al. Effectiveness of the diabetes education and self management for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: Cluster randomised controlled trial. *BMJ.* 2008;336(7642):491-495.

34. Sturt JA, Whitlock S, Fox C, et al. Effects of the Diabetes Manual 1:1 structured education in primary care. *Diabet Med.* 2008;25(6):722-731.

35. Tang TS, Ayala GX, Cherrington A, Rana G. A review of volunteer-based peer support interventions in diabetes. *Diabetes Spectr.* 2011;24(2):85-98.

36. Winkley K, Evwierhoma C, Amiel SA, Lempp HK, Ismail K, Forbes A. Patient explanations for non-attendance at structured diabetes education sessions for newly diagnosed Type 2 diabetes: a qualitative study. *Diabetic Medicine.* 2015;32(1):120-128.

37. Winkley K, Stahl D, Chamley M, et al. Low attendance at structured education for people with newly diagnosed type 2 diabetes: General practice characteristics and individual patient factors predict uptake. *Patient education and counseling.* 2016;99(1):101-107.

38. Simmons D, Bunn C, Cohn S, Graffy J. What is the idea behind peer-to-peer support in diabetes? *Diabetes Management.* 2013;3(1):61-70.

39. Davison KP, Pennebaker JW, Dickerson SS. Who talks? The social psychology of illness support groups. *Am Psychol.* 2000;55(2):205-217.

40. Ziebland S, Wyke S. Health and illness in a connected world: how might sharing experiences on the internet affect people's health? *Milbank Q.* 2012;90(2):219-249.

41. Lorig KR, Sobel DS, Stewart AL, et al. Evidence suggesting that a chronic disease self-management program can improve health status while reducing hospitalization: a randomized trial. *Med Care.* 1999;37(1):5-14.

42. Lorig KR, Sobel DS, Ritter PL, Laurent D, Hobbs M. Effect of a self-management program on patients with chronic disease. *Effective clinical practice: ECP.* 2000;4(6):256-262.

43. Krichbaum K, Aarestad V, Buethe M. Exploring the connection between self-efficacy and effective diabetes self-management. *Diabetes Educ.* 2003;29(4):653-662.

44. Heisler M. *Building Peer Support Programs to Manage Chronic Disease: Seven Models for Success.* . Oakland, CA: California Health Care Foundation;2006.

45. Glasgow RE, Toobert DJ, Gillette CD. Psychosocial Barriers to Diabetes Self-Management and Quality of Life. *Diabetes Spectr.* 2001;14(1):33-41.

46. Greenhalgh T. Patient and public involvement in chronic illness: beyond the expert patient. *BMJ.* 2009;338:b49.

47. National Institute for Clinical Excellence. TA60 Diabetes (types 1 and 2) – patient education models summary. http://www.nice.org.uk/guidance/index.jsp?action=byID&r=true&o=11496 Accessed 08.22, 2012.

48. Simmons D, Cohn S, Bunn C, et al. Testing a peer support intervention for people with type 2 diabetes: a pilot for a randomised controlled trial. *BMC Fam Pract.* 2013;14:5.

49. Wilson PM, Kendall S, Brooks F. The Expert Patients Programme: a paradox of patient empowerment and medical dominance. *Health Soc Care Community.* 2007;15(5):426-438.

50. Frost J, Garside R, Cooper C, Britten N. A qualitative synthesis of diabetes self-management strategies for long term medical outcomes and quality of life in the UK. *BMC Health Serv Res.* 2014;14:348.

51. Ockleford E, Shaw RL, Willars J, Dixon-Woods M. Education and self-management for people newly diagnosed with type 2 diabetes: a qualitative study of patients' views. *Chronic Illn.* 2008;4(1):28-37.

52. Jarvis J, Skinner TC, Carey ME, Davies MJ. How can structured self-management patient education improve outcomes in people with type 2 diabetes? *Diabetes Obes Metab.* 2010;12(1):12-19.

53. Davidson L. Recovery, self management and the expert patient – Changing the culture of mental health from a UK perspective. *Journal of Mental Health.* 2005;14(1):25-35.

54. Fox S. The Social Life of Health Information. Pew Internet and American Life, . 2011. http://www.pewinternet.org/2011/05/12/the-social-life-of-health-information-2011/. Accessed January, 2013.

55. Gray R, Fitch M, Davis C, Phillips C. A qualitative study of breast cancer self-help groups. *Psychooncology.* 1997;6(4):279-289.

56. Entwistle VA, France EF, Wyke S, et al. How information about other people's personal experiences can help with healthcare decision-making: a qualitative study. *Patient Educ Couns.* 2011;85(3):e291-298.

57. Ussher J, Kirsten L, Butow P, Sandoval M. What do cancer support groups provide which other supportive relationships do not? The experience of peer support groups for people with cancer. *Soc Sci Med.* 2006;62(10):2565-2576.

58. Madiba S, Canti-Sigaqa V. Barriers to participate in support groups for people living with HIV: a qualitative study with men receiving antiretroviral treatment in a HIV clinic in Mthatha, South Africa. *Glob J Health Sci.* 2012;4(6):119-128.

59. Sandaunet AG. The challenge of fitting in: non-participation and withdrawal from an online self-help group for breast cancer patients. *Sociol Health Illn.* 2008;30(1):131-144.

60. Locock L, Brown JB. 'All in the same boat'? Patient and carer attitudes to peer support and social comparison in Motor Neurone Disease (MND). *Soc Sci Med.* 2010;71(8):1498-1505.

61. Taylor SE. *Health psychology (6th Ed.).* Boston: McGraw Hill.; 2005

62. Sarafino EP. *Health psychology: Biopsychosocial interactions (5th Ed).* New York: Wiley; 2005.

63. Pendley JS, Kasmen LJ, Miller DL, Donze J, Swenson C, Reeves G. Peer and family support in children and adolescents with type 1 diabetes. *J Pediatr Psychol.* 2002;27(5):429-438.

64. Babamoto KS, Sey KA, Camilleri AJ, Karlan VJ, Catalasan J, Morisky DE. Improving diabetes care and health measures among hispanics using community health workers: results from a randomized controlled trial. *Health Educ Behav.* 2009;36(1):113-126.

65. Sutton S. Health behaviour: Psychosocial theories. In: Smelser NJ, Baltes PB, eds. *International encyclopaedia of the social and behavioural sciences* Oxford, England: Elsevier; 2001.

66. Weinstein ND, Rothman AJ, Sutton SR. Stage theories of health behavior: conceptual and methodological issues. *Health Psychol.* 1998;17(3):290-299.

67. Ajzen I, Fishbein M. *Understanding Attitudes and Predicting Social Behaviour.* Englewood Cliffs, NJ: Prentice-Hall; 1980.

68. Ajzen I. The theory of planned behaviour. *Organizational Behaviour and Human Decision Processes.* 1991;50:179–211.

69. Rogers RW. Cognitive and physiological processes in fear appeals and attitude change: a revised theory of protection motivation. In: Cacioppo JT, Petty RE, Shapiro D, eds. *Social Psychophysiology: A Sourcebook*. New York: Guilford Press; 1983:153–176.

70. Bandura A. *Social Foundations of Thought and Action: A Social Cognitive Theory.* Englewood Cliffs, NJ: Prentice-Hall; 1986.

71. Rosenstock IM. Historical Origins of the Health Belief Model. *Health Educ Behav.* 1974;2(4):328-335.

72. Lippke S, Ziegelmann JP. Theory-Based Health Behavior Change: Developing, Testing, and Applying Theories for Evidence-Based Interventions. *Applied Psychology.* 2008;57(4):698-716.

73. Schwarzer R, Fuchs R. Self-efficacy and health behaviours. In: Conner M, Norman P, eds. *Predicting health behaviour: Research and practice with social cognition models* Buckingham, UK: Open University Press; 1996:163–196.

74. Prochaska JO, DiClemente CC, Norcross JC. In search of how people change. Applications to addictive behaviors. *Am Psychol.* 1992;47(9):1102-1114.

75. Weinstein ND, Sandman PM. A model of the precaution adoption process: evidence from home radon testing. *Health Psychol.* 1992;11(3):170-180.

76. Gebhardt WA. Health behaviour goal model: Towards a theoretical framework for health behaviour change. 1997.

77. Leventhal H. Findings and Theories in the Study of Fear Communication in L. Berkowitz,(ed.) Advances in Experimental Social Psychology (Vo1. 5) San Diego. CA: Academic Press; 1970.

78. Leventhal H. Toward a comprehensive theory of emotion. *Adv Exp Soc Psychol.* 1980;13:139-207.

79. Hinyard LJ, Kreuter MW. Using narrative communication as a tool for health behavior change: a conceptual, theoretical, and empirical overview. *Health Educ Behav.* 2007;34(5):777-792.

80. Schwarzer R, Luszczynska A. Health behavior constructs: Theory, measurement, and research. *Self efficacy* 2007; http://dccps.cancer.gov/brp/constructs/self-efficacy/index.html.

81. Edelman RJ. *Psychosocial Aspects of the Health Care Process.* Essex: Pearson Education; 2000.

82. Leventhal H, Halm E, Horowitz C, Leventhal EA, Ozakinci G. Living with chronic illness: A contextualized, self-regulation approach. In: Sutton S, Baum A, Johnston M, eds. *The Sage Handbook of Health Psychology*. London: SAGE; 2004.

83. Weinman J, Petrie KJ, Moss-Morris R, Horne R. The illness perception questionnaire: a new method for assessing the cognitive representation of illness. *Psychology and health.* 1996;11(3):431-445.

84. Leventhal H, Leventhal EA, Contrada RJ. Self-regulation, health, and behavior: A perceptual-cognitive approach. *Psychol Health.* 1998;13(4):717-733.

85. Zimmerman BJ. Attaining self-regulation : a social cognitive perspective. In: Monique Boekaerts MZ, Paul RP, eds. *Handbook of self-regulation*: San Diego, Calif. : Academic Press; 2000:13-39.

86. Horne R, Weinman J, Hankins M. The beliefs about medicines questionnaire: The development and evaluation of a new method for assessing the cognitive representation of medication. *Psychol Health.* 1999;14(1):1-24.

87. Jansen DL, Heijmans MJ, Rijken M, et al. Illness perceptions and treatment perceptions of patients with chronic kidney disease: different phases, different perceptions? *Br J Health Psychol.* 2013;18(2):244-262.

88. Moore GF, Audrey S, Barker M, et al. Process evaluation of complex interventions: UK Medical Research Council (MRC) guidance. 2014.

89. Moore GF, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ.* 2015;350:h1258.

90. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ.* 2008;337:a1655.

91. French SD, Green SE, O'Connor DA, et al. Developing theory-informed behaviour change interventions to implement evidence into practice: a systematic approach using the Theoretical Domains Framework. *Implement Sci.* 2012;7:38.

92. Fix GM, Houston TK, Barker AM, et al. A novel process for integrating patient stories into patient education interventions: incorporating lessons from theater arts. *Patient Educ Couns.* 2012;88(3):455-459.

93. Sandelowski M. Theory unmasked: the uses and guises of theory in qualitative research. *Res Nurs Health.* 1993;16(3):213-218.

Chapter 3. Review of existing systematic reviews - A definition and systematic approach to components of shared patient experience in adults with type 2 diabetes

3.1 Introduction

Research into the effects of shared patient experience in diabetes care has often been conducted in the field of health behaviour research, where the idea of shared patient experience has most often been grouped under the term 'peer support'. However, as discussed in chapter 2, there are some notable definitional problems and gaps in the literature. The use of the term 'peer support' does not always reflect the idea of shared patient experience. To explore the varied meanings of the term 'peer support' in the diabetes-specific literature, Simmons et al. 2013[1], for instance, conducted discourse analysis using various peer-reviewed articles (e.g. descriptive reports, analysis papers, observational studies, systematic reviews, and pilot studies). They found a wide range of roles and interactions in the current conception of peer support by demonstrating two dimensions that define it including the nature of the support (ranging from confounding to instructing) and the nature of the relationship (ranging from a companion, as would happen naturally [e.g. on a park bench], to paraprofessional, where the individual has an explicit health service role)[1,2]. There is still disagreement between researchers about what peer support really means. Uncertainties about the relevance of studies based on 'peer support' may suggest that there is currently no common understanding of the idea of shared patient experience as a concept in the field of diabetes research. Yet, the lack of common understanding also creates challenges when attempting to synthesize shared patient experience studies, examining the impact of shared patient experience, and understanding how and why shared patient experience may contribute to psychosocial and health behaviour changes.

Therefore, a review of existing systematic reviews was conducted to clarify the concept of shared patient experience by examining explicit or implicit components of shared patient experience in

adults with type 2 diabetes as identified in clinical trials. In this process, an effort was also made to identify existing and on-going systematic reviews on shared patient experience in adults with type 2 diabetes (to establish a need for the new systematic review) as well as existing trials on the topic, and specifically around the decision-making process in starting insulin therapy. All the findings from this review were then used to inform and plan the development of a new systematic review that aims to examine the impact of shared patient experience in adults with type 2 diabetes (chapter 4)[i]. In order to have a better understanding of shared patient experience, the review was conducted in the context of type 2 diabetes in general rather than limiting its search to a context of the decision-making process to commence insulin therapy.

3.2 Aim

The research question this review aimed to answer was:

- How had shared patient experience (or had not) been incorporated/defined in previous interventions?

3.3 Methods

To answer the proposed research question, this review first explored characteristics of systematic review papers (e.g. operational definition of interventions), and then characteristics of individual studies included in systematic review papers (e.g. components of shared patient experience interventions).

[i] This review of existing systematic reviews is not looking into the effectiveness of shared patient experience interventions, but many of the studies as identified from this review are included in the systematic review (chapter 4), which explored its effect in detail.

3.3.1 Search methods for identification of systematic reviews and individual studies included in systematic reviews

A search protocol was developed using the following databases [DARE, CDSR, Ovid (EMBASE, PsycINFO, Medline), PROSPERO, and HTA]. Since systematic review methodology was applied more widely from 1995, the search was limited to studies published between 1995 and 2013. Owing to uncertainties about the relevance of studies based on 'peer support' in the diabetes literature (see section 3.1), the author initially discussed with supervisors the types of interventions that could include 'potential'[ii] idea of shared patient experience. Ten types of interventions were considered, including:

- social support programmes,
- diabetes behavioural programmes,
- community healthcare, worker-led diabetes care programmes,
- peer support programmes,
- lay-led disease care programmes,
- diabetes self-management education programmes,
- diabetes care programmes in socially disadvantaged populations,
- diabetes care programmes in low health literacy populations,
- culturally-appropriate diabetes care programmes, and
- shared medical appointment programmes.

The search strategy was conducted mainly by gathering key terms that appeared in studies and reviews of these interventions. Following this strategy, however, resulted in a total of around 4000

[ii] Currently, there is no agreed and accepted understanding for the idea of shared patient experience. Therefore, at the initial stage of this project, a working definition of shared patient experience was broadly defined as 'peers as patients encountering each other in a mutual and non-hierarchical relationship and sharing experiences of illness' (see chapter 2).

citations. After discussion with supervisors, this was considered too many to review owing to time constraints and to the potential inclusion of many inadequate papers. As such this was not considered an efficient approach to exploring the issue. The strategy was, therefore, re-constructed by using search terms based on studies and reviews of peer support interventions with guidance from an information specialist. As noted above, while the relevance of studies on 'peer support' in diabetes literature is not currently certain, peer support interventions were selected because the idea of shared patient experience has most often been grouped under the term 'peer support' (see section 3.1). The search terms included *story, narrative, testimony, anecdote, peer- (e.g. worker, group), lay- (e.g. facilitator, advisor), community- (e.g. representative, worker), illness experience, shared experience, expert patient, self-help group, group based- (e.g. diabetes self-management education, education, visit, care), shared medical appointment, social support, diabetes mellitus* etc. The 81 search terms relating to shared patient experience were combined with diabetes which was covered under the MeSH tree, and one search term relating to the review. The reference lists of the identified articles were also searched. Only reviews published in the English language were included in the analysis. The strategy for MEDLINE (OVID) is presented as an example in Appendix 3.1. The MEDLINE strategy was tailored to the other databases. Subsequent to the selection of eligible systematic reviews, all individual studies included in those reviews were searched.

3.3.2 Inclusion criteria

Separate inclusion criteria were defined at the initial stage for selecting systematic reviews (see below under *inclusion criteria 1 – for systematic reviews*) and then selecting individual studies included in systematic reviews (see below under *inclusion criteria 2 - for individual studies included in systematic reviews*).

Inclusion criteria 1 – for systematic reviews

Inclusion criteria 1 were applied at the stage where the author examined systematic review papers for their applicability. Review articles were included if they met the following criteria:

i. The review has been performed as a systematic review and/or meta-analysis of quantitative studies
ii. The review concerns types of interventions which include the 'potential' idea of shared patient experience (see footnote ii). Such an idea was expected to exist across ten types of interventions including social support programmes, peer support programmes, diabetes behavioural programmes, community healthcare worker-led diabetes care programmes, lay-led disease care programmes, diabetes self-management education programmes, diabetes care programmes in socially disadvantaged populations, diabetes care programmes in low health literacy populations, culturally-appropriate diabetes care programmes, and shared medical appointment programmes
iii. The sample population focuses on or included adults with type 2 diabetes

Inclusion criteria 2 – for individual studies included in systematic reviews

Inclusion criteria 2 were applied at the stage where the author examined individual studies included in systematic reviews for their applicability. Individual studies were included if they met the following criteria:

iv. Study design comprises of randomised controlled trials (RCTs)[iii]
v. The sample population focuses on adults with type 2 diabetes

[iii] Limiting the scope of this chapter to individual studies that adopt randomised controlled study designs was considered best and adopted since it allows the researcher to focus on interventions that are well-described/conducted and have been tested with patients in a rigorous manner.

vi. Interventions include the 'potential' idea of shared patient experience (individual studies included in the reviews on social support, peer support, community healthcare worker-led, lay-led programmes individual studies were chosen *if* the source of support were 'patients' themselves; individual studies included in the reviews on diabetes education/self-management programmes, diabetes care for socially disadvantaged/low health literacy populations, and culturally-sensitive populations individual studies were chosen *if* the programme was based on 'group-based care' and/or an 'interactive discussion format'; and individual studies included in the review on shared medical appointment were chosen *if* the programme included the element of peer support)

Regarding inclusion criteria for the types of interventions (inclusion criteria vi and vii), different criteria were applied at the screening stage of individual studies included in systematic reviews: inclusion criterion vi (listed above) was applied at the stage of assessing *title/abstract* sections of individual studies, whereas inclusion criterion vii (listed below) was applied at the stage of assessing the *full-text* of individual studies:

vii. Studies include the 'potential' idea of shared patient experience which was agreed on by the author and supervisors (e.g. individual studies were included if patients were sharing their own/others' experiences of health issues or equally contributing their own/others' experiences of illness to the discussion)

3.3.3 Exclusion criteria

The separate exclusion criteria were defined for excluding systematic reviews (see below under *exclusion criteria 1 – for systematic reviews*) and individual studies included in systematic reviews (see below under *exclusion criteria 2 – for individual studies included in systematic reviews*).

Exclusion criteria 1 – for systematic reviews

Exclusion criteria 1 were applied at the stage where the author examined the systematic review papers for their applicability. At this stage, reviews were excluded if they met the following criteria:

viii. Conference abstract, dissertation, and protocol are eliminated as the data is more likely to be incomplete

ix. A systematic review and/or meta-synthesis of qualitative studies are eliminated

Exclusion criteria 2 – for individual studies included in systematic reviews:

Exclusion criteria 2 were applied especially when the author examined the *full-text* of individual studies included in systematic reviews for their applicability. At this stage, studies were excluded if they met the following criterion:

x. Description of shared patient experience is vague or not explicit

xi. Studies do not include the 'potential' idea of shared patient experience which was agreed on by the author and supervisors (e.g. individual studies were excluded if patients were not sharing their own/others' experiences of health issues, if the programme was group-based but no interactive discussion where patients equally contributed their own/others' experiences of illness to the discussion was included, or if the programme was based on one-to-one/peer-to-peer format where one peer was just giving a lecture without equally contributing his/her own/others' experiences of illness to the discussion)

3.3.4 Selection of studies

Selection of systematic reviews

The database and reference list searches were conducted and the identified papers were imported into Endnote. After the removal of duplicates, the author examined title/abstract and then the full-texts of all the papers for their applicability according to the inclusion and exclusion criteria 1 (i – iii, viii, and ix).

Selection of individual studies included in each systematic review

The reference list of each systematic review was searched and the identified papers were listed in Excel. After the removal of duplicates, the author examined title/abstract and then the full-texts of all the papers for their applicability according to the inclusion and exclusion criteria 2 (iv –vii and x).

3.3.5 Data extraction

Data extraction for systematic reviews

All relevant data were extracted and summarised by the author in a data extraction table, in terms of: citation (record number, author, title, year); aim of review; type of interventions focused on in review; characteristics of patient group (type of diabetes); operational definition of the interventions (from all operational definitions retrieved, the author attempted to extract several components of interventions that potentially help to clarify the elements of interventions focused on in the reviews, especially in terms of elements of shared patient experience such as contents, and/or facilitators of the intervention. For interventions on social support and peer support, definitions of these concepts were also extracted); study design included in systematic reviews; and a total number of individual studies included in a review.

Data extraction for individual studies included in each systematic review

All relevant data were extracted and summarised by the author in a data extraction table in terms of: citation (record number, author, title, year); aim of the intervention; type of interventions focused on in systematic reviews; and components of shared patient experience interventions including types of facilitators and mode of delivery (e.g. individual versus group, remote versus face-to-face, and role-model versus non-role model).

3.3.6 Data synthesis/Investigation of heterogeneity

Data synthesis for systematic reviews

The degree of heterogeneity between the systematic reviews was explored specifically in terms of: characteristics of patient group; study design included in systematic reviews; type of interventions focused on in the reviews; and operational definition of the interventions. Please see section 3.4.

Data synthesis for individual studies included in each systematic review

The degree of heterogeneity between the individual studies was explored specifically in terms of: type of interventions focused on in systematic; and components of shared patient experience interventions including types of facilitators, and mode of delivery (e.g. individual versus group, remote versus face-to-face, and role-model versus non-role model). Please see section 3.5.

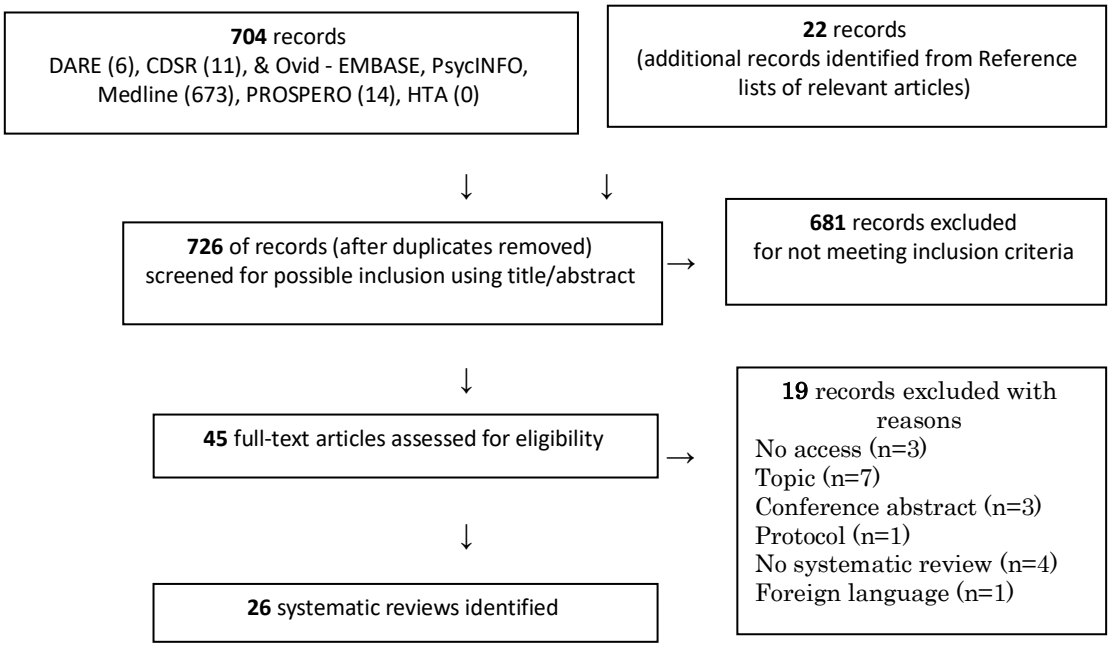
3.4 Results for systematic reviews

3.4.1 Included reviews

Figure 3.1 illustrates the flow of papers through the review process. 726 papers, including 704 papers identified from the database and 22 papers identified from reference lists of relevant articles, were screened by reading title/abstract and 681 papers were excluded. Full-texts for the

remaining 45 were read, of which 19 papers not meeting the inclusion criteria were eliminated. As a result, 26 reviews were included.

Figure 3.1 Flow chart of review of systematic reviews



A summary of characteristics of included systematic reviews is presented in Appendix 3.2, and the results are provided below.

3.4.2 Characteristics of patient group

The reviews involved the following patient groups: patients with type 2 diabetes only (13 reviews)[3-15], adult diabetic patients (five reviews)[16-20], patients with type 1 and type 2 diabetes (three reviews)[21-23], patients with chronic diseases (three reviews)[24-26], patients with any types of diabetes (one review)[27], and unclear patient group but includes type 2 patients (one review)[28].

3.4.3 Study designs included in reviews

Eight reviews included interventions which only used randomised controlled trial (RCT) design[5,6,8,10,12,14,24,26] while the other reviews included interventions which used various study

designs including RCTs and non-RCTs (e.g. quasi-experimental trials, action research, cross-sectional, retrospective cohort, prospective observational study, interrupted time series, cross-sectional survey, or descriptive studies)[3,4,7,9,11,13,15-23,25,27,28]. Also, three reviews were performed as a systematic review and meta-analysis[3,6,12], three as meta-analysis[5,8,16], while the rest of the reviews were performed solely as a systematic review[4,7,9-11,13-15,17-28].

3.4.4 Types of interventions focused on in systematic reviews

26 systematic reviews broadly focused on ten types of interventions that are expected to include the 'potential' idea of shared patient experience, namely interventions focused on diabetes self-management education programmes (ten reviews)[3,5,7-10,12,16,21,23], peer support programmes (four reviews)[17,20,24,28], culturally-appropriate diabetes care programmes (three reviews)[6,19,27], social support programmes (two reviews)[13,15], diabetes behaviour programmes (two reviews)[11,14], community healthcare worker-led diabetes care programmes (one review)[18], lay-led disease care programmes (one review)[26], diabetes care programmes in socially disadvantaged populations (one review)[22], diabetes care programmes for low health literacy populations (one review)[4], and shared medical appointment programmes (one review)[25].

3.4.5 Operational definition of interventions

The operational definition of interventions varied significantly depending on the focus of each review. As noted in section 3.3.5, from all operational definitions retrieved, the author attempted to extract several components of interventions that potentially help to clarify the elements of shared patient experience (e.g. contents, facilitators of the intervention, definitions for concepts of 'social support' and 'peer support')[iv]. A summary of the results is given below:

[iv] A summary of results describes the reviewers' own explanation of what they did rather than the author's interpretation.

Reviews on lay-led diabetes care programmes **(one review paper)**

- This review covered lay-led diabetes care interventions[26] that are defined as structured programmes for people with chronic conditions which were judged by the authors to be primarily educational and primarily addressing self-management of diabetes; that are delivered by 'lay people' who commonly but not invariably have a chronic disease themselves; and that incorporate elements of 'peer support', as long as these were primarily addressed at disease self-management

Reviews on social support programmes **(two review papers)**

- This review covered social support interventions[15] that incorporate elements of 'social support' as defined by Taylor (1998), which can be distinguished into four categories including emotional, appraisal, informational, and tangible support[29]; and that aim at increasing the well-being of the receiver
- This review covered social support interventions[13] that incorporate elements of 'social support', which is a multifaceted experience that involves voluntary associations and formal and informal relationships with others as defined by Bardach et al., (2011)[30], which can be positive or negative and can arise from different sources, including family members, friends, and peers (informal support) and healthcare professionals and organizations (formal support) as defined by Van Dam et al., (2005)[15]; and which can be distinguished into four categories including emotional, tangible, informational, and companionship as defined by Ford et al., (1998)[31]

Reviews on community healthcare worker-led diabetes care programmes **(one review paper):**

- This review covered community healthcare worker-led diabetes care interventions[18] that involved a ‘community healthcare worker’ (either the sole focus of the intervention or one component of a multi-component intervention or team) who is defined as any healthcare worker who (i) carried out functions related to healthcare delivery, (ii) was trained in some way in the context of the interventions, (iii) had no formal professional

or paraprofessional training in healthcare, and (iv) had a relationship with the community being served

Reviews on peer support programmes **(four review papers):**

- This review covered peer support interventions[20] that are led by a volunteer peer supporter (peer supporters were considered to be volunteers if they were not full- or part-time employees of the clinics, organizations, or universities in which they served; programmes in which peer supporters received a stipend or honorarium used to offset the costs of participation such as transportation and childcare were not included; family members as peer supporters were excluded); that include an explicit training component for peer supporters; and that focus on self-management rather than prevention
- This review covered online peer support interventions[28] that studied a virtual community (or had a virtual community component), defined for the purpose of this study as a group of individuals with similar or common health related interests and predominantly non-professional backgrounds (patients, healthy consumers, or informal caregivers) who interact and communicate publicly through a computer communication network such as the internet, or through any other computer based tool (including non-text based systems such as voice bulletin board systems), allowing social networks to build over distance; whose content focused on health or healthcare issues in the broadest sense, including emotional and social support, health education, or health related behaviour change
- This review covered peer support interventions[17] that incorporate elements of 'peer support' as defined by Dennis (2003), namely support from a person who has experiential knowledge of a specific behaviour or stressor and similar characteristics (e.g. age, gender, disease status, socio-economic status, religion, ethnicity, culture) as the target population[32]; that aim at improving the care or management of diabetes; and that describe a specific programme led by peers who provide support to adults with diabetes

- This review covered telephone-delivered peer support interventions[24] that incorporate elements of 'peer support' as defined by Dennis et al. (2002), that is provision of emotional, appraisal and informational assistance by a created social network member who possesses experiential knowledge of a specific behaviour or stressor and similar characteristics as the target population[33]; and that are delivered using the telephone by a peer supporter who is someone selected to provide support because they have similar or relevant health experience (peer supporters were expected to be provided with minimum training to ensure the preservation of 'peerness' and to avoid professionalism and the subsequent creation of 'para-professionals')

Reviews on diabetes self-management education programmes **(ten review papers):**

- This review covered diabetes management interventions[9] addressing patients' barriers, clinicians' barriers, and self-management
- This review covered diabetes education interventions[21] which aim to reduce the incidence of foot ulceration in people with diabetes mellitus
- This review covered diabetes education interventions[7] which aim at disseminating knowledge and skills brought about using a number of approaches; and which can be carried out with the normal range of personnel available in diabetes care
- This review covered diabetes self-management education interventions[10] that examine as broadly as possible the effectiveness of diabetes education; and that are delivered by any provider type, any medium (written, oral, video, computer), individual- or group-based, and any duration and intensity
- This review covered diabetes education interventions[16] that are designed to improve patient knowledge, self-care behaviours including skill performance or compliance (adherence), metabolic control, and/or psychological outcomes including stress reduction, coping, adaptation

- This review covered diabetes self-care management interventions[8] which use educational (e.g. techniques based on didactic-oriented intervention focusing on the knowledge acquisition, skills and information in order to improve diabetes self-management) or behavioural/psychosocial (e.g. cognitive, behavioural or motivational approaches including relaxation, problem-solving, or motivational interviewing) strategies aimed at stimulating the performance of self-care to increase target behaviour actions such as blood glucose monitoring, diet care and physical activity
- This review covered education and behavioural interventions[5] that included a behavioural or counselling component aimed at improving long-term diabetes self-care behaviours
- This review covered group-based diabetes self-management education interventions[12] which describe group-based education specific for people with type 2 diabetes; and which contain a minimum of one session lasting for one hour
- This review covered group-based diabetes self-management education interventions[3] which are based on learner/patient-centred education; which include or exclude family and friends; and which include a minimum of one session lasting for one hour
- This review covered group visit diabetes care interventions[23] that include both education and elements of an individual office visit; and that involve a certified diabetes educator as part of the group visit provider team

Reviews on diabetes behaviour programmes **(two review papers):**

- This review covered behaviour-focused interventions[14] that test the effects of modification of provider–patient interaction and provider consulting style on patient diabetes self-care and diabetes outcomes
- This review covered web-based behavioural interventions[11] which focus on exchange of information via a website between a healthcare provider and a patient; and which intervene on physical activity, nutrition, self-monitoring or weight loss

Reviews on shared medical appointment programmes **(one review paper):**

- This review covered shared medical appointment interventions[25] which involve a series of medical visits including at least one healthcare professional caring for a group of patients; and where the medical provider addressed each patient's unique medical needs individually, with the potential to make changes in medication, but in the context of the group setting

Reviews on diabetes self-management programmes for socially disadvantaged populations **(one review paper):**

- This review covered diabetes self-management interventions targeting socially disadvantaged diabetic patients[22] that included home glucose monitoring, regulation of diet and exercise, adherence to and self-adjustment of medication, and attendance at office appointments when needed or as scheduled by the provider

Reviews on diabetes self-management programmes for low health literacy populations **(one review paper):**

- This review covered diabetes self-management interventions targeting low health literacy populations[4] that reported on the association between health literacy and diabetes self-management tasks

Reviews on culturally-appropriate diabetes care programmes **(three review papers):**

- This review covered culturally appropriate diabetes health education interventions for ethnic minority communities[6] that incorporate elements of 'culturally appropriate education' which is defined as education that is tailored to the cultural or religious beliefs and linguistic skills of the community being approached, taking into account likely literacy skills; and that include adapting established health education to innovative delivery methods, such as using community-based health advocates, or delivering it to same gender groups, or adapting dietary advice to fit in with the likely diet of a particular community

- This review covered diabetes self-care interventions for African American adults or Latino adults[19] which aimed at changing knowledge, beliefs, or behaviour
- This review covered culturally competent diabetes care interventions for any ethnic minority population[27] which reported the impact of culturally competent programmes on any outcome measures

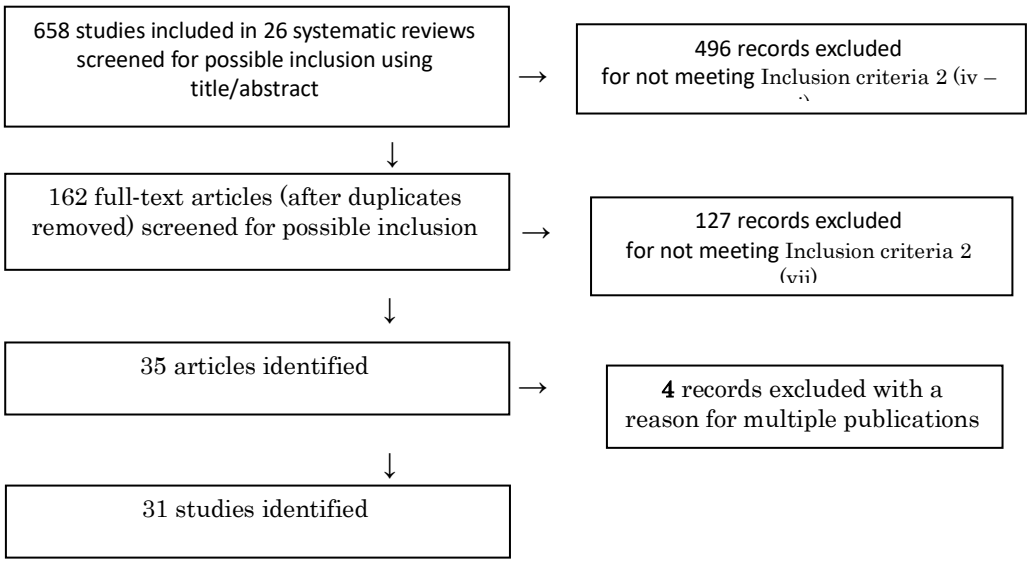
3.5 Results for individual studies included in systematic reviews

3.5.1 Included studies

At this stage, individual studies included in 26 systematic reviews were assessed to clarify further the idea of shared patient experience. Figure 3.2 illustrates the flow of papers through the review process. 658 papers included in 26 systematic reviews were screened using title/abstract and 496 papers not meeting inclusion criteria 2 (iv – vi) were excluded. Full-texts for the remaining 162 papers were read, of which 127 papers not meeting inclusion criteria 2 (vii) and four multiple duplications were eliminated[v]. As a result, 31 studies were included. A full process of identifying individual studies included in systematic reviews is also given in Appendix 3.3.

[v] Multiple publications describing the same contents of interventions were collated and assessed as one study.

Figure 3.2 Flow chart of review of individual studies included in systematic reviews



A summary of characteristics among included studies is presented in Appendix 3.4, and the results are provided below.

3.5.2 Types of interventions focused on in systematic reviews that included components of shared patient experience

31 RCTs were considered to contain the idea of shared patient experience. These studies were included in systematic reviews of nine types of interventions, including interventions for diabetes self-management education programmes (15 RCTs)[34-49], culturally-appropriate diabetes care programmes (four RCTs)[50-53], peer support programmes (four RCTs)[54-57], social support programmes (two RCTs)[58,59], diabetes behaviour programmes (two RCTs)[60,61], lay-led diabetes care programmes (one RCT)[62], community healthcare worker-led diabetes care programmes (one RCT)[63], diabetes self-management programmes for socially disadvantaged populations (one RCT)[64] and shared medical appointment programmes (one RCT)[65]. A systematic review of interventions for diabetes self-management programmes for low health literacy populations[4] did not contain studies including components of shared patient experience.

3.5.3 Components of shared patient experience interventions

Through the analysis of 31 RCTs, some common components of shared patient experience interventions were identified in terms of types of facilitators, and mode of delivery (e.g. individual versus group, remote versus face-to-face, and role-model versus non-role model).

Types of facilitators

All the studies except for two were delivered by facilitator(s)[34-40,42-55,57-68]. The interventions were most frequently delivered by various combinations of healthcare professionals (16 studies, 52%), including dieticians (eight studies)[35,43,44,47,53,63,64], nurses (four studies)[44,53,60,63], physicians (two studies)[47,65-68], nurse case managers (two studies)[53,55], diabetes nurses (two studies)[34,38], social workers[60], health educators[65-68], psychologists[60], clinical psychologists[46], podiatrists[52], exercise physiologists[64], pharmacists[45], and exercise leaders[51] (one study each). 15 studies were delivered by various combinations of non-healthcare professionals including peer educators/mentors/advisors who had diabetes (seven studies)[36,39,40,48,49,54,58,62], researchers (four studies)[36,42,48,49,61], community workers who had diabetes[63], peer support facilitators who did not have diabetes but trained in group dynamics[57], promotora who were bilingual clinic employees and did not have diabetes[59], lay health advisors who did not have diabetes[37], and health advocates who did not have diabetes but were trained using an accredited curriculum[50] (one study each). Two interventions involved both healthcare professionals and non-healthcare professionals in the delivery of the intervention[63,65-68]. In three studies, the interventions were delivered in combination on a facilitator-led and non-facilitator-led basis[39,42,62]

Mode of delivery in shared patient experience

Of the 31 studies, the mode of delivery was *face-to-face* in 21 studies (68%)[34,35,37,38,40,43-47,50-57,59,64]; *remote* in eight studies including via computer[36,39,42,48,49,60,61], video[41], and telephone[58]; *face-to-face* and *remote* (video) in two studies[62,63]; *group-based* in 30 studies (97%)[34-47,50-57,59-64]; and *individual-based* in one study[58]. Three studies (10%) used a *role model* during the intervention:

one study used modelling action planning by a peer who had diabetes[39]; two studies did not report the details[40,53]. Overall, the most frequently examined type of shared patient experience intervention was a healthcare professional-led, face-to-face, group-based format where a group of patients shared their illness experiences interactively without having a role-model (13 studies – 42%)[34,35,38,43-47,51-53,55,65-68].

3.6 Discussion

3.6.1 Main findings

The main findings of the review of systematic reviews (and individual studies included in systematic reviews), and answers to the proposed research question can be described as follows:

Main findings from systematic reviews

The review of existing systematic reviews identified 26 systematic reviews that focused on ten types of interventions that were expected to include the 'potential' idea of shared patient experience (see section 3.3.1), namely interventions for:

- diabetes self-management education programmes,
- peer support programmes,
- culturally-appropriate diabetes care programmes,
- social support programmes,
- diabetes behaviour programmes,
- lay-led diabetes care programmes,
- community healthcare worker-led diabetes care programmes,
- diabetes self-management programmes for socially disadvantaged populations,
- shared medical appointment programmes, and

- diabetes self-management programmes for low health literacy populations.

However, none of the operational definitions of these interventions described in the reviews was considered sufficiently to reflect the 'potential' idea of shared patient experience. The idea of shared patient experience, therefore, was not clarified at this stage.

Main findings from individual studies included in systematic reviews

At the next stage, 658 individual studies included in 26 systematic reviews were assessed to clarify the idea of shared patient experience. This identified a total of 31 RCTs that were considered to contain such an idea. These RCTs were included in systematic reviews of the nine (out of ten) types of interventions as listed above (except for systematic reviews of interventions for diabetes self-management programmes for low health literacy populations). Yet the majority of the RCTs did not describe the idea of shared patient experience as a particular concept.

These 31 RCTs, therefore, were further analysed, and some common components of shared patient experience interventions were identified in terms of types of facilitators and mode of delivery (e.g. individual versus group, remote versus face-to-face, and role-model versus non-role model). The identification of such common components also enabled the construction of a working definition for the idea of shared patient experience, which was defined by the author for the purpose of this project as the "*Provision of and/or learning from patients' personal accounts about health, health care, and health decision-making"*. In constructing this working definition, an effort was also made to assemble all the common components of shared patient experience interventions identified from this review into a brief, accessible, and useful frame of reference.

On the other hand, in the process of examining the 31 RCTs, it was found that there were no systematic reviews where all the individual studies (RCTs and non-RCTs) included in the reviews contained the idea of shared patient experience (as defined above), suggesting that none of the 26

systematic reviews included in this review was on shared patient experience in adults with type 2 diabetes. Owing to the restriction in search method[vi], such a finding does not indicate that there are currently no existing systematic reviews on shared patient experience in adults with type 2 diabetes. However, given that the 26 systematic reviews focused various types of interventions that often included the idea of shared patient experience (as defined in the previous page), but that none of the reviews was on shared patient experience in adults with type 2 diabetes, this could imply that the likelihood of finding systematic reviews on shared patient experience in adults with type 2 diabetes is quite low regardless of the restriction in search method. Also, the review found that the 31 RCTs that include the idea of shared patient experience were conducted on type 2 diabetes care in general, but not specifically around the decision-making process in starting insulin therapy in type 2 diabetes.

3.6.2 Strengths and limitations

To the best of the author's knowledge, this review is the first to provide a working definition of shared patient experience developed on the basis of clinical trials of shared patient experience in type 2 diabetes. Also, this review used a comprehensive search of the literature developed with support from an experienced information specialist using seven databases and hand-searching of reference lists of relevant articles. Yet there are also some limitations.

Firstly, for the reasons mentioned above (section 3.3.1), developing the search strategy was challenging at the initial stage. While guidance was provided by the information specialist to develop the strategy, given that the strategy was conducted using search terms based mainly on studies and reviews of peer support, rather than using studies and reviews of all ten types of interventions which were expected to include potential components of shared patient experience,

[vi] Given that the strategy was conducted using search terms based mainly on studies and reviews of peer support, rather than using studies and reviews of all ten types of interventions which were expected to include potential components of shared patient experience, this strategy might have failed to identify some potentially eligible systematic reviews (see sections 3.3.1 and 3.6.2).

this strategy might have failed to identify some potentially eligible systematic reviews (as noted in footnote vi). In fact, the chance of this strategy missing some eligible systematic reviews is considered not so low, given that the individual studies including the components of shared patient experience were observed in systematic reviews of various types of interventions (and most frequently observed in systematic reviews of interventions for diabetes self-management education programmes).

Secondly, as noted in section 3.3.2, the different criteria (in relation to types of interventions) were applied when screening individual studies included in systematic reviews: inclusion criterion vi was applied at the stage of assessing *title/abstract* sections of individual studies, whereas inclusion criterion vii was applied at the stage of assessing the *full-text* of individual studies. Inclusion criterion vii however, is not likely to be replicable[vii] since this criterion was purely based on discussion among the author and supervisors. Yet, considering the background to the aim of this review - the lack of common understanding of shared patient experience as a concept, and the fact that this review was conducted to clarify the idea of shared patient experience, this may be unavoidable.

Thirdly, in this review, the scope of the search for individual studies identified from the 26 systematic reviews was confined to RCTs for the reason noted above. Inclusion of other study designs might have shed light on some new elements of shared patient experience that were not identified by this review, and led to the development of a more concrete working definition.

Finally, shared patient experience components in the individual studies were, in general, poorly described. This might have resulted in missing some studies that actually included such components.

[vii] Replicability refers to whether others can select the same studies when using the same inclusion criteria.

3.7 Conclusion

The review explored the 26 systematic reviews and identified 31 RCTs containing the idea of shared patient experience. These RCTs were found across various types of interventions. However, no particular concept that describes the idea of shared patient experience was observed in the majority of the 31 RCTs. As such, these RCTs were further analysed, and a working definition for the idea of shared patient experience was proposed, which was defined by the author for the purpose of this study as the "*Provision of and/or learning from patients' personal accounts about health, health care, and health decision- making".*

These findings may suggest that research on shared patient experience is not well-established in a context of type 2 diabetes and is still in its infancy. The utilization of a consistent definition of shared patient experience and the recognition of the common components of shared patient experience interventions as identified in this review, however, could provide a common understanding for the idea of shared patient experience among researchers. Such a common understanding may, in turn, lead to an advancement of the existing research on shared patient experience in type 2 diabetes by cumulating shared patient experience studies, and deepening understanding about the impacts of shared patient experience on psychosocial and health behaviour changes.

The review also found that currently the likelihood of identifying systematic reviews on shared patient experience in adults with type 2 diabetes is low (hence this is a good gap to fill), and that none of the RCTs included in the systematic reviews that contain the idea of shared patient experience was conducted specifically around the decision-making process in starting insulin therapy in type 2 diabetes.

Overall, this review highlights the need for a new systematic review that aims to examine the impact of shared patient experience in adults with type 2 diabetes, and informs its development such as by identifying a working definition of shared patient experience. Based on all these results, a new systematic review will be conducted in the next stage of this thesis (chapter 4).

3.8 References

1. Simmons D, Bunn C, Cohn S, Graffy J. What is the idea behind peer-to-peer support in diabetes? *Diabetes Management.* 2013;3(1):61-70.
2. Simmons D. Peer support: time to tap the (largely) untapped. *Practical Diabetes.* 2013;30(6):246-250.
3. Deakin T, McShane CE, Cade JE, Williams RD. Group based training for self-management strategies in people with type 2 diabetes mellitus. *Cochrane database of systematic reviews (Online).* 2005(2):CD003417.
4. Fransen MP, von Wagner C, Essink-Bot M-L. Diabetes self-management in patients with low health literacy: Ordering findings from literature in a health literacy framework. *Patient Educ Couns.* 2012;88(1):44-53.
5. Gary TL, Genkinger JM, Guallar E, Peyrot M, Brancati FL. Meta-Analysis of Randomized Educational and Behavioral Interventions in Type 2 Diabetes. *Diabetes Educ.* 2003;29(3):488-501.
6. Hawthorne K, Robles Y, Cannings-John R, Edwards AG. Culturally appropriate health education for Type 2 diabetes in ethnic minority groups: a systematic and narrative review of randomized controlled trials. *Diabet Med.* 2010;27(6):613-623.
7. Loveman E, Frampton GK, Clegg AJ. The clinical effectiveness of diabetes education models for Type 2 diabetes: a systematic review. *Health Technol Assess.* 2008;12(9):1-116, iii.

8. Minet L, Møller S, Vach W, Wagner L, Henriksen JE. Mediating the effect of self-care management intervention in type 2 diabetes: A meta-analysis of 47 randomised controlled trials. *Patient Educ Couns.* 2010;80(1):29-41.

9. Nam S, Chesla C, Stotts NA, Kroon L, Janson SL. Barriers to diabetes management: Patient and provider factors. *Diabetes Res Clin Pract.* 2011;93(1):1-9.

10. Norris SL, Engelgau MM, Narayan KM. Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials. *Diabetes Care.* 2001;24(3):561-587.

11. Ramadas A, Quek KF, Chan CKY, Oldenburg B. Web-based interventions for the management of type 2 diabetes mellitus: A systematic review of recent evidence. *Int J Med Inform.* 2011;80(6):389-405.

12. Steinsbekk A, Rygg LO, Lisulo M, Rise MB, Fretheim A. Group based diabetes self-management education compared to routine treatment for people with type 2 diabetes mellitus. A systematic review with meta-analysis. *BMC Health Serv Res.* 2012;12:213.

13. Strom JL, Egede LE. The Impact of social support on outcomes in adult patients with type 2 diabetes: A systematic review. *Curr Diab Rep.* 2012;12(6):769-781.

14. Van Dam HA, Van Der Horst F, Van Den Borne B, Ryckman R, Crebolder H. Provider-patient interaction in diabetes care: Effects on patient self-care and outcomes - A systematic review. *Patient Educ Couns.* 2003;51(1):17-28.

15. Van Dam HA, Van Der Horst FG, Knoops L, Ryckman RM, Crebolder HFJM, Van Den Borne BHW. Social support in diabetes: A systematic review of controlled intervention studies. *Patient Educ Couns.* 2005;59(1):1-12.

16. Brown SA. Studies of educational interventions and outcomes in diabetic adults: A meta-analysis revisited. *Patient Educ Couns.* 1990;16(3):189-215.

17. Dale JR, Williams SM, Bowyer V. What is the effect of peer support on diabetes outcomes in adults? A systematic review. *Diabet Med.* 2012;29(11):1361-1377.

18. Norris SL, Chowdhury FM, Le K, et al. Effectiveness of community health workers in the care of persons with diabetes (Structured abstract). *Diabet Med.* 2006;23(5):544-556. http://onlinelibrary.wiley.com/o/cochrane/cldare/articles/DARE-12006001871/frame.html.

19. Sarkisian CA, Brown AF, Norris KC, Wintz RL, Mangione CM. A systematic review of diabetes self-care interventions for older, African American, or Latino adults. *Diabetes Educ.* 2003;29(3):467-479.

20. Tang TS, Ayala GX, Cherrington A, Rana G. A review of volunteer-based peer support interventions in diabetes. *Diabetes Spectr.* 2011;24(2):85-98.

21. Dorresteijn Johannes AN, Kriegsman Didi MW, Assendelft Willem JJ, Valk Gerlof D. Patient education for preventing diabetic foot ulceration. *Cochrane Database of Systematic Reviews.* 2012(10). http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD001488.pub4/abstract.

22. Glazier RH, Bajcar J, Kennie NR, Willson K. A systematic review of interventions to improve diabetes care in socially disadvantaged populations. *Diabetes Care.* 2006;29(7):1675-1688.

23. Riley S, Marshall ES. Group visits in diabetes care: A systematic review. *Diabetes Educ.* 2010;36(6):936-944.

24. Dale J, Caramlau Isabela O, Lindenmeyer A, Williams Susan M. Peer support telephone calls for improving health. *Cochrane Database of Systematic Reviews.* 2008(4). http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006903.pub2/abstract.

25. Edelman D MJ, Oddone E, et al. Shared Medical Appointments for Chronic Medical Conditions: A Systematic Review. 2012.

26. Foster G, Taylor Stephanie JC, Eldridge S, Ramsay J, Griffiths Chris J. Self-management education programmes by lay leaders for people with chronic conditions. *Cochrane Database of Systematic Reviews.* 2007(4). http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005108.pub2/abstract.

27. Zeh P, Sandhu HK, Cannaby AM, Sturt JA. The impact of culturally competent diabetes care interventions for improving diabetes-related outcomes in ethnic minority groups: a systematic review. *Diabet Med.* 2012;29(10):1237-1252.

28. Eysenbach GP, P; Englesakis, M; Rizo, C; Stern, A. Health related virtual communities and electronic support groups: Systematic review of the effects of online peer to peer interactions. *BMJ: British Medical Journal.* 2004;328.

29. Taylor SE. *Health Psychology, 4th ed.* Boston: McGraw-Hill; 1999.

30. Bardach SH, Tarasenko YN, Schoenberg NE. The role of Social Support in Multiple Morbidity: Self-Management among rural residents. *J Health Care Poor Underserved.* 2011;22(3):756-771.

31. Ford ME, Tilley BC, McDonald PE. Social support among African-American adults with diabetes. Part 1: Theoretical framework. *J Natl Med Assoc.* 1998;90(6):361-365.

32. Dennis CL. Peer support within a health care context: a concept analysis. *Int J Nurs Stud.* 2003;40(3):321-332.

33. Dennis C-L, Hodnett E, Gallop R, Chalmers B. The effect of peer support on breast-feeding duration among primiparous women: a randomized controlled trial. *CMAJ.* 2002;166(1):21-28.

34. Adolfsson ET, Walker-Engstrom M, Smide B, Wikblad K. Patient education in type 2 diabetes: a randomized controlled 1-year follow-up study. *Diabetes Res Clin Pract.* 2007;76(3):341-350.

35. Anderson RM, Funnell MM, Nwankwo R, Gillard ML, Oh M, Fitzgerald JT. Evaluating a problem-based empowerment program for African Americans with diabetes: results of a randomized controlled trial. *Ethn Dis.* 2005;15(4):671-678.

36. Glasgow RE, Boles SM, McKay HG, Feil EG, Barrera M, Jr. The D-Net diabetes self-management program: long-term implementation, outcomes, and generalization results. *Prev Med.* 2003;36(4):410-419.

37. Holtrop JS, Hickner J, Dosh S, Noel M, Ettenhofer TL. "Sticking to it -- diabetes mellitus": a pilot study of an innovative behavior change program for women with type 2 diabetes. *American Journal of Health Education.* 2002;33(3):161-166.

38. Hornsten A, Lundman B, Stenlund H, Sandstrom H. Metabolic improvement after intervention focusing on personal understanding in type 2 diabetes. *Diabetes Res Clin Pract.* 2005;68(1):65-74.

39. Lorig K, Ritter PL, Laurent DD, et al. Online diabetes self-management program: a randomized study. *Diabetes Care.* 2010;33(6):1275-1281.

40. Lorig K, Ritter PL, Villa F, Piette JD. Spanish diabetes self-management with and without automated telephone reinforcement: two randomized trials. *Diabetes Care.* 2008;31(3):408-414.

41. McCulloch DK, Mitchell RD, Ambler J, Tattersall RB. Influence of imaginative teaching of diet on compliance and metabolic control in insulin dependent diabetes. *British Medical Journal Clinical Research Ed.* 1983;287(6408):1858-1861.

42. McKay HG, King D, Eakin EG, Seeley JR, Glasgow RE. The diabetes network internet-based physical activity intervention: a randomized pilot study. *Diabetes Care.* 2001;24(8):1328-1334.

43. Miller CK, Edwards L, Kissling G, Sanville L. Evaluation of a theory-based nutrition intervention for older adults with diabetes mellitus. *J Am Diet Assoc.* 2002;102(8):1069-1081.

44. Ridgeway NA, Harvill DR, Harvill LM, Falin TM, Forester GM, Gose OD. Improved control of type 2 diabetes mellitus: a practical education/behavior modification program in a primary care clinic. *South Med J.* 1999;92(7):667-672.

45. Sarkadi A, Rosenqvist U. Experience-based group education in Type 2 diabetes: a randomised controlled trial. *Patient Educ Couns.* 2004;53(3):291-298.

46. White N, Carnahan J, Nugent CA, Iwaoka T, Dodson MA. Management of obese patients with diabetes mellitus: comparison of advice education with group management. *Diabetes Care.* 1986;9(5):490-496.

47. Zapotoczky H, Semlitsch B, Herzog G, et al. A controlled study of weight reduction in type 2 diabetics treated by two reinforcers. *Int J Behav Med.* 2001;8(1):42-49.

48. Barrera M, Jr., Glasgow RE, McKay HG, Boles SM, Feil EG. Do Internet-based support interventions change perceptions of social support?: An experimental trial of approaches for supporting diabetes self-management. *Am J Community Psychol.* 2002;30(5):637-654.

49. McKay GH, Glasgow RE, Feil EG, Boles SM, Barrera Jr M. Internet-based diabetes self-management and support: Initial outcomes from the diabetes network project. *Rehabil Psychol.* 2002;47(1):31-48.

50. Greenhalgh T, Campbell-Richards D, Vijayaraghavan S, et al. New models of self-management education for minority ethnic groups: pilot randomized trial of a story-sharing intervention. *Journal of Health Services & Research Policy.* 2011;16(1):28-36.

51. Glasgow RE, Toobert DJ, Hampson SE, Brown JE, Lewinsohn PM, Donnelly J. Improving self-care among older patients with type II diabetes: the "Sixty Something..." Study. *Patient Educ Couns.* 1992;19(1):61-74.

52. Baradaran HR, Knill-Jones RP, Wallia S, Rodgers A. A controlled trial of the effectiveness of a diabetes education programme in a multi-ethnic community in Glasgow *BMC Public Health.* 2006;6:134.

53. Anderson-Loftin W, Barnett S, Bunn P, Sullivan P, Hussey J, Tavakoli A. Soul food light: culturally competent diabetes education. *Diabetes Educ.* 2005;31(4):555-563.

54. Baksi AK, Al-Mrayat M, Hogan D, Whittingstall E, Wilson P, Wex J. Peer advisers compared with specialist health professionals in delivering a training programme on self-management to people with diabetes: a randomized controlled trial. *Diabet Med.* 2008;25(9):1076-1082.

55. Heisler M, Vijan S, Piette JD, Makki F. A reciprocal peer support intervention improves glycemic control better than usual nurse case management among diabetes patients with poor glycemic control. *J Gen Intern Med.* 2010;25:S214.

56. Murrock CJ, Higgins PA, Killion C. Dance and peer support to improve diabetes outcomes in African American women. *Diabetes Educ.* 2009;35(6):995-1003.

57. Pratt C, Wilson W, Leklem J, Kingsley L. Peer support and nutrition education for older adults with diabetes. *J Nutr Elder.* 1987;6(4):31-43.

58. Long JA, Jahnle EC, Richardson DM, Loewenstein G, Volpp KG. Peer mentoring and financial incentives to improve glucose control in African American veterans: a randomized trial.[Summary for patients in Ann Intern Med. 2012 Mar 20;156(6):I-50; PMID: 22431687]. *Ann Intern Med.* 2012;156(6):416-424.

59. Lujan J, Ostwald SK, Ortiz M. Promotora diabetes intervention for Mexican Americans. *Diabetes Educ.* 2007;33(4):660-670.

60. Bond GE, Burr RL, Wolf FM, Feldt K. The effects of a web-based intervention on psychosocial well-being among adults aged 60 and older with diabetes: a randomized trial. *Diabetes Educ.* 2010;36(3):446-456.

61. Liebreich T, Plotnikoff RC, Courneya KS, Boule N. Diabetes NetPLAY: A physical activity website and linked email counselling randomized intervention for individuals with type 2 diabetes. *International Journal of Behavioral Nutrition and Physical Activity.* 2009;6(18).

62. De Weerdt I, Visser AP, Kok G, Van der Veen EA. Randomized controlled evaluation of an education program for insulin treated patients with diabetes: Effects on psychosocial variables. *Patient Educ Couns.* 1989;14(3):191-215.

63. Brown SA, Garcia AA, Kouzekanani K, Hanis CL. Culturally competent diabetes self-management education for Mexican Americans: the Starr County border health initiative. *Diabetes Care.* 2002;25(2):259-268.

64. Agurs-Collins TD, Kumanyika SK, Ten Have TR, Adams-Campbell LL. A randomized controlled trial of weight reduction and exercise for diabetes management in older African-American subjects. *Diabetes Care.* 1997;20(10):1503-1511.

65. Trento M, Passera P, Tomalino M, et al. Group visits improve metabolic control in type 2 diabetes: a 2-year follow-up. *Diabetes Care.* 2001;24(6):995-1000.

66. Trento M, Passera P, Tomalino M, et al. Therapeutic group education in the follow-up of patients with non-insulin treated, non insulin dependent diabetes mellitus. *Diabetes Nutr Metab.* 1998;11:212–216.

67. Trento M, Passera P, Borgo E, et al. A 5-year randomized controlled study of learning, problem solving ability, and quality of life modifications in people with type 2 diabetes managed by group care. *Diabetes Care.* 2004;27(3):670-675.

68. Trento M, Passera P, Bajardi M, et al. Lifestyle intervention by group care prevents deterioration of Type II diabetes: a 4-year randomized controlled clinical trial. *Diabetologia.* 2002;45(9):1231-1239.

3.9 Appendices

Appendix 3.1: Strategy for MEDLINE (OVID)

1. vignette*.tw.
2. (story or stories).tw.
3. Narration/
4. 1 or 2 or 3
5. (narrative* adj3 (individual or patient* or personal or illness or people*)).tw.
6. (testimon* adj3 (individual or patient* or personal or illness or people*)).tw.
7. (anecdote* adj3 (individual or patient* or personal or illness or people*)).tw.
8. (story or stories or storytelling*).tw.
9. 5 or 6 or 7 or 8
10. (peer* adj2 (worker* or group* or support* or training* or trainer* or educator* or education or mentor* or listening or counsel* or leader* or coach* or influence* or intervention* or advisor* or candidate* or counsellor* or partner*)).ti,ab.
11. (lay* adj2 (facilitator* or advisor* or worker* or educator* or trainer* or mentor* or tutor* or leader*)).ti,ab.
12. (community adj2 (representative* or advisor* or worker* or educator* or trainer* or mentor*)).ti,ab.
13. promotora*.ti,ab.
14. (diabetes buddies or diabetes buddy or fellow patient* or patient navigator*).ti,ab.
15. (peer led or peer delivered or peer initiated).ti,ab.
16. (experience* adj2 (illness or shared or peer*)).ti,ab.
17. expert patient*.ti,ab.
18. (self-help group* or support group*).ti,ab.
19. (group visit* or cluster visit* or group care* or group education* or group-based educational programme* or group based training* or group based diabetes self-management education).ti,ab.
20. (shared medical appointment* or group medical appointment*).ti,ab.
21. social support*.ti,ab.
22. 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21
23. 4 or 9 or 22
24. exp Diabetes Mellitus/
25. diabet*.ti,ab.
26. 24 or 25
27. 23 and 26
28. limit 27 to "reviews (best balance of sensitivity and specificity)"
29. remove duplicates from 28
30. limit 27 to "reviews (maximizes specificity)"
31. remove duplicates from 30

Appendix 3.2: Characteristics of included reviews

Reference	Title	Aim	Type of participant	Type of intervention	Study design	Operational definition of interventions
Foster 2007	Self-management education programmes by lay leaders for people with chronic conditions	To assess systematically the effects of lay-led self-management education programmes for people with chronic conditions	chronic disease	lay-led self-management education intervention	RCTs	lay-led diabetes care interventions that were defined as structured programmes for people with chronic conditions which were judged by the authors to be primarily educational, primarily addressing self-management of disease; that were delivered by 'lay people' who commonly but not invariably have a chronic disease themselves; that incorporated elements of 'peer support', as long as it was primarily educational and primarily addressed disease self-management
Van Dam 2005	Social support in diabetes: A systematic review of controlled intervention studies	To determine effect of social support interventions on health outcomes in primary and outpatient care for type 2 diabetes	type 2 diabetes	SS intervention	RCTs or quasi-experimental trials with pre-/post-test design	social support interventions that incorporate elements of 'social support', which can be distinguished into four categorises including emotional, appraisal, informational, and tangible support as defined by Taylor (1998); and that aim at increasing the well-being of the receiver
Strom 2012	The Impact of social support on outcomes in adult patients with type 2 diabetes: A systematic review	To examine the impact of social support on outcomes in adults with type 2 diabetes	type 2 diabetes	SS intervention	RCTs, cross-sectional, cohort, or intervention studies	social support interventions that incorporate elements of 'social support', which is a multifaceted experience that involves voluntary associations and formal and informal relationships with others as defined by Bardach et al., (2011), which can be positive or negative and can arise from different sources, including family members, friends, and peers (informal support) and healthcare professionals and organizations (formal support) as defined by Van Dam et al., (2005); and which can be distinguished into four categorises including emotional, tangible, informational, and companionship as defined by by Ford et al., (1998)
Norris 2006	Effectiveness of community health workers (CHW)s in the care of persons with diabetes	To evaluate the effectiveness of interventions involving CHWs in the care of diabetics	adults (18 years old or older) with diabetes		RCTs, controlled before–after trials, and studies with a before–after or post intervention only design	community healthcare worker-led diabetes care interventions that involved a 'community healthcare worker' who is defined as any healthcare worker who (i) carried out functions related to healthcare delivery, (ii) was trained in some way in the context of the interventions, (iii) had no formal professional or paraprofessional training in healthcare, and (iv) had a relationship with the community being served; that involved community healthcare workers who were either the sole focus of the intervention or one component of a multi-component intervention or team
Tang 2011	A Review of Volunteer-Based Peer Support Interventions in Diabetes	To examine the association between the implementation strategies in volunteer-based peer support interventions and diabetes-related health outcomes	adult diabetic patients of middle-aged to older (52.9–72.7 years)	volunteer-based PS interventions	RCTs or quasi-experimental (e.g., pre-/post or case-comparison) study design.	peer support interventions that are led by a volunteer peer supporter (peer supporters were considered to be volunteers if they were not full- or part-time employees of the clinics, organizations, or universities in which they served. Programs in which peer supporters received a stipend or honorarium used to offset the costs of participation such as transportation and childcare were not included. Also, family members as peer supporters were excluded in this study); that include an explicit training component for peer supporters; and that focus on self-management rather than prevention

Dale 2012	What is the effect of peer support on diabetes outcomes in adults? A systematic review	To systematically review evidence of the impact and effectiveness of peer support in adults living with diabetes.	adults with diabetes	PS intervention	RCTs or quasi-RCTs, controlled clinical trials, before-and-after studies, interrupted time series, descriptive studies or case studies	peer support interventions that aim at improving the care or management of diabetes, that describe a specific programme which led by peers providing support to adults with diabetes; and that incorporate elements of 'peer support', as defined by Dennis (2003) as support from a person who has experiential knowledge of a specific behaviour or stressor and similar characteristics (e.g. age, gender, disease status, socio-economic status, religion, ethnicity, culture) as the target population
Dale 2008	Peer support telephone calls for improving health	1. To assess the effects of peer support telephone calls for improving the health and quality of life of individuals as well as their carers, on outcomes including physical, psychological, behavioural and other health outcomes 2. To determine the health areas in which peer support telephone calls have been most successful 3. To identify the factors associated with success in improving health, and the types of intervention found to be most successful, and to use this to develop a classification of peer support telephone calls 4. To explore the relationship between training and the development of para-professionalism among peer supporters	people living with acute or long-term illness, carers of people with acute or long-term illness, parents, people with psychological symptoms, and people requiring screening or who had any other health and well-being related concerns.	telephone-delivered PS intervention	RCTs	telephone-delivered peer support interventions that are delivered using telephone by peer supporter who is someone selected to provide support because they have similar or relevant health experience; that incorporate elements of 'peer support', as defined by Dennis et al. (2002) as a provision of emotional, appraisal and informational assistance by a created social network member who possesses experiential knowledge of a specific behaviour or stressor and similar characteristics as the target population, and who are provided a minimum training for peer support to ensure the preservation of 'peerness' and to avoid profes- sionalism and the subsequent creation of 'para-professionals' (i.e. the loss of 'peerness')
Eysenbach 2004	Health related virtual communities and electronic support groups: systematic review of the effects of online peer to peer interactions	To compile and evaluate the evidence on the effects on health and social outcomes of computer based peer to peer communities and electronic self support groups, used by people to discuss health related issues remotely	not clear	online PS intervention	RCTs, non-RCTs, and cohort studies	online peer support interventions that studied a virtual community (or had a virtual community component), defined for the purpose of this study as a group of individuals with similar or common health related interests and predominantly non-professional backgrounds (patients, healthy consumers, or informal caregivers) who interact and communicate publicly through a computer communication network such as the internet, or through any other computer based tool (including non-text based systems such as voice bulletin board systems), allowing social networks to build over a distance; whose content focused on health or healthcare issues in the broadest sense, including emotional and social support, health education, or health related behaviour change
Nam 2011	Barriers to diabetes management: Patient and provider factors	To summarize existing knowledge regarding various barriers of diabetes management from the perspectives of both patients and clinicians	type 2 diabetes	intervention in diabetes management	cross-sectional studies, RCTs, observational studies and qualitative studies	diabetes management interventions addressing patients' barriers, clinicians' barriers, and self-management
Dorresteijn 2012	Patient education for preventing diabetic foot ulceration	To assess the effects of patient education on the prevention of foot ulcers in patients with diabetes mellitus	type 1 & 2 diabetes	educational intervention	prospective RCTs	diabetes education interventions which aim to reduce the incidence of foot ulceration in people with diabetes mellitus

Loveman 2008	The clinical effectiveness of diabetes education models for Type 2 diabetes: a systematic review	To examine the clinical effectiveness of patient education models for adults with Type 2 diabetes	type 2 diabetes	educational intervention	RCTs and controlled clinical trials	diabetes education interventions which aimed at disseminating knowledge and skills brought about using a number of approaches, which can be carried out with the normal range of personnel available in diabetes care
Norris 2001	Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials	To systematically review the effectiveness of self-management training in type 2 diabetes.	type 2 diabetes	Self-management training interventions	RCTs	diabetes self-management education interventions that involved diabetes self-management education as either the sole focus of the intervention or one component of a multi-component intervention (only if the effects of the educational component could be examined separately); that were delivered by any provider type, any medium (written, oral, video, computer), individual- or group-based, and any duration and intensity
Brown 1990	Studies of educational interventions and outcomes in diabetic adults: A meta-analysis revisited.	The purpose was to determine: (1) the effects of patient education on specific outcome variables; and (2) the relationships between effects of education and characteristics of the studies and/or subjects	see below	self-care management intervention	an experimental design that included both treatment and control groups or a one group pre-test/post-test design	diabetes education interventions that were designed to improve patient knowledge; self-care behaviours including skill performance or compliance (adherence); metabolic control; and/or psychological outcomes including stress reduction, coping, adaptation
Minet 2010	Mediating the effect of self-care management intervention in type 2 diabetes: A meta-analysis of 47 randomised controlled trials	To perform a meta-analysis assessing the effects of self-care management interventions in improving glycaemic control in type 2 diabetes by analysing the impact of different study characteristics on the effect size	type 2 diabetes	self-care management intervention	RCTs	diabetes self-care management interventions which used educational (e.g. Techniques based on didactic-oriented intervention focusing on the knowledge acquisition, skills and information in order to improve diabetes self-management) or behavioural/psychosocial (e.g. he intervention was based on cognitive, behavioural or motivational approaches, or if the study specified that the patients were receiving psychologically centred counselling involving relaxation, problem-solving, or motivational interviewing) strategies aimed to stimulate the performance of self-care to increase target behaviour actions such as blood glucose monitoring, diet care and physical activity
Gary 2003	Meta-Analysis of Randomized Educational and Behavioural Interventions in Type 2 Diabetes	To assess the effect of educational and behavioural interventions on body weight and glycaemic control in type 2 diabetes	type 2 diabetes	education and behavioural Interventions	RCTs	education and behavioural Interventions that included behavioural or counselling component aimed at improving long-term diabetes self-care behaviours
Steinsbekk 2012	Group based diabetes self-management education compared to routine treatment for people with type 2 diabetes mellitus. A systematic review with meta-analysis.	To assess effects of group-based DSME compared to routine treatment on clinical, lifestyle and psychosocial outcomes in type-2 diabetes patients.	type 2 diabetes	group-based DSME intervention	RCTs	group-based diabetes self-management education interventions which described group-based education specific for people with type 2 diabetes; whose duration of education was a minimum of one session lasting for one hour

Deakin 2005	Group based training for self-management strategies in people with type 2 diabetes mellitus	To assess the effects of group-based (six or more people), patient-centred diabetes training on clinical, lifestyle and psychosocial outcomes both in the short (four to six months) and longer-term (more than 12 months) compared with routine care delivered on a one-to-one basis, or a combination of the two To observe whether the setting (primary / secondary care), the educator (physician, nurse, dietitian, other health professional, peer educator), the type of educational model or the duration/intensity of the group-based education programme affects the outcomes	type 2 diabetes	group based patient-centred self-management interventions	RCTs and controlled clinical trials	group-based diabetes self-management education interventions which were based on learner/patient-centred education; which included or excluded family and friends; which had a minimum of six participants in each group; and which included a minimum of one session lasting for one hour
Riley 2010	Group visits in diabetes care: A systematic review	To systematically review the evidence on group visits in diabetes to determine if the group visit or traditional care is more effective in achieving positive patient outcomes in patients with diabetes To examine different approaches to the model, the delivery of the patient education component, and the strength of the study data to develop suggestions for how diabetes educators can best facilitate this model of care	type 1 and 2 diabetes	group-based DSME intervention	non-RCTs	group visits diabetes care interventions that included both education and elements of an individual office visit; and that involved certified diabetes educator as part of the group visit provider team
Van Dam 2003	Provider-patient interaction in diabetes care: Effects on patient self-care and outcomes - A systematic review.	To determine effect of modification of provider-patient interaction and provider consulting style on patient diabetes self-care and diabetes outcomes, in general practice or hospital outpatient settings	type 2 diabetes	behaviour focused interventions	RCTs	patient behaviour focused interventions that test the effects of modification of provider–patient interaction and provider consulting style on patient diabetes self-care and diabetes outcomes
Ramadas 2011	Web-based interventions for the management of type 2 diabetes mellitus: A systematic review of recent evidence	To provide a descriptive discussion of web-based behavioural interventions for the management of type 2 diabetes mellitus	type 2 diabetes	web-based behavioural interventions	RCTs or quasi-experimental designs	web-based behavioural interventions which focused on exchange of information via a website between a healthcare provider and a patient; which intervened on physical activity, nutrition, self-monitoring or weight loss
Edelman 2012	Shared Medical Appointments for Chronic Medical Conditions: A Systematic Review	To summarize the effects of SMA on staff, patient, and economic outcomes and to evaluate whether the impact varied by clinical condition or specific intervention components	chronic medical conditions	shared medical appointments interventions	cluster RCTs, nonrandomized cluster controlled trials, controlled before-and-after studies, or interrupted time series designs	shared medical appointment interventions which involved a series of medical visits where at least one health care professional cares for a groups of patients; and where the medical provider addresses each patient's unique medical needs individually, with the potential to make changes in medications, but in the context of the group setting

Glazier 2006	A systematic review of interventions to improve diabetes care in socially disadvantaged populations	To identify and synthesize evidence about the effectiveness of patient, provider, and health system interventions to improve diabetes care among socially disadvantaged populations	type 1 and 2 diabetes	interventions in diabetes care for socially disadvantaged populations	RCTs, controlled trials, or before- and-after studies with a contemporaneous control group.	diabetes self-management interventions that target socially disadvantaged diabetic patients; that include home glucose monitoring, regulation of diet and exercise, adherence to and self adjustment of medications, and attendance at office appointments when needed or as scheduled by the provider
Fransen 2012	Diabetes self-management in patients with low health literacy: Ordering findings from literature in a health literacy framework	To review the literature on the association between HL and diabetes self-management and the possible mediating variables in this pathway	type 2 diabetes	diabetes self-management intervention in patients with low health literacy:	non-RCTs	diabetes self-management interventions that reported on the association between health literacy and diabetes self-management tasks
Hawthorne 2010	Culturally appropriate health education for Type 2 diabetes in ethnic minority groups: a systematic and narrative review of randomized controlled trials	To determine if culturally appropriate health education is more effective than 'usual' health education for people with diabetes from ethnic minority groups living in high- and upper-middle-income countries	type 2 diabetes	culturally appropriate diabetes health education intervention	RCTs	culturally appropriate diabetes health education interventions that incorporated elements of 'culturally appropriate education' which was defined as education that was tailored to the cultural or religious beliefs and linguistic skills of the community being approached, taking into account likely literacy skills; that could include adapting established health education to innovative delivery methods, such as using community-based health advocates, or delivering it to same gender groups, or adapting dietary advice to fit in with the likely diet of a particular community; where participants belonged to ethnic minority communities resident in upper-middle and high-income countries (ethnic minority communities refers to upper middle and high income countries, where there are sizeable numbers of people resident who originate from other countries, with identifiable differences in culture, religion or language, from the majority or dominant population and likely to be disadvantaged in terms of health)
Sarkisian 2003	A systematic review of diabetes self-care interventions for older, African American, or Latino adults	To identify and examine published self-care interventions designed to improve glycaemic control or quality of life (QoL) among older, African American, or Latino adults	adults with diabetes	diabetes self-care interventions for older, African American, or Latino adults	RCTs or non-RCTs	diabetes self-care interventions which aimed at changing knowledge, beliefs, or behaviour among adults with diabetes
Zeh 2012	The impact of culturally competent diabetes care interventions for improving diabetes-related outcomes in ethnic minority groups: a systematic review	To examine the evidence on culturally competent interventions tailored to the needs of people with diabetes from ethnic minority groups	any type of diabetes	culturally competent diabetes care interventions	RCTs or non-RCTs	culturally competent diabetes care interventions which reported the impact of culturally competent programmes on any outcome measures to any ethnic minority population within a majority population globally with any type of diabetes

RCTs = randomised controlled trials; PS = peers support; SS = social support; SR = systematic review; DSME = diabetes self-management education

Appendix 3.3: Process of selecting individual studies included in systematic reviews

Reference	Foster 2007	Van Dam 2005	Strom 2012	Norris 2006	Tang 2011	Dale 2012	Dale 2008	Eysenbach 2004	Nam 2011	Dorresteijn 2012	Loveman 2008	Norris 2001	Brown 1990	Minet 2010	Gary 2003	Steinsbekk 2012	Deakin 2005	Riley 2010	Van Dam 2003	Ramadas 2011	Edelman 2012	Glazier 2006	Fransen 2012	Hawthorne 2010	Sarkisian 2003	Zeh 2012
Type of interventions SRs focused on	Lay	SS		CHW	PS				DSME										behavioural		SMA	SDP	LHL	Culture		
# of studies included in each SR (including duplicates)	18	6	36	18	12	25	7	38	80	12	20	72	82	47	18	23	11	8	8	20	25	26	11	12	12	11
# of studies which met inclusion criteria 2 (iv - vi) (including duplicates) Total # of studies after removing duplicates (n = 162)	4	5	9	8	7	14	0	2	7	1	14	59	27	28	9	23	10	0	0	16	5	8	0	11	6	3
# of studies which met inclusion criteria 2 (vii)	3	2	5	2	3	10	0	1	1	0	6	13	4	8	2	12	6	0	0	5	2	2	0	5	2	2
	3*	6*		2*	12*				41*										5*		2*	2*	0	8*		
	31 (after removing duplicates and 4 multiple publications)																									

SR = systematic review; SS = social support programme; PS = peer support programme; CHW = community healthcare worker-led diabetes care programme ; Lay = lay-led disease care programmes; DSME = diabetes self-management education programme; Behavioural = diabetes behaviour programme; SMA = shared medical appointment programme; SDP = diabetes self-management programme for socially disadvantaged populations; * = after removing duplicates found between SRs of the same type of interventions; LHL = diabetes self-management programme for low health literacy populations ; Culture = culturally-appropriate diabetes care programme

Appendix 3.4: Characteristics of individual studies included in systematic reviews

Reference	Type of intervention focused on in systematic reviews	Mode of delivery in shared patient experience					
		Facilitattor(s)	Remote	Face-to-face	Individual	Group	Role model
Anderson-Loftin / 2005	Culture	x local registered dietician		x		x	x
		x nurse case manager					
Lujan / 2007	SS	x promotra (non-patient)		x		x	
Lorig / 2008	DSME	x peer educator (patient)		x		x	x
Long / 2012	SS	x peer mentor (patient)	x phone		x		
Holtrop / 2002	DSME	x lay health advisor (non-patient)		x		x	
Pratt / 1987	PS	x peer support facilitator (non-patient)		x		x	
De Weerdt / 1989	Lay	x peer (patient)	x video film	x		x	
Lorig / 2010	DSME	x peer (patient)	x online			x	x
Glasgow / 2003	DSME	x peer (patient)	x online			x	
		x research staff					
McKay / 2002, Barrera / 2002	DSME	x peer (patient)	x online			x	
		x research staff					
		x peer (patient)					
		x research staff					
Liebreich / 2009	Behavioural	x research staff	x online			x	
McKay /2001	DSME		x online			x	
		x research staff					
Bond / 2010	Behavioural	x nurse, social worker & psychologist	x online			x	

Baradaran / 2006	Culture	x bilingual podiatrist & dietician		x		x	
Anderson / 2005	DSME	x nurse & dietitian		x		x	
Agurs-Collins / 1997	SDP	x registered dietitian & exercise physiologist		x		x	
Adolfsson / 2007	DSME	x physicians & diabetes specialist nurses		x		x	
Hornsten / 2005	DSME	x diabetes nurses		x		x	
White / 1986	DSME	x clinical psychologist		x		x	
Greenhalgh / 2011	Culture	x health advocates		x		x	
Ridgeway / 1999	DSME	x nurse & dietician		x		x	
Sarkadi / 2004	DSME	x pharmacist		x		x	
Murrock / 2009	PS			x		x	
Trento / 1998, 2001, 2002, 2004	SMA	x physicians & health educator		x		x	
Brown / 2002	CHW	x bilingual nurse, dietitian, & community worker (patient)	x video film	x		x	
McCulloch / 1983	DSME		x video film			x	
Miller / 2002	DSME	x dietitian		x		x	
Glasgow / 1992	Culture	x trained exercise leader		x		x	
Zapotoczky / 2001	DSME	x dietitian		x		x	
Heisler / 2010	PS	x nurse case manager		x		x	
Baksi / 2008	PS	x peer advisor (patient)		x		x	

SS = social support programme; PS = peer support programme; CHW = community healthcare worker-led diabetes care programme ; Lay = lay-led disease care programmes; DSME = diabetes self-management education programme; Behavioural = diabetes behaviour programme; SMA = shared medical appointment programme; SDP = diabetes self-management programme for socially disadvantaged populations; Culture = culturally-appropriate diabetes care programme

Chapter 4. Systematic review of randomized controlled trials on effects of shared patient experience on health in adults with type 2 diabetes

4.1 Introduction

The results of the previous chapter reporting a review of existing systematic reviews demonstrated a need for a new systematic review on the effect of shared patient experience in adults with type 2 diabetes, and informed its development by identifying a working definition and the common components of shared patient experience. A systematic review is an overview of all available high quality research evidence on a particular research question. It uses explicit, systematic methods that are selected with a view to minimizing bias, thus providing a high level of evidence on the effectiveness and methods of interventions from which conclusions can be drawn and decisions made[1]. With unmanageable amounts of information, including evidence from healthcare research, it is unlikely that healthcare providers, consumers, researchers, and policy makers will have the time, skills and resources to find, appraise and interpret this evidence and to incorporate it into healthcare decisions. Systematic reviews respond to this need by identifying, appraising and synthesizing research-based evidence and presenting it in an accessible format[2,3]. A systematic review of randomized controlled trials (RCTs) on the effect of shared patient experience in adults with type 2 diabetes was conducted to explore methods that have been used to evaluate shared patient experience in adults with type 2 diabetes and its impact. The results of the review of existing systematic reviews (chapter 3) identified no RCTs on shared patient experience specifically around decision-making about insulin. This indicated that there was a possibility of finding only a few or no studies at all if limiting the search specifically to the context of insulin decision-making. Thus, in order not to overlook relevant studies, the systematic review was widened to examine a context of management of type 2 diabetes in general.

4.2 Aim

The research question this review aimed to answer was:

- Could shared patient experience interventions improve health in the context of type 2 diabetes care in general? And what methods have been used to evaluate such interventions (e.g. components of shared patient experience)?

4.3 Methods

4.3.1 Search methods for identification of studies

The databases searched were the Cochrane library databases (CENTRAL, DARE, CDSR), MEDLINE, EMBASE, PsycINFO, and CINAHL. While there are uncertainties about the relevance of studies on 'peer support' in diabetes literature, the results from chapter 3 (section 3.6.1) informed nine types of interventions that often include the idea of shared patient experience. As such, at the initial stage of developing the search strategy, the author tested the search strategy by gathering key terms that appeared in studies and reviews of the nine types of interventions. Yet this failed to capture about one third of the 31 RCTs of shared patient experience interventions that had been identified from the review of systematic reviews (chapter 3). Additional search terms that could be incorporated into the search strategy were, therefore, explored. This was followed by the author reviewing the 31 RCTs, and identifying terms commonly used in the RCTs to describe the idea of shared patient experience. A total of 123 search terms relating to shared patient experience were selected and combined with diabetes which was covered under the MeSH tree, and seven search terms relating to randomized controlled trial (RCT). The reference lists of the identified articles were also searched. Also, the review of systematic reviews (chapter 3) found that none of the 31 interventions including components of shared patient experience that were identified from the 26 systematic reviews was published in a language other than English.

Therefore, only studies published in the English language were included in the analysis. Moreover, since the pilot search limited to studies published between January 1960 and December 1979 did not identify any articles, the search was limited to studies published between January 1980 and June 2013. The strategy for MEDLINE (OVID) is presented as an example in Appendix 4.1. The MEDLINE strategy was tailored to the other databases.

4.3.2 Inclusion criteria

Types of studies

To identify study design that could provide evidence of efficacy based on unbiased study design, this review only included RCTs[4].

Types of participants

Databases were searched for studies where the sample population included adults with type 2 diabetes with any degree of disease severity and with any comorbidity. If the studies did not clearly define the diabetes as type 2, participants had to be described as 'adults' or a minimum of 80% of participants had to be 18 years of age or older. Type 2 diabetes is largely a disease of adulthood. It was believed that social influences such as peer support relevant to children and adolescents with either type 1 or type 2 diabetes were sufficiently different to warrant a separate review.

Types of interventions

The intervention studies were included if they described a specific programme which included an explicit component of shared patient experience. This was defined for the purpose of this study as "*provision of and/or learning from patients' personal accounts about health, health care, and health decision-making"* (see chapter 3).

Second, interventions were selected if they included shared patient experience components with either these strategies as sole focus of the intervention or as one component of a multi-component intervention. If shared patient experience was one of the components of a multi-component intervention, the majority (in terms of time) of the intervention needed to include a shared patient experience component for inclusion/consideration in the main analysis. Third, interventions had to focus on self-management rather than prevention, which aimed at improving diabetes-related health. Finally, interventions could be delivered in any setting.

Types of outcome measures

All the reported outcome measures in relation to diabetes-related health and health behaviour were included (whether validated or by self-report). For clinical measures, quality and outcomes framework (QOF) recommends a measurement of certain indicators for people with type 2 diabetes such as body mass index (BMI), blood pressure, haemoglobin A1c (HbA1c), cholesterol, smoking status, foot examination, albumin:creatinine ratio, and serum creatinine to improve control of blood pressure, cholesterol and blood glucose levels and reduce the risk of any complications of diabetes (e.g. cardiovascular disease, kidney failure and lower limb amputation)[5]. Some of the clinical measures that were recommended in QOF and/or frequently measured across the shared patient experience studies were selected. Advice from one of the supervisors who is a clinician was also sought in selecting the outcome measures.

Types of comparison groups

RCTs that compared a shared patient experience intervention with a non-shared patient experience control group [i.e. routine treatment receiving the standard of care recommended in that country (e.g. regular follow-up with health professionals and a full diabetes annual review); a waiting list; no intervention; and other types of intervention] were included.

A summary of the inclusion criteria for studies follows below:

- The study participants include adults with type 2 diabetes with any degree of disease severity and with any comorbidity. If the studies did not clearly define the type of diabetes as being type 2, participants needed to be described as 'adults' or a minimum of 80% of participants had to be 18 years of age or older.
- Interventions use RCT design
- Interventions describe a specific programme that included an explicit component of shared patient experience, which was defined for the purpose of this study as "*Provision of and/or learning from patients' personal accounts about health, health care, and health decision- making"*
- Interventions include shared patient experience components with either these strategies as sole focus of the intervention or as one component of a multi-component intervention
- Interventions focus on self-management rather than prevention and aims at improving diabetes-related health
- Interventions can be delivered in any setting
- Outcome measures are in relation to diabetes-related health and health behaviour
- Comparison groups (non-shared patient experience control group) include routine treatment receiving the standard of care recommended in that country, a waiting list, no intervention, and other types of intervention
- Studies must be published in English

4.3.3 Exclusion criteria

Studies were excluded if they met the following criteria:

- The study includes a mixed group of type 1 and type 2 participants

- The paper consists of conference abstract, dissertation, and protocol
- The study does not explicitly describe shared patient experience components

4.3.4 Selection of studies

The database and reference list searches were conducted and the identified papers were imported into Endnote. After the removal of duplicates, the author assessed title/abstract of all the articles for their applicability according to the inclusion and exclusion criteria. A second reviewer randomly selected 8% of the articles, and scanned the *title/abstract* sections of these references. Disagreements on inclusion, exclusion, or reasons for exclusion were not discussed between the author and the second reviewer.

4.3.5 Identification of full-text of eligible studies

The full text of all the papers that were eligible was read and further assessed solely by the author according to the selection criteria. No second reviewer was assigned to identify the *full-text* of all eligible papers.

4.3.6 Data extraction and management

All relevant data were extracted and summarised solely by the author in a data extraction table without a second reviewer. The following items were reported: citation (record number, author, year); geographic location; setting; description of participants (number of participants including those lost to follow-up, baseline characteristics, compliance, age, gender, ethnicity, duration of diabetes, treatment received/receiving, social/demographic details); the nature of interventions (number of treatments, frequency and duration of intervention, length of follow-up, theoretical basis, extent of shared patient experience components integrated in treatment group(s), shared patient experience components including mode of delivery, roles and contents); and details of comparison group. Also, for each study the following data on outcome measures were extracted:

principal and secondary outcome measures; method of data collection (e.g. questionnaire, physical measurements); and timing of outcome assessment (including length of follow-up). The results of each study were extracted in terms of outcome measures, mean, standard deviation (SD), percentages, and P-values.

4.3.7 Data synthesis/Investigation of heterogeneity

Overall, the shared patient experience interventions displayed considerable heterogeneity in terms of mode of delivery, roles, contents, type of outcome measures, and method of data collection used to assess each outcome measure. This made it difficult to pool data for any one endpoint from a number of studies. Because of the heterogeneity of the included studies the data were presented narratively and in tabular form. As discussed below (section 4.4), the difference between the studies was explored specifically in terms of: intervention setting; participants; nature of interventions including duration of intervention, shared patient experience components, extent of shared patient experience components integrated in treatment group(s), and theoretical framework of interventions; comparison group; and types of outcome and outcome measure.

4.3.8 Assessment of bias risk of included studies

Assessing the risk of bias for included RCTs is necessary when conducting a systematic review to assess the extent to which any associated bias could impact on its findings and conclusion[6]. While there is currently no consensus on the best approach tool for assessing risk of bias, Viswanathan et al. (2012)[7] recommend the following general principles when selecting a tool to assess risk of bias in systematic reviews: demonstrate acceptable validity and reliability, or show transparency in how assessments are made by providing explicit support for each assessment; specifically address items related to risk of bias (internal validity), and preferably based on empirical evidence of bias; where available, specific to the study designs being evaluated; and avoid the presentation of risk-of-bias assessment as a composite score, that is, an overall numerical rating of study risk of bias across items. Since the Cochrane method of risk of bias

satisfies these principles, the quality of reporting of each randomised trial was assessed largely on the quality criteria specified by the guidelines of the Cochrane handbook[8]. Judgements on the criteria were made solely by the author for each of the 42 studies without input from a second reviewer.

For this review, studies on the following five quality elements were assessed: sequence generation, allocation concealment, blinding of outcome assessors, completeness of outcome data, and selective reporting. Because blinding of patients and healthcare providers is not feasible considering the nature of the interventions studied (educational interventions were the majority), judgement was based solely on the information provided about blinding of outcome assessors. Each quality element was assessed using criteria described in a study quality guide by the Cochrane Consumers and Communication Review Group[5] and the Cochrane Handbook[8]. The result was categorised into low risk of bias, unclear, or high risk of bias: risk of bias for sequence generation was considered low (if 'truly random methods' were used such as computer-generated random numbers, random number tables, coin toss, or die toss)[5], unclear (if unable to judge low or high risk of bias due to absence of reporting), or high (if 'inadequate methods' were used that produce a predictable assignment pattern such as birth dates)[5,8]; risk of bias for allocation concealment was considered low (if 'adequate allocation concealment approaches' were used such as central computer randomisation and allocation, sequentially numbered, opaque sealed envelopes, where sequence for allocating participants to groups is truly hidden from investigators)[5], unclear (if unable to judge low or high risk of bias due to absence of reporting), or high (if 'inadequate approaches' were used such as non-opaque envelopes, medical record numbers, where a sequence may be accessed or predicted by investigators before allocation to groups has occurred)[5]; risk of bias for blinding of outcome assessors was considered low (if all the outcomes were assessed by assessors who were blinded to group assignment)[8], unclear (if unable to judge low or high risk of bias due to absence of reporting), or high (if all the outcomes were assessed by assessors who were not blinded to group assignment); risk of bias for

completeness of outcome data was considered low (if no dropouts; or if number and reasons for dropouts were completely described, and analysis was by intention-to-treat)[8], unclear (if unable to judge low or high risk of bias due to absence of reporting), or high (if number of dropouts was more than 20%, reasons for dropouts were likely to be related to true outcomes such as lack of efficacy[8], and intention-to-treat analysis was not conducted[8]); risk of bias for selective reporting was considered low (if primary and/or secondary outcomes were described and all the pre-specified outcomes were measured and reported)[5,8], unclear (if unable to judge low or high risk of bias due to absence of reporting), or high (if outcomes were reported according to their statistical significance, with non-significant results being withheld)[8]. The results of the assessment were incorporated into the review through systematic narrative description of and commentary on each of these domains, leading to an overall assessment of the included studies' risk of bias and a judgement about the internal validity of the review's results.

4.4 Results

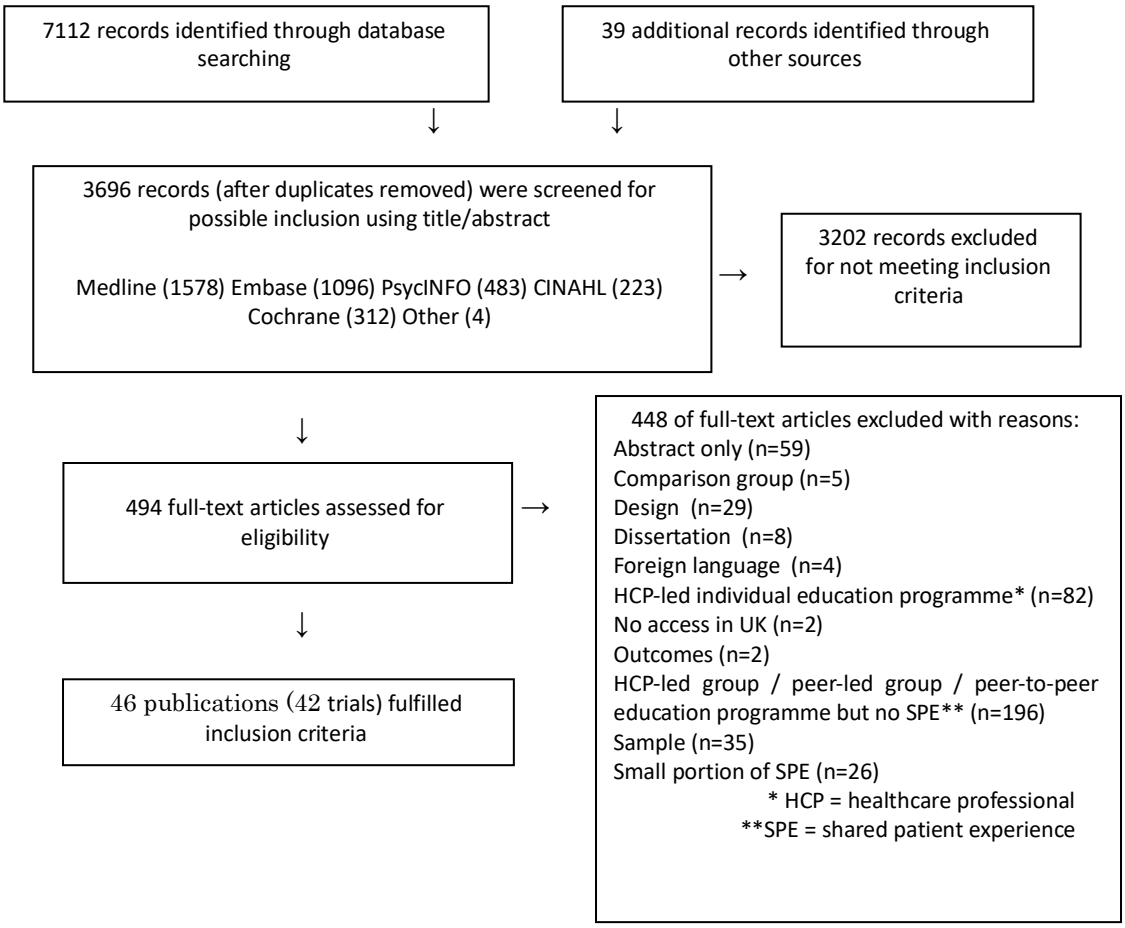
4.4.1 Included studies

Figure 4.1 illustrates the flow of papers through the review process. 3696 unique papers identified were screened by reading title/abstract and 3202 were excluded. Full-texts for the remaining 494 were read and 448 papers not meeting the inclusion criteria were eliminated. As a result, a total of 42 studies reported in 46 publications were included[9-54]. Among the 46 publications, six reported data from the same studies by either reporting other outcome measures[49,50] or long-term follow-ups[45,52-54].

The second reviewer randomly selected 8% (n=342) of the 3696 articles, and scanned the title/abstract of these references using the above mentioned inclusion/exclusion criteria. The second reviewer selected eight out of 342 papers. The number of the papers selected from the 342

papers by the first reviewer was also explored. It was found that the first reviewer selected 59 out of 342 papers and that the eight papers selected by the second reviewer were all included in the 59 papers selected by the first reviewer.

Figure 4.1 Flow chart of review of studies (date of the database search: **August/2013**)



Characteristics of the included studies are summarised in Appendices 4.2 and 4.3, and discussed below in terms of: the settings and populations of the included studies (sections 4.4.2 and 4.4.3); the nature of the interventions (sections 4.4.4, 4.4.5, 4.4.6, and 4.4.7); comparison groups (section 4.4.8); and outcomes measures (section 4.4.9).

4.4.2 Intervention setting

26 studies (65%) were conducted in the United States of America (USA)[11-13,15-17,19,20,24,26,28,30-39,42,44,46,47,49,50], three each in the United Kingdom (UK)[14,21,25] and in Sweden[9,27,43], and two in Italy[45,51-54]. The remaining papers were produced in: Australia[41], the Netherlands[22], Canada[29], Norway[40], Iran[10], Taiwan[48], Thailand[18], and Argentina[23] (one study each). 13 studies (33%) took place in a hospital[10,11,16,18,21,22,25,28,30,37,40,45,51-54], 11 studies in the community[12,23,32,33,36,38,41-44,47], and eight in primary care scenarios[9,13,14,20,26,27,34,39]. The seven studies using a computer platform were conducted in a home setting[15,17,24,29,31,35,49,50], and three studies did not report[19,46,48].

4.4.3 Participants

Sample sizes ranged from 26[41] to 761[31] adults (mean 139), with a total of 5781 adults recruited in the 42 studies. Overall, 49% of recruited participants were female[10-19,21,23,25,27,28,30-32,34,35,38,40-42,44,45,47-54] (excluding eight studies that did not report participants' gender[9,22,24,29,33,37,39,43], three studies directed exclusively at women[20,26,36], and one study at men[46]). The mean age of the study participants ranged from 44 to 69 years (mean = 59.3; SD = 5.65).

17 out of 42 studies (40%) were directed at participants from non-white ethnic groups: nine studies focused on African Americans[11,13,17,20,30,36,42] including one study involving over 96% of African American participants[12]; three studies focused on Mexican Americans[16,33,38]; and one study each focused on Thais[18], Taiwanese[48], South Asians[14] and African Caribbeans[25] in the UK, and Pacific Islanders in the USA[44]. In four studies over 80% of participants were white[15,26,35,40]. Four studies recruited a mixture of Hispanics, African Americans, American Indians, Alaskans, and Whites in the USA[28,31,34,37]. 18 studies did not report the racial or ethnic breakdown of the sample[9,10,19,21-24,27,29,32,39,41,43,45-47,49-54]. Duration of diabetes was reported in 24 trials; in nine of those it was between ten and 16 years[15,22,30,36,39,44,46,49-51], and in 15 trials it was between five and nine years[10,12-14,16,23,25,29,34,35,40,42,43,45,48,52-54].

4.4.4 Duration of intervention

Duration of the intervention lasted from six weeks[12] to 5 years[53]. Programmes varied in frequency with the least intensive being three or four hours per year[53], and with the most intense education programme being 12 hours in one month[22]. Frequency of the intervention was not clear in 11 studies[14,17,18,24,27,28,30,35,37,44,49,50]. The length of follow-up was between three and six months for 22 (52%) of the trials[10-15,19,21,26,28-33,35,37,44,46-50], seven to ten months for six of the trials[17,18,22,24,34,38], one year for ten trials[9,16,23,25,27,36,39-42], and two years for two trials[20,43]. One trial which published its findings in four publications reported follow-up at one year[54], at two years[45], at four years[52], and at five years[53].

4.4.5 Type of intervention including shared patient experience components & the extent of shared patient experience components integrated in treatment group(s)

Components of shared patient experience were incorporated in various types of interventions including diabetes self-management education interventions (12 studies – 29%)[9,12,15,17,24,31,32,37,40,43,46,49,50], peer support interventions (six studies)[18,23,30,36,41,47], culturally-adapted/competent diabetes self-management education interventions (five studies)[13,16,25,42,44], health behaviour interventions (four studies)[11,21,26,35], health education interventions (three studies)[10,22,28], group-visit interventions [45,51-54] (two studies), culturally-relevant diabetes self-management training interventions[20], social support interventions[34], promotora-led diabetes interventions [33], culturally-sensitive peer-led diabetes education interventions[38], self-efficacy-enhancing interventions[48], counselling interventions[29], culturally-appropriate health education interventions[14], health education/behaviour interventions[39], shared medical appointments interventions[19], and person-centred interventions[27] (one study each). Shared patient experience components were the sole focus of the intervention in 12 (29%) out of 42 studies. The types of interventions in these 12 studies included diabetes self-management education interventions (four studies – 33%)[32,40,43,46], peer support interventions (three studies)[18,30,36], culturally-adapted/competent diabetes self-management education interventions (two studies)[25,44], social

support interventions[34], health behaviour interventions[26], and culturally-appropriate health education interventions[14] (one study each).

4.4.6 Components of shared patient experience

Mode of delivery in shared patient experience

All the studies except for five[17,18,23,28,36] were delivered by facilitator(s). In about half of all cases (21 studies – 50%), the interventions were delivered by various combinations of healthcare professionals, including nurses[10,12,13,15,20,39,48,51] and dieticians[11-14,16,39,41,51] (eight studies each), diabetes specialist nurses (four studies)[9,27,34,40], physicians[9,41,45,52-54] and pharmacists[19,42,43] (three studies each), clinical psychologists[20,46] and health educators[10,45,52-54] (two studies each), psychiatrists[34], psychologists[15], social workers[15], podiatrists[14], exercise physiologists[11], psychiatric mental health nurses[20], nurse educators[41], and general internists[37] (one study each), in addition to one study[21] which was not clear about the details. 11 studies were delivered by various combinations of non-healthcare professionals including a peer educator/mentor/counsellor who had diabetes[30,32,38,44], a peer who had diabetes[22,24,31,49,50], and research staff[24,29,35,49,50] (four studies each), peer support facilitators who did not have diabetes[47], promotora who did not have diabetes[33], a lay health advisor who did not have diabetes[26], and health advocates[25] (one study each). Two studies involved both healthcare professionals and non-healthcare professionals in the delivery of the intervention: one study used a nurse, a dietician, and a community worker who had diabetes[16]; and one study used a pharmacist, a dentist, a social worker, a podiatrist, and a peer counsellor who had diabetes[42]. In three studies, the interventions were delivered in combination on a facilitator-led and non-facilitator-led basis[22,31,35].

Of the 42 studies, the mode of shared patient experience delivery was *face-to-face* in 29 studies (70%)[9-14,18-21,25-27,32-34,36-47,51-54]; *remote* in ten studies including via computer[15,17,24,29,31,35,49,50], telephone[23,30], and online video[28]; both *face-to-face* and *remote* (video) in three studies[16,22,48]; *group-based* in 39 studies (93%)[9-22,24-27,29,31-54]; and *individual-based* in three studies[23,28,30]. Only

four studies (10%) used a *role model* during the intervention: one study used positive modelling by patients who were successfully using self-care activities[48]; one study used modelling action planning by a peer who had diabetes[31]; and two studies did not report the details[13,32]. Overall, the most frequently examined type of shared patient experience was a *healthcare professional-led, face-to-face, group-based format where a group of patients shared their illness experiences interactively without having a role-model* (20 studies – 48%)[9-14,19-21,27,34,37,39-43,45,46,51-54].

Roles and Contents of shared patient experience

The most frequent role of shared patient experience was gathering/providing information (e.g. suggestions, advice, feedback) relevant to the aim of each intervention (e.g. exercise, diet) (27 studies – 64%)[9-11,14,15,17-20,22,23,26-28,30,33,36,37,39,40,42-45,47,48,51-54]. Three interventions were conducted to provide participants mainly with emotional support[32,38,41]. 11 studies involved both roles (informational and emotional)[12,13,16,24,25,29,31,34,35,46,49,50]. In five studies, the role of shared patient experience was not clear[11,21,24,31,49,50]. The kind of topics discussed in each intervention (e.g. exercise, diet) was evident in the majority of studies, whereas specific kinds of 'peers' experiences' reported in relation to such topics were described in less than half of the studies (40% - 17 out of 42 studies): 16 studies involved stories of both patients' perceived barriers (e.g. difficulties, problems, obstacles, challenges, struggles, concerns, frustrations) and enablers (e.g. solutions, successes) to diabetes self-management activities (e.g. making behavioural changes)[9,14,16,19,23,24,27,28,32,42,44,45,48-54]; and one study focused only on peers' positive experiences with active self-care[22].

4.4.7 Theoretical framework of interventions

Seven studies (17%) used self-efficacy theory[20,24,29,36,42,44,49,50], of which five studies used this theory in combination with other theoretical model(s) such as social support theory (two studies)[24,49,50], complexity theory (one study)[36], stages of change model and adult learning theory (one study)[42], or the trans-theoretical model of behaviour change (one study)[20]. Other than self-

efficacy theory, 11 studies based the intervention on a range of different models/approaches such as the empowerment-based behaviour change model[9,12] (two studies), the middle-range theory of community empowerment[33], the peer educator or promotora model[38], the theory of reasoned action[22], the multilevel social-ecological model of diabetes self-management[35], the coordinated service delivery model[17], cognitive linguistic theory[37], the peer support approach[23], the person-centred approach[27], Gagne's theory of learning[28], and component design theory[28] (one study each). Three studies developed a model for the purpose of conducting the intervention: one study developed the story sharing model based on qualitative studies of the illness narratives in ethnic minority groups specifically to address the needs of limited English speakers with diabetes living in deprived inner-city areas[25]; one study developed the precede-proceed model of health promotion based on focus groups of the outpatient population[41]; and one study developed the group management approach based on reference-group theory[46]. Two studies did not use theoretical models but reported that they developed the intervention based on a needs assessment of the targeted population conducted[14,32]. The theoretical basis informing the design of the intervention was not reported or unclear in about half of the studies (19 studies)[10,11,13,15,16,18,19,21,26,30,31,34,39,40,43,45,47,48,51-54].

4.4.8 Comparison group

In 19 studies (45%), the comparison group received routine treatment. Routine treatment varied depending on the study's country of origin and its health care systems. This included: usual/standard/routine medical/diabetes care by physicians at the clinics (13 studies)[9,10,14,15,17,18,27,30,36,38,41,45,51-54]; whatever care participants had been previously receiving ranging from community clinics to specialist care[31,32]; usual one-on-one patient education by the clinic staff[33,48]; and referral to a local standard/traditional diabetes class[13,25] (two studies each). Three studies stated that the control group received routine treatment and were given the option to join/assigned the intervention programme after the study[12,26,44]. In two studies, the control group was placed on a waiting list to receive the intervention after the study[40,43]. In one study the control

group was given the option either to be placed on a waiting list to be offered the intervention programme after the study or receive the usual care[16]. In 13 studies, the comparison group received other types of intervention or part of the intervention offered to the treatment group[11,19,21,23,24,28,29,34,35,37,42,46,49,50], and the comparison group in one study received other types of intervention in addition to routine treatment[20]. In three studies the content of the comparison group was not clear[22,39,47].

4.4.9 Types of outcome measures

Diabetes health-related outcome measures were combined into five subcategories within the dependent variables of this study, that is, knowledge outcome, psychosocial outcomes (measured in terms of quality of life, self-efficacy, psychological distress, social support, illness perception, outcome expectation, locus of control, treatment satisfaction, normative belief, motivation to comply, and intention to behaviour), clinical outcomes (measured in terms of HbA1c, weight, high-density lipoprotein cholesterol, total cholesterol, BMI, systolic blood pressure), health behaviour outcomes (measured in terms of diet, physical activity, self-monitoring of blood glucose, foot care, medication adherence, smoking activity, amount of medication consumed/prescribed, insulin use, communication with physicians, and behaviours related to home blood glucose monitoring)[i], and health service utilization outcomes (measured in terms of primary care, clinic, and/or emergency room visits and hospitalisation). The studies showed a great heterogeneity in the type of outcomes and outcome measures[ii].

Knowledge outcome

Diabetes knowledge was assessed in 20 studies[9-12,14,16,17,20,23,28,33,34,37,39,40,42,44-46,51] using 15 different measurements, which included: an understanding subscale from the Diabetes Care

[i] This review found no outcomes measuring decision-making in starting insulin treatment.

[ii] When primary studies used one measure that included multiple constructs, they were included if each construct of the measure was individually assessed.

Profile (DCP)[12,44]; and a problem solving ability scale (Condotte di Riferimento) (CdR)[45,51-54] (two studies each); a 12-item questionnaire developed for the study[40]; a modified version of the Diabetes Knowledge Assessment (DKN) scale[34]; a bilingual (English and Spanish) Diabetes Knowledge Questionnaire (DKQ)[33]; a diabetes knowledge test developed for an earlier study[20]; a nutrition knowledge questionnaire[11] adapted from Fanelli, 1988[55]; a 7-item study specific questionnaire developed for the study and partially adopted from the World Health Organization Quality of Life Abbreviated Version scale (WHOQOL)[9]; a diabetes ABCs questionnaire developed for the study[37]; the Spoken Knowledge in Low Literacy in Diabetes Scale (SKILL-D)[28]; a 16-item questionnaire adapted from DKN scale[42]; a Life Skills test, published by the Diabetes Education Society[39]; a questionnaire developed by the Education Study Group of the Italian Society for Diabetes (GISED)[45,52-54]; and a diabetes knowledge instrument developed for the study[16] (one study each). One study included multiple measures to report the outcome including a questionnaire developed by GISED and CdR[45]. In five studies measurement was unclear[10,14,17,23,46].

Psychosocial outcomes

Quality of life refers to perceived impact of diabetes on general health such as physical, mental, social, functional life. This was assessed in 17 studies[10,16-20,25,31,32,39-42,45,50] using 13 different measurement tools including the Medical Outcomes Study - Short Form-36 (SF36) in five studies[20,39-42], an activity limitation scale developed for an earlier study[31,32], and an Italian version of the modified Diabetes Quality of Life (DQOL) questionnaire[45,51-54] (two studies each), the SF-36 for Veterans (VR-36)[19], the WHOQOL Abbreviated Version scale (WHOQOL-BREF)[10], a Thai version of the WHOQOL-BREF scale[18], a story-based scale developed for an earlier study[25], a Norwegian version of the Q-5D Visual Analogue Scale[40], a subscale of the health belief instrument[16], a single item from the national health survey[32], a Diabetes-related Problems questionnaire (DRP)[39], a health status measure for African Americans with type 2 diabetes developed for an earlier study[42], the Short-Form General Health Survey (SF-12)[50], and a 10-item

study specific questionnaire developed for the study and partially adopted from the WHOQOL assessment[9] (one study each). Four studies included multiple measures to report the outcome: one study used SF36 and a health status measure for African Americans with type 2 diabetes developed for an earlier study[42]; one study used SF36 and a Norwegian version of the Q-5D Visual Analogue Scale[40]; one study used SF36 and DRP[39]; and one study used an activity limitation scale developed for an earlier study and a single item from the national health survey[32]. In one study measurement was unclear[17].

Self-efficacy refers to belief in the ability to manage diabetes. This was assessed in 13 studies[9,12,15,19,20,25,26,28,29,31-33,48] using 12 different measurements including a bilingual (English and Spanish) Diabetes Health Belief Measure (DHBM)[33], a diabetes self-efficacy scale developed for an earlier study[31], a Spanish version of the diabetes self-efficacy scale[32], an appraisal of diabetes scale[26], the Diabetes Self-Efficacy Questionnaire (DSEQ)[20], a Chinese version of the Diabetes Management Self-Efficacy Scale (C-DMSES)[48], the Diabetes Empowerment Scale (DES)[15], the Diabetes Empowerment Scale Short-Form (DESSF)[12], the perceived competence scale[19], a 10-item study specific questionnaire developed for the study and partially adopted from the WHOQOL assessment[9], the Rasch measurement[28], and the Patient Enablement Instrument (PEI)[25] (one study each). In two studies the measurements used were not clear[26,29].

Psychological distress (e.g. depression, anxiety) was assessed in 15 studies[15,20,22-24,27,29,31,32,34,35,40,50,51,56] using 15 different measurements including the Problem areas in diabetes scale (PAID)[15,20,40], and the Centre for Epidemiologic Studies Depression Scale (CES-D)[15,24,50] (three studies each), the health distress scale[31,32] in two studies, the Revised Problem Areas in Diabetes 2 scale (PAID-2)[56], the Psychological Integration Scale (ATT 39)[34], the somatic anxiety subscale of the Crown-Crisp Index[20], a Dutch version of the State Trait Anxiety Inventory (STAI)[22], the Patient Health Questionnaire (PHQ-9)[31], the 5-item World Health Organization Well-Being Index (WHO-5)[23], an emotional coping response measurement adapted from the

emotional well-being subscale[29], the STAI[51], a 10-item version of CES-D[35], the diabetes distress screening scale[23], and the 22-item Well-Being Questionnaire (WBQ-22)[27] (one study each). Four studies included multiple measures to report the outcome: one study used the somatic anxiety subscale of the Crown-Crisp Index and PAID[20]; one study used the diabetes distress screening scale and WHO-5[23]; one study used PHQ-9 and the health distress scale[31]; and one study used CES-D and PAID[15].

Social support refers to perceived support from others such as friends, family, and peers. This was assessed in seven studies[15,16,20,24,29,47,49] using eight different measurement tools including the Diabetes Support Scale (DSS) in three studies[15,24,49], the Arizona social support schedule[47], a modified version of the Interpersonal Support Evaluation List (ISEL)[49], a subscale of DCP[20], a modified version of the Health Care Climate Questionnaires (MHCCQ)[20], the social support scale[29], the observational learning scale[29], and a subscale of the health belief instrument[16] (one study each). In two studies the outcome was reported using multiple measures: one study used the social support scale and the observational learning scale[29]; and one study used DCP and MHCCQ[20].

Illness perception refers to perceived barriers and seriousness of diabetes. This was assessed in four studies[12,14,16,23] using three different measurements including the 'seriousness of diabetes' subscale of the diabetes attitude scale[12], DCP[12], and a subscale of the health belief instrument[16] (one study each). One study included multiple measurements to report the outcome, namely the 'seriousness of diabetes' subscale of the diabetes attitude scale and DCP[12]. Measurement was not clear in two studies[14,23].

Outcome expectation refers to the belief that behaviour will have the desired effect. This was assessed in two studies[29,48] using two different measurements including a Chinese version of the Perceived Therapeutic Efficacy Scale (C-PTES)[48] and an outcome expectation scale adapted from

two sources including (1) the decisional balance scale as adapted for a Canadian population by Plotnikoff et al., 2001[57] and (2) the physical activity expectations scale, as used by Liebreich et al., 2009[29].

Locus of control refers to individuals' tendency to perceive the events that influence them (either positively or negatively) as a result of their own abilities, characteristics, and behaviours or as a result of chance, fate, and powerful others. This was assessed in four studies[22,34,46,51] using one measurement, namely the Multidimensional Health Locus of Control (MHLC) scale[34,51]. One study used the Internal Health Locus of Control subscale of the MHLC scale[46], while one used a Dutch version of the MHLC scale[22].

Treatment satisfaction was assessed in two studies[27,40] using one measurement, namely the Diabetes Treatment Satisfaction Questionnaire (DTSQ).

Normative belief, which refers to beliefs about the views of significant others (what an individual thinks others would want or expect him/her to do); *motivation to comply*, which refers to how important it is to an individual to do what s/he thinks significant others expect; and *intention to behaviours* were assessed in one study each[22], whereas measurements for these outcomes were not clear.

Clinical outcomes

HbA1c was assessed in 34 studies[9-13,16,17,19-21,23-28,30-34,36,38-47,50-54], of which 22 studies reported measurements[9-11,13,16,24,27,28,31-34,36,38-40,42,44-47,50-54]. The majority used laboratory measurements except for one study that used a finger-stick procedure[33], which may not give as accurate results as those carried out in a laboratory (see Appendix 4.4 for more details). Measurement was not reported in 12 studies[12,16,17,19-21,23,25,26,30,41,43].

Weight was assessed in 20 studies[11-13,16,17,19-21,27,36,38-42,44-47,51-54] using three different measurements including a balance scale in five studies[13,16,20,36,38], electronic scale[42], and portable scale[47] (one study each). In 13 studies measurement was unclear[11,12,17,19,21,27,39-41,44-46,51-54].

High density lipoprotein cholesterol was assessed in 19 studies[11-13,16,19-21,23-25,27,34,38-41,44,45,51-54] using six different measurements including the colorimetric method with Johnson and Johnson's Vitros 250[13], enzymatic methods (35-37) with an Olympus AU 5000 analyzer[11], the Cholestech analyzer[44], Standard clinical laboratory methods[27], a method using lipase, glycerol kinase, oxidase/peroxidase[39], and the oxidase/peroxidase method[41] (one study each). Two studies reported that the measurement was conducted in laboratories[38,40]. Measurement was not clear in the other studies[12,16,19-21,23-25,34,45,51-54].

Total cholesterol was assessed in 18 studies[12,13,16,19-21,23-25,27,34,38-41,44,45,51-54]. While measurement was not clear in 12 studies[12,16,19-21,23-25,27,34,45,51-54], the rest of the studies reported that they used laboratory measurements (see Appendix 4.4 for more details).

Systolic blood pressure was assessed in 16 studies[11,12,17,19-21,23,25,27,28,36,38,40,42,44,51] using six different measurements including standard sphygmomanometers[38], stethoscopes[38], a mercury manometer[20], a conventional Baum mercury sphygmomanometer[11], an Omron HEM-907 automated blood pressure monitor (Omron Healthcare, Inc, Vernon Hills, IL)[42], and a sphygmomanometer (All Heart Standard, AllHeart.com-Professional Appearances, Inc, Vernon Hills, IL)[36]. In one study research assistants asked participants about their blood pressure readings[28]. In two studies measurements were taken manually by trained nurses, with the patient in a sitting position after a minimum of 5 minutes' rest[27,40]. One study included multiple measures including standard sphygmomanometers, and stethoscopes to report the outcome[38]. Measurement was not clear in the other studies[12,17,19,21,23,25,44,51].

BMI was assessed in 16 studies[9,11,13,16-18,23,25-27,32,38,40,41,43,45,52-54] using two different measurement methods. BMI was calculated by dividing weight in kilograms by height in metres squared (four studies)[11,13,2716], or from weight[40]. One study reported that measurement was conducted in a laboratory[38]. In the remaining ten studies measurement was not clear[9,17,18,23,25,26,32,41,43,45,52-54].

Health behaviour outcomes

Diet was assessed in 13 studies[11,13,14,17,19,21,22,24,26,28,40-42] using ten different measurement tools including the Summary of Diabetes Self-care Activities Assessment (SDSCA) tool in two studies[19,28], the Food Habits Questionnaire (FHQ)[13], a behaviour risk factor survey[26], the Kristal Fat and Fibre Behaviour (FFB)[24], a block fat screener[24], a healthy eating scale[17], a 5- day food diary[21], a 1- week food frequency questionnaire adapted from a 1-year semi-quantitative food frequency questionnaire[11], the Fred Hutchinson 12-page Food Frequency Questionnaire (FFQ)[42], and a 3-day food record[41] (one study each). Only one study included multiple measurements to report the outcome, namely FFB and block fat scanner[24]. In two studies measurement was unclear[22,40]

Physical activity was assessed in 13 studies[11,17,19,22,23,26,28,29,31,32,35,41,42] using seven different measurement tools including a physical activities scale in three studies[17,31,32], SDSCA in two studies[19,28], the Physical Activity Scale for the Elderly Questionnaire (PASE)[11], the Godin Leisure-Time Exercise Questionnaire (GLTEQ)[26], a modified version of the GLTEQ[29], the Behavioural Risk Factor Surveillance System (BRFSS)[35], and the CSA (WAM 7164) Activity Monitor[42] (one study each). In three studies measurement was not clear[22,23,41].

Self-monitoring of blood glucose was assessed in five studies[19,22,23,28,32] using two different measurement tools including SDSCA in two studies[19,28] and weekly frequency of glucose monitoring[23,32] (two studies each). Measurement in one study was not clear[22].

Foot care was assessed in four studies[17,19,28,40] using two measurement tools including SDSCA in two studies[19,28], and an adherence to diabetes management practices scale in one study[17]. Measurement in one study was not clear[40].

Medication adherence was assessed in three studies[19,28,40]. One study[28] included multiple measurements to report the outcome including SDSCA and a 4-item measure developed by Morisky et al. in 1986[58]. In two studies measurement was not clear[19,40]

Amount of medication consumed/prescribed was assessed in three studies[19,23,28] in terms of the number of prescribed medications targeting diabetes and cardiovascular risk factors[19], the amount of drug consumption to control hyperglycaemia, hypertension and dyslipidemia[23], and the number of prescribed oral diabetes medications and blood pressure medications[28].

Insulin use was assessed in three studies[22,28,32] in terms of frequency of self-devised adjustments of insulin dose in one study[22], and frequency of insulin use[28,32].

Smoking activity was assessed in two studies[19,28] using one measurement tool, namely SDSCA.

The measurements for *communication with physicians* which was assessed in two studies[32,46], and *behaviours related to home blood glucose monitoring* which was assessed in one study[22] was not clear.

Health service utilization outcomes

Primary care, clinic, and/or emergency room visits were assessed in six studies[19,23,31,32,40,48]. Two studies used a self-reported questionnaire[40,48]. In the other studies measurement was not clear[19,23,31,32].

Hospitalisation which was assessed in two studies used a self-reported questionnaire[23,48].

4.4.10 Risk of bias in included studies

Methodological quality of the included studies was presented in Appendix 4.5. Overall, none of the studies scored low risk in all five of the bias categories: Risk of bias for sequence generation was considered low in 16 (38%) of the studies and unclear in 26 (62%) of the studies; allocation concealment was considered low in five (12%) of the studies, unclear in 36 (86%) of the studies, and high in one (2%) of the studies; blinding of outcome assessors was considered low in two (5%) of the studies, and unclear in 40 (95%) of the studies; completeness of outcome data was considered low in four (10%) of the studies, and unclear in 38 (91%) of the studies; selective reporting was considered low in seven (17%) of the studies, and unclear in 35 (83%) of the studies.

Sequence generation

Sixteen (38%) of the studies reported their method of generating the randomisation and the methods used were considered adequate. Random table numbers[17,31,38,45,48,51-54] were used in six studies, a computerized random number generator[13,20,30,42,44] in five studies, permuted block randomisation in two studies[25,40], a randomly generated numbers sequence[28], a coin flip[36], and unmarked envelopes drawn from a box[43] in one study each. 26 (62%) of the studies did not provide the details of how sequence generation was conducted, although they made reference to it by stating that participants were randomly allocated to either intervention or control groups[9-12,14-16,18,19,21-24,26,27,29,32-35,37,39,41,46,47,49,50].

Allocation concealment

Five (12%) of the studies reported using adequate allocation concealment approaches including sequentially numbered opaque sealed envelopes in four studies[9,30,42,44], and a pre-numbered container administered serially to participants in one study[18], and were considered as low risk. One (2%) of the studies which reported that no allocation concealment was conducted was rated

as high risk[40]. For the remaining 36 (86%) studies, the method of allocation concealment was unclear[10-12,14,16,17,19,20,22-24,26-29,31-39,41-43,45-48], although one of them made reference to it by stating that the research assistant enrolling participants was blinded to group assignment[13].

Blinding of outcome assessors

Two (5%) of the studies reported blinding of outcome assessors for all the included outcomes that was considered adequate[38,42]. 40 (95%) of the studies did not provide sufficient information to be confident that assessors were blinded[9-37,39-41,43-48].

Completeness of outcome data

All the studies, except for five, reported information on the losses to follow-up (numbers of and/or reasons for drop-outs)[9-11,13,14,16,18-40,42-46,48]. Intention-to-treat analysis means that participants were compared in the groups to which they were originally randomly assigned regardless of whether they actually received the treatment, their subsequent withdrawal or deviation from the protocol[59]. 11 studies reported analysis to be by intention to treat[9,13,26,29-31,37,40,42,44,52]. In one study which was reported in four publications, one paper reported the intention to treat analysis at the four year assessment[52] and not in the three other papers (at the one[54], two[45], and five[53] year assessment). Four (10%) of the studies reported both losses to follow-up (numbers of and reasons for drop-outs) and analysis to be by intention to treat, and were considered as low risk[29,40,42,52]. For the remaining 38 (91%) of the studies, the method of completeness of outcome data was not clear[9-28,30-39,41,43-51,53,54].

Selective reporting

A wide variety of outcomes was examined across the studies. Seven (17%) of the studies reported primary/secondary outcomes and measured all the pre-specified outcomes, and was considered as low risk[13,17,30,31,40,43,45,52-54]. The remaining 35 (83%) of the studies did not provide sufficient information on selective reporting: primary/secondary outcomes were not clear in 26 studies[9-

[12,14,15,18,21,23,24,28,29,32-37,39,41,42,46-51]; and primary/secondary outcomes were reported in eight studies, but not all the pre-specified outcomes were measured and reported[16,19,20,22,26,27,38,44].

4.4.11 Effects of interventions

The results were presented in terms of the outcome measures. A broad range of knowledge, psychosocial, clinical, health behaviour, and health service utilization outcome measures were reported on, reflecting the diverse objectives of the shared patient experience interventions and the associated studies[iii]. The findings reported by the studies are summarized in Appendix 4.4[iv].

Knowledge

Diabetes knowledge was assessed in 20 out of 42 studies. About half of the studies (nine studies) found significant improvement in knowledge scores in the shared patient experience group compared to the control group[9,10,12,16,33,37,40,44,45,52-54]. The rest of the studies found no statistically significant differences between groups[11,14,17,20,23,28,34,39,42,46].

Psychosocial outcomes

Shared patient experience interventions showed statistically significant improvement in quality of life, self-efficacy, psychological distress, social support, outcome expectation, locus of control, normative belief, motivation to comply, and intention to behaviours compared to the control group. No differences were found with illness perception and treatment satisfaction.

[iii] Effects of interventions were reported using statistical significance that described differences between the groups in the means of their changes from baseline to endpoint (whether the differences between groups are statistically significant at the final follow-up point).

[iv] When primary studies included multiple measures of the same construct, the result of the construct was reported as 'significant' if one of the measures showed 'significant' differences between groups. Also, one trial was reported in four publications (exploring follow-up at 12 months, two, four, and five years). The result of the trial was reported as 'significant' if one of the publications showed 'significant' differences between groups. Results of all four publications are included in Appendix 4.4.

Quality of life:

17 studies measured the impact of shared patient experience on quality of life. In six studies, patients who received the interventions showed statistically significant improvement in quality of life compared with those who did not receive the intervention[17,18,20,42,45,51-53]. The rest of the studies found no significant differences[9,10,16,19,25,31,32,39-41,50].

Self-efficacy:

Six out of 13 studies reported a significant improvement in self-efficacy[15,26,29,31,32,48], while one study showed a statistically significant deterioration in the intervention group[33]. There were no significant differences for the other six studies[9,12,19,20,25,28].

Psychological distress:

Of the 15 studies measuring the impact of shared patient experience on psychological distress, three studies found a statistically significant decrease in psychological distress in the treatment group[15,20,32]. The remaining ten studies found no significant differences[22-24,27,29,31,34,35,40,44,50,51].

Social support:

Data regarding social support were available for six of the seven studies except for one study that did not report the result[47]. Three studies showed significant improvement when compared with the control group[15,20,24]. Three studies found no significant differences[16,29,49].

Illness perception:

None of the four studies measuring the impact of shared patient experience on illness perception found a statistically significant differences between groups[12,14,16,23].

Locus of control:

Two out of four studies found a statistically significant improvement in locus of control in the treatment group[22,51], while the others found no significant differences[34,46].

Outcome expectation:

Two studies measured the impact of shared patient experience on outcome expectation. In one study, patients who received the interventions showed a statistically significant improvement in outcome expectation compared with those who did not receive the intervention[48]. The other study found no significant differences[29].

Treatment satisfaction:

Out of two studies measuring treatment satisfaction, none of the studies found significant differences[27,40].

Normative belief:

One study measuring normative belief showed a statistically significant improvement when compared with the control group[22].

Motivation to comply:

One study reported a statistically significant improvement in motivation to comply when compared with the control group[22].

Intention to behaviour:

One study measuring intention to behaviour showed a statistically significant improvement when compared with the control group[22].

Clinical outcomes

Shared patient experience interventions showed statistically significant improvement in HbA1c, systolic blood pressure, high-density lipoprotein cholesterol, BMI, and weight compared to the control group. No differences were found with total cholesterol.

HbA1c:

Of the 34 studies measuring the impact of shared patient experience intervention on HbA1c, 15 studies found shared patient experience to have a statistically significant beneficial impact. 18 studies found no statistically significant differences[9,10,12,13,17,20,21,23-26,28,34,39,40,42,50], and one study did not report the result[47].

Weight:

Data regarding weight were available for 18 of the 20 studies (two studies did not report the result[44,47]). Only two reported a significant reduction in body weight in the intervention group[11,21]. There were no significant differences for the other studies[12,13,16,17,19,20,27,36,38-42,45,46,51-54].

High-density lipoprotein cholesterol:

19 studies measured the impact of shared patient experience on high-density lipoprotein cholesterol. Only in three studies did patients who received the interventions show a statistically significant improvement in high-density lipoprotein cholesterol compared with those who did not receive the intervention[21,27,45]. 15 studies found no significant differences[11-13,16,19,20,23-25,34,38-41,51], and one study did not report the result[44].

Total cholesterol:

Data regarding changes in total cholesterol were available for 16 of the 18 studies (two studies did not report the result[27,44]), of which none found a statistically significant reduction in total cholesterol[12,13,16,19-21,23-25,34,38-41,45,51-54].

Systolic blood pressure:

Of the 16 studies measuring systolic blood pressure, only two studies found a statistically significant reduction in the shared patient experience group[19,36]. 12 found no significant differences[11,12,17,20,21,23,25,28,38,40,42,51], and two studies did not report the result[27,44].

BMI:

Two out of 16 studies found a statistically significant improvement in BMI in the intervention group[11,13], while the rest of the studies found no significant differences[9,16-18,23,25-27,32,38,40,41,43,45,52-54].

Health behaviour outcomes

Shared patient experience interventions showed statistically significant improvement in diet, physical activity, self-monitoring of blood glucose, foot care, amount of medication consumed/prescribed, insulin use, communication with physicians, and behaviours related to home blood glucose monitoring compared to the control group. No differences were found with medication adherence and smoking activity.

Diet:

13 studies measured the impact of shared patient experience on diet. In two studies, patients who received the interventions showed a statistically significant improvement in diet compared with those who did not receive the intervention[13,26]. One study showed a statistically significant deterioration in the intervention[21]. The others found no significant differences[11,17,19,22,24,28,40-42,50].

Physical activity:

Of the 13 studies measuring physical activity, two found a statistically significant improvement[29,42], while one study showed a statistically significant deterioration in the intervention group[28]. The other ten studies found no significant differences[11,17,19,22,23,26,31,32,35,41].

Self-monitoring of blood glucose:

One of the five studies that used self-monitoring of blood glucose as an outcome measure reported statistically significant improvements in the shared patient experience group[22], while four found no significant differences[19,23,28,32].

Foot care:

Of the four studies measuring foot care, one study found a statistically significant improvement in the intervention group[40]. No significant differences were found in the other three studies[17,19,28].

Medication adherence:

None of the three studies showed a statistically significant improvement in medication adherence[19,28,40].

Smoking activity:

Data on smoking activity were available for one[19] of the two studies[19,28], which found no significant differences.

Amount of medication consumed/prescribed:

Of the three studies measuring amount of medication consumed/prescribed, two studies found a statistically significant reduction in the intervention group[19,28]. No significant differences were found in one study when compared with the control gorup[23].

Insulin use:

One out of three studies showed a statistically significant improvement in frequency of self-devised adjustments of insulin dose when compared with the control group[22]. Two showed no significant differences[28,32].

Communication with physicians:

Of the two studies measuring communication with physicians[32,46], one study found a statistically significant improvement in the intervention group[46].

Behaviours related to home blood glucose monitoring

One study reported that patients in the shared patient experience group were more likely to engage in behaviours related to home blood glucose monitoring (e.g. carrying sugar; having glucagon at home; and keeping a record diary) than those in the control group[22].

Health service utilization outcomes

Shared patient experience interventions showed statistically significant improvement in primary care, clinic, and/or emergency room visits and hospitalisation compared to the control group.

Primary care, clinic, and/or emergency room visits:

One out of the six studies reported fewer emergency room visits when compared with the control[48]. No significant differences in the number of primary care, clinic, and/or emergency room visits were reported in the other studies[19,23,31,32,40]

Hospitalisation:

Of the two studies measuring hospitalisation[23,48], one study showed fewer instances of hospitalization when compared with the control group[48].

4.4.12 Studies published since the completion of original search

Studies published between 2014 and 2017 were searched using the same search strategy and the databases from MEDLINE, EMBASE, and PsycINFO. This identified a total of 278 studies, of which (after duplicates removed) about 30% of the papers (n = 78) were randomly selected. By using the same inclusion and exclusion criteria, 78 studies were screened for titles and abstracts,

from which 52 articles were excluded. Full texts for the remaining 26 were read and 21 papers not meeting the inclusion criteria were eliminated. As a result, a total of five studies were included[60-64]. Overall there were no significant new findings to be added to this review except for one new finding: in one diabetes self-management education intervention, one of the topics included in one part of shared patient experience components concerned healthcare providers' and patients' perceived barriers toward insulin therapy[60]. The characteristics of the five new studies are summarised below:

Four studies[60,62-64], except for one conducted in Australia[61], were from countries which were not included in this review, including China[62], Mexico[60], Austria[64], and Germany[63] (one study each). Sample sizes ranged from 208[62] to 670[61] adults (mean = 290), with a total of 1451 adults. The mean age of the study participants ranged from 43.3[63] to 63[64]. None of the five studies reported the racial or ethnic breakdown of the sample, assuming that participants were recruited from dominant communities in the country in which the studies were conducted.

As with this review, components of shared patient experience were incorporated in several types of interventions, including peer support interventions[62,64], diabetes self-management education interventions[60], narrative interventions[61], and cognitive behavioural interventions[63]. Yet, shared patient experience components were the sole focus of the intervention in none of the studies. Duration of the intervention lasted from three weeks[61] to 14 months[64]. The length of follow-up was between five[61] and 12 months[63]. All the studies except for one[61] were delivered by facilitator(s) including: non-healthcare professionals (peer educators who had diabetes or had lived with relatives or closely worked with people with diabetes[60] and a peer supporter who had diabetes[64]); healthcare professionals (a psychologist[63]); or healthcare professionals (nurses) and non-healthcare professionals (peer supporters who had diabetes)[62]. In the majority of the studies, the mode of shared patient experience delivery was *face-to-face,* and *group-based*[60,62-64]. Only one study used a *remote* (DVD) and *individual-based* format[61]. Also, one study used patients'

models to communicate positive attitudes toward diabetes self-management activities[61]. The role of shared patient experience was either informational[61-63] or informational and emotional[60,64]. Specific kinds of peers' experiences were described in two studies: one study involved stories of patients' perceived barriers toward insulin therapy[60] while another study contained stories that provide other patients with positive attitudes towards diabetes self-management[61].

Patients who received the interventions showed statistically significant improvement in: knowledge outcome[60,62] (two studies); psychosocial outcomes (two studies) including *psychological distress*[63] and *self-efficacy*[61]; clinical outcomes (one study) including *HbA1c, total cholesterol,* and *BMI* [62]; and health behaviour outcomes (one study) including *diet, physical activity*, and *foot care* [61]. One study which measured *quality of life,* showed a statistically significant deterioration in the intervention[64].

4.5 Discussion

4.5.1 Main findings

This review identified 42 RCTs examining the effects of shared patient experience in the context of type 2 diabetes care in general: there are currently no RCTs on the impact of shared patient experience conducted specifically in the context of decision-making about starting insulin in type 2 diabetes. The trials targeted a range of diabetes-related issues using a total of 30 diabetes health-related outcomes such as clinical, psychosocial, health behaviour, health service utilisation, and knowledge. These studies were conducted in the UK, the USA, Sweden, Australia, the Netherlands, Canada, Norway, Iran, Taiwan, Thailand, Argentina, and Italy, and related to a range of conditions and target populations. A summary of the main findings is given below.

In a total of 5781 adults recruited in the 42 studies, 49% of recruited participants were female. The mean age of the study participants ranged from 44 to 69 years (mean = 59.3; SD = 5.65), and the duration of diabetes ranged from five to 16 years. Also, half of the participants were from non-white ethnic groups including African Americans, Mexican Americans, American Indians, Pacific Islanders in the USA, Alaskans, South Asians and African Caribbeans in the UK, Thais, and Taiwanese.

Shared patient experience was incorporated in various types of interventions such as social support, diabetes self-management education, and peer support interventions. Also, shared patient experience was the sole focus of the intervention in about 30% of all the studies. While there was considerable variation in, and combination of, the shared patient experience components (e.g. mode of delivery, roles, and contents), overall, the most frequently examined type of shared patient experience was *a healthcare professional-led, face-to-face, group-based format where a group of patients gathering/providing information (e.g. suggestions, advice, feedback) about their/others' illness experiences through stories of perceived barriers (e.g. difficulties, problems, obstacles, challenges, struggles, concerns, frustrations) and enablers (e.g. solutions, successes) to diabetes self-management activities (e.g. making behavioural changes) without having a role-model.* About half of the shared patient experience interventions were based on theories, whereas there was considerable variation in, and combination of, the theoretical models.

There was wide variation in terms of the comparison group. Moreover, the studies showed massive heterogeneity in types of outcomes and outcome measures. For instance, one of the psychosocial outcomes, *psychological distress* was assessed in 15 studies using 15 different measurements, while one of the clinical outcomes, *insulin use* was assessed in three studies using two different measurements.

In sum, while the evidence from this review was not specific to the context of decision-making in starting insulin in type 2 diabetes, the shared patient experience showed some potential to improve diabetes health-related outcomes. The most favourable findings were for psychosocial, clinical, and knowledge outcomes, with shared patient experience interventions demonstrating statistically significant improvements in self-efficacy (six out of 13 trials), diabetes knowledge (nine out of 20 trials), and HbA1c (15 out of 34 trials). However, as with previous systematic reviews on peer support interventions in adults with diabetes such as Tang et al. (2011)[65] and Dale et al. (2012)[66] that include shared patient experience interventions[v], inconsistent effects of shared patient experience interventions made the results difficult to interpret (outcomes were inconsistent in magnitude and direction across studies): there were positive effects of interventions in most types of outcomes considered, but also studies reporting negative or no significant effects of the interventions. There was also a significant risk of bias evident in most of studies.

4.5.2 Strengths and limitations

Unlike previous reviews, to the author's knowledge this review is the first to bring together the evidence on the effectiveness of shared patient experience interventions designed to improve health in adults with type 2 diabetes. Such evidence is based on a broad and thorough systematic search of the literature, where the studies included in the review were identified from the five databases in addition to hand-searching of the 658 RCTs included in 26 systematic reviews and key journals. Also, the review only included RCTs because this type of study design generally provide evidence of efficacy based on unbiased study design[67].

However, there are several limitations to this systematic review. For instance, the review can only give limited direction about the effectiveness of shared patient experience interventions for adults with type 2 diabetes. This reflects the complex and heterogeneous multi-component nature of the

[v] As reported in chapter 3, previous systematic reviews on 'peer support' interventions include studies that do not reflect the idea of shared patient experience.

interventions. Consistent with findings from other systematic reviews on 'peer support' interventions that include interventions based on shared patient experience[65,66,68-70], shared patient experience interventions were delivered by various combinations of modes of delivery, roles, and contents, which has been further complicated by poor reporting of methodological details (incomplete reporting of the exact nature of the roles and contents of shared patient experience). Not only are shared patient experience interventions complex in themselves, but they exist in complex intervention designs which are heterogeneous in numerous aspects. This includes: location; frequency and duration of contact; target population; the extent of shared patient experience components integrated with other health services; theoretical framework; and the type of outcomes and outcome measures. This made it difficult to synthesise data at any one endpoint from a number of studies, and interpret any demonstrated effects. As such, the review did not identify superiority of any type of shared patient experience that appears most important to achieving specific diabetes outcomes.

This review also based its conclusion solely on statistical significance (P-values)[vi]. P-values, however, can be affected by the size of the sample and the size of the effect. One would get a 'significant' result either if the sample were big (even if the actual effect size were small) or if the effect were large (despite having only a small sample)[71-73]. For instance, in some of the studies included in this review, 'significant' results might have been reported even if the actual effect size is small (clinically not relevant) due to a large sample size. Effect size, on the other hand, is weighted according to the sample size, and explains how much the size of an intervention effect (difference between average score of intervention group and average score of control group)[72] [vii]. To understand and gain a more detailed insight into the full impact of an intervention, reporting

[vi] Statistical significance is the probability that the observed difference between two groups is due to chance and calculated by p-value. A small p-value (e.g. $p<0.05$) means that an intervention effect is very unlikely to have happened by chance and thus provides evidence against the null hypothesis.

[vii] The way in which the effect of an intervention can be measured depends on the nature of the data being collected (e.g. the mean difference for continuous outcomes).

both P-values and effect size are important. The results of this review, therefore, need to be interpreted cautiously.

> Here, the effect size of HbA1c is examined as an example. 34 out of 42 studies measured the impact of shared patient experience intervention on HbA1c, of which the p-values of 15 studies reached significance. The effect size (a score of intervention group minus a score of control group) of these studies ranged between -0.06 to -1.6, with an average score of -0.59, suggesting that a P-value with regard to HbA1c is clinically relevant. The effect size of the 18 studies which did not reach significance ranged between -0.09 and -1.1, with an average score of -0.38. This demonstrates the results of a P-value with regard to HbA1c are not clinically relevant. Taking into account the effects sizes observed, the conclusion for intervention effect of HbA1c as reported using a P-value is considered to be clinically relevant.

Subgroup analysis to identify the characteristics of individuals and the specific geographical location that may particularly be of benefit for shared patient experience was not conducted due to a lack of studies. For instance, only three out of 42 studies were conducted in the UK[14,21,25], of which two of the studies were directed at ethnic minority populations, such as South Asians[14], and African Caribbean and South Asians[25]. Yet, it is unclear to what extent shared patient experience interventions delivered in other countries are transferable to the UK setting and these ethnic minority populations in the UK. Cultural elements, not only in terms of ethnicity, but also of traditions and customs, may have an impact upon outcomes. Patient health beliefs and attitudes could differ from one country to another and may also affect outcomes.

The heterogeneous nature of shared patient experience interventions in terms of modes of delivery, roles, and contents (as noted above) may be partly due to poor study design in the shared patient experience interventions. The Medical Research Council (MRC) framework emphasises the need to establish the theoretical basis of how a complex intervention, such as shared patient experience

has the anticipated effect, to optimise its design and implementation[74]. A theoretical basis informs not only the components of shared patient experience interventions (e.g. contents) but the most appropriate outcomes to measure and when to measure them. A theoretical basis also permits predictions to be made for outcomes that are/are not expected to change, which provides a powerful test of the intervention's effects. Yet, few interventions were underpinned by a clear theoretical basis: while some studies reported having used existing theoretical model(s) or having developed a new model and used it in the intervention development, none of the studies clearly described the selection of the shared patient experience components based on the chosen theoretical model(s). Such issues surrounding study design are also pointed out by previous systematic reviews on peer support interventions[66,68,69,75] and diabetes self-management education interventions[76] that include shared patient experience interventions. Most appeared to have adopted a pragmatic approach to the intervention development.

Reaching firm conclusions about the effectiveness of shared patient experience interventions was also hindered by a paucity of high-quality trials that restricts the ability to generalise findings. For example, some of the studies may exhibit participation-expectation bias: while psychosocial outcome measures were included in the majority of studies and most such measures are self-reported, *blinding of participants* was not possible in a shared patient experience. Yet, results of self-reporting measures filled in by participants knowing that they were in the intervention group, may be compromised as some participants may try to anticipate the desired effect or to give socially desirable answers. This might have increased some confounding and/or bias in patients' outcomes.

Blinding of outcome assessors was unclear or not performed in the majority of studies. A failure to blind assessors of outcomes in RCTs may result in bias because outcome assessments are influenced by the assessors' conscious or unconscious predispositions — for example, because of hope or expectations, often favouring the experimental intervention[77]. Psychosocial outcomes

collected by a patient-reported method (e.g. quality of life) may be more susceptible to risk of bias from blinding outcome assessors compared to objective outcomes measured by an independent clinician (e.g. HbA1c).

Allocation concealment and *sequence generation* were also unclear in the majority of the studies. Considering baseline characteristics of intervention and control groups, which were quite similar for the majority of the studies, however, it is assumed that intervention and control groups would be reasonably balanced. Similar methodological limitations are also reported in previous systematic reviews on peer support interventions[66,69,70,75] and diabetes education interventions[78] that include interventions based on shared patient experience. In addition, overall quality in reporting of design issues was poor. Yet, owing to time constraints, there was a lack of follow-up with authors of the primary studies to clarify methodological details and results.

The search strategy was limited to the English language. Given the prior assessment as conducted in chapter 3 (see section 4.3.1), however, it is assumed that the findings were not influenced due to such a limitation. There is also a time gap between the point when the last search was conducted (August 2013) and the submission of the thesis. Yet, as discussed in section 4.4.12, brief assessment was conducted for some new studies identified since the search was last conducted, and suggests that this does not make a significant change in the conclusion of this review.

One of the challenges in conducting a review was developing replicable inclusion criteria. For instance, the criterion in relation to types of interventions (see section 4.3.2) was defined as follows: the intervention studies were included if they described a specific programme which included an explicit component of shared patient experience, which was defined (in chapter 3) for the purpose of this study as "provision of and/or learning from patients' personal accounts about health, health care, and health decision-making". However, replicability of such a criterion (whether others can select the same studies when using the same inclusion criterion) was not

adequate at some stages of screening database records, especially at the stage of assessing title/abstract sections of studies. This was mainly because a component of shared patient experience (as defined in the criterion) was not usually described in the title/abstract of the interventions. The interventions that included such a component could not be identified merely by reading the title/abstract unless the full text had been read. An additional criterion describing a shared patient experience component in broader terms was thus applied, especially at the stage of assessing title/abstract sections of studies to strengthen the replicability: interventions were included if the study concerned nine types of interventions which often include the idea of shared patient experience[viii] such as interventions for diabetes self-management education programmes, peer support programmes, culturally-appropriate diabetes care programmes, social support programmes, diabetes behaviour programmes, lay-led diabetes care programmes, community healthcare worker-led diabetes care programmes, diabetes self-management programmes for socially disadvantaged populations, and shared medical appointment programmes. As discussed in chapter 3, the utilization of a consistent definition of shared patient experience (such as the one defined in the criterion) may provide a common understanding of the idea of shared patient experience among researchers. Such a common understanding may, in turn, help develop commonly used criteria about shared patient experience components that are applicable at any stage of study selection.

The final selection of studies (by screening of the *full-text* papers) and the data extraction were all conducted without a second reviewer although the Cochrane handbook strongly recommends including more than one person in these processes[79]. For instance, the inclusion of a second reviewer is crucial at the stage of scanning the *full-text* references to reduce the possibility of discarding relevant papers[79]. The inclusion of another person for the data extraction is also important to 'minimize error and reduce potential biases being introduced by review authors'[79],

[viii] As noted in section 4.3.1, the results from chapter 3 informed the nine types of interventions that often include the idea of shared patient experience.

and especially when extracting information that involves 'subjective interpretation and information that is critical to the interpretation of results (e.g. outcome data)'[79]. The absence of a second reviewer at the stages of screening the *full-text* papers and extracting data may suggest that this review has some potential for overlooking some relevant papers and/or making errors in extracting the data. The results thus need to be interpreted with caution. Yet, since this work is exploratory and narrative, the findings from one person appear to be robust.

Finally, synthesis of the included studies was carried out through narrative analysis with no quantitative meta-analysis because of the considerable heterogeneity in the interventions, the designs, and the outcome measures described in the included studies (which meant that data could not be pooled statistically). Narrative syntheses, however, do not account for differences in precision and statistical heterogeneity among studies. Hence, the findings of this review need to be interpreted cautiously.

4.5.3 Future research

In future, there will be a need to develop an intervention based on shared patient experience conducted specifically in the context of decision-making in starting insulin treatment in type 2 diabetes. While shared patient experience showed some potential to improve diabetes-related health in general, this review identified no trials examining its impact in insulin decision-making. In developing such an intervention, future research appears to need more detailed attention to intervention design such as the use of theory by linking theory to the process involved in all aspects of its implementation (e.g. how theory informed the design of the roles and contents of shared patient experience), and the provision of clear and detailed description about the intervention. Many factors (e.g. roles, mode of delivery, and contents of shared patient experience, the extent of shared patient experience components integrated with other health services) seem to contribute to the effectiveness of shared patient experience and each of these requires careful consideration during intervention design. Failure to recognize these variations may lead to

inappropriate conclusions about the effectiveness of these interventions and also to inappropriate application of research results. Along with theoretical model(s), qualitative studies may also contribute to understanding why/how people want shared patient experience (e.g. users' perceived beliefs/attitudes toward the use of shared patient experience), and facilitate the intervention design. The methodological limitations identified in this review also need to be addressed in future studies. These include the use of adequate methods of randomisation and allocation concealment to prevent selection bias, and clear reporting on the use of blinding to prevent detection bias and the analysis of how those who drop out of the study are treated. While this review included validated and un-validated self-report measures, considering the nature of shared patient experience interventions where blinding of participants is often not possible, the use of validated instruments for self-reporting measures may minimise some bias in patients' outcomes.

4.6 Conclusion

The results of the review provide promising evidence to inform the potential use of shared patient experience to improve health in the context of type 2 diabetes care in general. Nevertheless, despite being based upon the best available empirical evidence, this review could only provide limited evidence on the type of shared patient experience that appears most important to achieving specific outcomes. This reflects the complex and heterogeneous multi-component nature of the interventions, which has been further complicated by poor study design, and incomplete reporting of methodological details. Also, the evidence from this review was not specific to the context of decision-making in starting insulin in type 2 diabetes, since there are currently no trials on the impact of shared patient experience in such a context.

There are still many uncertainties about the evidence to support the design and development of an intervention based on shared patient experience in the process of decision-making in starting

insulin therapy (e.g. the selection of intervention components such as information content, modes of delivery, and roles of shared patient experience). Yet, the design of interventions requires a systematic approach based on theory, evidence, and feasibility with a strong rationale for design and explicit reporting of the intervention development process[80]. As such, a narrative literature review of qualitative studies (chapter 5 – part 1), a secondary analysis of an existing collection of qualitative interviews (chapter 5 – part 2), and a primary qualitative study (chapter 6) are being conducted to provide complementary evidence to inform a possible/pilot design of a future intervention based on shared patient experience.

4.7 References

1. Green S, Higgins JPT, Alderson P, Clarke M, Mulrow CD, Oxman AD. Introduction. In: Higgins JPT, Green S, eds. *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]*: The Cochrane Collaboration; 2011.
2. Mulrow CD. Systematic Reviews: Rationale for systematic reviews. *BMJ.* 1994;309(6954):597-599.
3. Cook DJ, Mulrow CD, Haynes RB. Systematic reviews: synthesis of best evidence for clinical decisions. *Ann Intern Med.* 1997;126(5):376-380.
4. Reeves BC, Deeks JJ, Higgins JPT, Wells GA, Group OBOTCN-RSM. Including non-randomized studies. In: Higgins JPT, Green S, eds. *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]*: The Cochrane Collaboration; 2011.
5. Ryan R, Hill S, Prictor M, McKenzie J. Study Quality Guide. *Cochran Consumers and Communication Review Group* May, 2013; http://cccrg.cochrane.org/sites/cccrg.cochrane.org/files/public/uploads/StudyQualityGuide_May 2013.pdf. Accessed 1/12/2016.

6. Hrobjartsson A, Boutron I, Turner L, Altman DG, Moher D. Assessing risk of bias in randomised clinical trials included in Cochrane Reviews: the why is easy, the how is a challenge. *Cochrane Database Syst Rev.* 2013(4):Ed000058.

7. Viswanathan M, Ansari MT, Berkman ND, et al. Assessing the Risk of Bias of Individual Studies in Systematic Reviews of Health Care Interventions. 2012. Available at: http://www.effectivehealthcare.ahrq.gov/.

8. Higgins JPT, Altman DG, (editors). Assessing risk of bias in included studies. In: Higgins JPT, Green S, eds. *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]*: The Cochrane Collaboration 2011; 2011:187-242.

9. Adolfsson ET, Walker-Engstrom M, Smide B, Wikblad K. Patient education in type 2 diabetes: a randomized controlled 1-year follow-up study. *Diabetes Res Clin Pract.* 2007;76(3):341-350.

10. Aghamolaei T, Eftekhar H, Mohammad K, et al. Effects of a health education program on behavior, HbA1c and health-related quality of life in diabetic patients. *Acta Med Iran.* 2005;43(2):89-94.

11. Agurs-Collins TD, Kumanyika SK, Ten Have TR, Adams-Campbell LL. A randomized controlled trial of weight reduction and exercise for diabetes management in older African-American subjects. *Diabetes Care.* 1997;20(10):1503-1511.

12. Anderson RM, Funnell MM, Nwankwo R, Gillard ML, Oh M, Fitzgerald JT. Evaluating a problem-based empowerment program for African Americans with diabetes: results of a randomized controlled trial. *Ethn Dis.* 2005;15(4):671-678.

13. Anderson-Loftin W, Barnett S, Bunn P, Sullivan P, Hussey J, Tavakoli A. Soul food light: culturally competent diabetes education. *Diabetes Educ.* 2005;31(4):555-563.

14. Baradaran HR, Knill-Jones RP, Wallia S, Rodgers A. A controlled trial of the effectiveness of a diabetes education programme in a multi-ethnic community in Glasgow *BMC Public Health.* 2006;6:134.

15. Bond GE, Burr RL, Wolf FM, Feldt K. The effects of a web-based intervention on psychosocial well-being among adults aged 60 and older with diabetes: a randomized trial. *Diabetes Educ.* 2010;36(3):446-456.

16. Brown SA, Garcia AA, Kouzekanani K, Hanis CL. Culturally competent diabetes self-management education for Mexican Americans: the Starr County border health initiative. *Diabetes Care.* 2002;25(2):259-268.

17. Carter EL, Nunlee-Bland G, Callender C. A patient-centric, provider-assisted diabetes telehealth self-management intervention for urban minorities. *Perspect Health Inf Manag.* 2011;8:1b.

18. Chaveepojnkamjorn W, Pichainarong N, Schelp FP, Mahaweerawat U. A randomized controlled trial to improve the quality of life of type 2 diabetic patients using a self-help group program. *Southeast Asian J Trop Med Public Health.* 2009;40(1):169-176.

19. Cohen LB, Taveira TH, Khatana SAM, Dooley AG, Pirraglia PA, Wu W-C. Pharmacist-led shared medical appointments for multiple cardiovascular risk reduction in patients with type 2 diabetes. *Diabetes Educ.* 2011;37(6):801-812.

20. D'Eramo Melkus G, Chyun D, Vorderstrasse A, Newlin K, Jefferson V, Langerman S. The effect of a diabetes education, coping skills training, and care intervention on physiological and psychosocial outcomes in black women with type 2 diabetes. *Biol Res Nurs.* 2010;12(1):7-19.

21. Daly ME, Paisey R, Millward BA, et al. Short-term effects of severe dietary carbohydrate-restriction advice in Type 2 diabetes--a randomized controlled trial. *Diabet Med.* 2006;23(1):15-20.

22. De Weerdt I, Visser AP, Kok G, Van der Veen EA. Randomized controlled evaluation of an education program for insulin treated patients with diabetes: Effects on psychosocial variables. *Patient Educ Couns.* 1989;14(3):191-215.

23. Gagliardino JJ, Arrechea V, Assad D, et al. Type 2 diabetes patients educated by other patients perform at least as well as patients trained by professionals. *Diabetes Metab Res Rev.* 2013;29(2):152-160.

24. Glasgow RE, Boles SM, McKay HG, Feil EG, Barrera M, Jr. The D-Net diabetes self-management program: long-term implementation, outcomes, and generalization results. *Prev Med.* 2003;36(4):410-419.

25. Greenhalgh T, Campbell-Richards D, Vijayaraghavan S, et al. New models of self-management education for minority ethnic groups: pilot randomized trial of a story-sharing intervention. *Journal of Health Services & Research Policy.* 2011;16(1):28-36.

26. Holtrop JS, Hickner J, Dosh S, Noel M, Ettenhofer TL. "Sticking to it -- diabetes mellitus": a pilot study of an innovative behavior change program for women with type 2 diabetes. *American Journal of Health Education.* 2002;33(3):161-166.

27. Hornsten A, Lundman B, Stenlund H, Sandstrom H. Metabolic improvement after intervention focusing on personal understanding in type 2 diabetes. *Diabetes Res Clin Pract.* 2005;68(1):65-74.

28. Khan MA, Shah S, Grudzien A, et al. A diabetes education multimedia program in the waiting room setting. *Diabetes Ther.* 2011;2(3):178-188.

29. Liebreich T, Plotnikoff RC, Courneya KS, Boule N. Diabetes NetPLAY: A physical activity website and linked email counselling randomized intervention for individuals with type 2 diabetes. *International Journal of Behavioral Nutrition and Physical Activity.* 2009;6(18).

30. Long JA, Jahnle EC, Richardson DM, Loewenstein G, Volpp KG. Peer mentoring and financial incentives to improve glucose control in African American veterans: a randomized trial.[Summary for patients in Ann Intern Med. 2012 Mar 20;156(6):I-50; PMID: 22431687]. *Ann Intern Med.* 2012;156(6):416-424.

31. Lorig K, Ritter PL, Laurent DD, et al. Online diabetes self-management program: a randomized study. *Diabetes Care.* 2010;33(6):1275-1281.

32. Lorig K, Ritter PL, Villa F, Piette JD. Spanish diabetes self-management with and without automated telephone reinforcement: two randomized trials. *Diabetes Care.* 2008;31(3):408-414.

33. Lujan J, Ostwald SK, Ortiz M. Promotora diabetes intervention for Mexican Americans. *Diabetes Educ.* 2007;33(4):660-670.

34. Maxwell AE, Hunt IF, Bush MA. Effects of a social support group, as an adjunct to diabetes training, on metabolic control and psychosocial outcomes. *Diabetes Educ.* 1992;18(4):303-309.

35. McKay HG, King D, Eakin EG, Seeley JR, Glasgow RE. The diabetes network internet-based physical activity intervention: a randomized pilot study. *Diabetes Care.* 2001;24(8):1328-1334.

36. Murrock CJ, Higgins PA, Killion C. Dance and peer support to improve diabetes outcomes in African American women. *Diabetes Educ.* 2009;35(6):995-1003.

37. Naik AD, Teal CR, Rodriguez E, Haidet P. Knowing the ABCs: a comparative effectiveness study of two methods of diabetes education. *Patient Educ Couns.* 2011;85(3):383-389.

38. Philis-Tsimikas A, Fortmann A, Lleva-Ocana L, Walker C, Gallo LC. Peer-led diabetes education programs in high-risk Mexican Americans improve glycemic control compared with standard approaches: a Project Dulce promotora randomized trial. *Diabetes Care.* 2011;34(9):1926-1931.

39. Ridgeway NA, Harvill DR, Harvill LM, Falin TM, Forester GM, Gose OD. Improved control of type 2 diabetes mellitus: a practical education/behavior modification program in a primary care clinic. *South Med J.* 1999;92(7):667-672.

40. Rygg LO, Rise MB, Gronning K, Steinsbekk A. Efficacy of ongoing group based diabetes self-management education for patients with type 2 diabetes mellitus. A randomised controlled trial. *Patient Educ Couns.* 2012;86(1):98-105.

41. Samaras K, Ashwell S, Mackintosh AM, Fleury AC, Campbell LV, Chisholm DJ. Will older sedentary people with non-insulin-dependent diabetes mellitus start exercising? A health promotion model. *Diabetes Res Clin Pract.* 1997;37(2):121-128.

42. Samuel-Hodge CD, Keyserling TC, Park S, Johnston LF, Gizlice Z, Bangdiwala SI. A randomized trial of a church-based diabetes self-management program for African Americans with type 2 diabetes. *Diabetes Educ.* 2009;35(3):439-454.

43. Sarkadi A, Rosenqvist U. Experience-based group education in Type 2 diabetes: a randomised controlled trial. *Patient Educ Couns.* 2004;53(3):291-298.

44. Sinclair KA, Makahi EK, Shea-Solatorio C, Yoshimura SR, Townsend CK, Kaholokula JK. Outcomes from a diabetes self-management intervention for Native Hawaiians and Pacific People: Partners in Care. *Ann Behav Med.* 2013;45(1):24-32.

45. Trento M, Passera P, Tomalino M, et al. Group visits improve metabolic control in type 2 diabetes: a 2-year follow-up. *Diabetes Care.* 2001;24(6):995-1000.

46. White N, Carnahan J, Nugent CA, Iwaoka T, Dodson MA. Management of obese patients with diabetes mellitus: comparison of advice education with group management. *Diabetes Care.* 1986;9(5):490-496.

47. Wilson W, Pratt C. The impact of diabetes education and peer support upon weight and glycemic control of elderly persons with noninsulin dependent diabetes mellitus (NIDDM). *Am J Public Health.* 1987;77(5):634-635.

48. Wu S-FV, Lee M-C, Liang S-Y, Lu Y-Y, Wang T-J, Tung H-H. Effectiveness of a self-efficacy program for persons with diabetes: a randomized controlled trial. *Nurs Health Sci.* 2011;13(3):335-343.

49. Barrera M, Jr., Glasgow RE, McKay HG, Boles SM, Feil EG. Do Internet-based support interventions change perceptions of social support?: An experimental trial of approaches for supporting diabetes self-management. *Am J Community Psychol.* 2002;30(5):637-654.

50. McKay GH, Glasgow RE, Feil EG, Boles SM, Barrera Jr M. Internet-based diabetes self-management and support: Initial outcomes from the diabetes network project. *Rehabil Psychol.* 2002;47(1):31-48.

51. Trento M, Basile M, Borgo E, et al. A randomised controlled clinical trial of nurse-, dietitian- and pedagogist-led Group Care for the management of Type 2 diabetes. *J Endocrinol Invest.* 2008;31(11):1038-1042.

52. Trento M, Passera P, Bajardi M, et al. Lifestyle intervention by group care prevents deterioration of Type II diabetes: a 4-year randomized controlled clinical trial. *Diabetologia.* 2002;45(9):1231-1239.

53. Trento M, Passera P, Borgo E, et al. A 5-year randomized controlled study of learning, problem solving ability, and quality of life modifications in people with type 2 diabetes managed by group care. *Diabetes Care.* 2004;27(3):670-675.

54. Trento M, Passera P, Tomalino M, et al. Therapeutic group education in the follow-up of patients with non-insulin treated, non insulin dependent diabetes mellitus. *Diabetes Nutr Metab.* 1998;11:212–216.

55. Faneli MT. Effective nutrition education for older adults. *Topics of Clinical Nutrition* 1988;3(65-71).

56. Sinclair KiA, Makahi EK, Shea-Solatorio C, Yoshimura SR, Townsend CK, Kaholokula J. Outcomes from a diabetes self-management intervention for Native Hawaiians and Pacific people: Partners in care. *Annals of Behavioral Medicine.* 2013;45(1):24-32.

57. Plotnikoff RC, Hotz SB, Birkett NJ, Courneya KS. Exercise and the transtheoretical model: a longitudinal test of a population sample. *Prev Med.* 2001;33(5):441-452.

58. Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. *Med Care.* 1986;24(1):67-74.

59. Gupta SK. Intention-to-treat concept: A review. *Perspect Clin Res.* 2011;2(3):109-112.

60. Anzaldo-Campos MC, Contreras S, Vargas-Ojeda A, Menchaca-Diaz R, Fortmann A, Philis-Tsimikas A. Dulce Wireless Tijuana: A Randomized Control Trial Evaluating the

Impact of Project Dulce and Short-Term Mobile Technology on Glycemic Control in a Family Medicine Clinic in Northern Mexico. *Diabetes Technol Ther.* 2016;18(4):240-251.

61. Campbell T, Dunt D, Fitzgerald JL, Gordon I. The impact of patient narratives on self-efficacy and self-care in Australians with type 2 diabetes: stage 1 results of a randomized trial. *Health Promot Int.* 2015;30(3):438-448.

62. Deng K, Ren Y, Luo Z, Du K, Zhang X, Zhang Q. Peer Support Training Improved the Glycemic Control, Insulin Management, and Diabetic Behaviors of Patients with Type 2 Diabetes in Rural Communities of Central China: A Randomized Controlled Trial. *Medical Science Monitor : International Medical Journal of Experimental and Clinical Research.* 2016;22:267-275.

63. Hermanns N, Schmitt A, Gahr A, et al. The effect of a Diabetes-Specific Cognitive Behavioral Treatment Program (DIAMOS) for patients with diabetes and subclinical depression: results of a randomized controlled trial. *Diabetes Care.* 2015;38(4):551-560.

64. Johansson T, Keller S, Winkler H, et al. *Effectiveness of a Peer Support Programme versus Usual Care in Disease Management of Diabetes Mellitus Type 2 regarding Improvement of Metabolic Control: A Cluster-Randomised Controlled Trial.* Vol 20162016.

65. Tang TS, Ayala GX, Cherrington A, Rana G. A review of volunteer-based peer support interventions in diabetes. *Diabetes Spectr.* 2011;24(2):85-98.

66. Dale JR, Williams SM, Bowyer V. What is the effect of peer support on diabetes outcomes in adults? A systematic review. *Diabet Med.* 2012;29(11):1361-1377.

67. Ryan R, Hill S, Broclain D, Horey D, Oliver S, Prictor M. Study Design Guide. June 2013 http://cccrg.cochrane.org/author-resources.

68. Lloyd-Evans B, Mayo-Wilson E, Harrison B, et al. A systematic review and meta-analysis of randomised controlled trials of peer support for people with severe mental illness. *BMC Psychiatry.* 2014;14:39.

69. Dale J, Caramlau Isabela O, Lindenmeyer A, Williams Susan M. Peer support telephone calls for improving health. *Cochrane Database of Systematic Reviews.* 2008(4). http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006903.pub2/abstract.

70. Bassuk EL, Hanson J, Greene RN, Richard M, Laudet A. Peer-Delivered Recovery Support Services for Addictions in the United States: A Systematic Review. *J Subst Abuse Treat.* 2016;63:1-9.

71. Coe R. It's the effect size, stupid: what "effect size" is and why it is important. Annual Conference of the British Educational Research Association; 2002; University of Exeter, Exeter, Devon, England, September 12–14, 2002.

72. Sullivan GM, Feinn R. Using Effect Size—or Why the P Value Is Not Enough. *J Grad Med Educ.* 2012;4(3):279-282.

73. Aarts S, van den Akker M, Winkens B. The importance of effect sizes. *European Journal of General Practice.* 2014;20(1):61-64.

74. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ.* 2008;337:a1655.

75. Ali K, Farrer L, Gulliver A, Griffiths KM. Online Peer-to-Peer Support for Young People With Mental Health Problems: A Systematic Review. *JMIR Ment Health.* 2015;2(2).

76. Steinsbekk A, Rygg LO, Lisulo M, Rise MB, Fretheim A. Group based diabetes self-management education compared to routine treatment for people with type 2 diabetes mellitus. A systematic review with meta-analysis. *BMC Health Serv Res.* 2012;12:213.

77. Hróbjartsson A, Thomsen ASS, Emanuelsson F, et al. Observer bias in randomized clinical trials with measurement scale outcomes: a systematic review of trials with both blinded and nonblinded assessors. *CMAJ : Canadian Medical Association Journal.* 2013;185(4):E201-E211.

78. Loveman E, Frampton GK, Clegg AJ. The clinical effectiveness of diabetes education models for Type 2 diabetes: a systematic review. *Health Technol Assess.* 2008;12(9):1-116, iii.

79. Higgins JPT, Deeks JJ, (editors). Selecting studies and collecting data. In: Higgins JPT, Green S, eds. *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]*: The Cochrane Collaboration 2011; 2011:151-186.

80. French SD, Green SE, O'Connor DA, et al. Developing theory-informed behaviour change interventions to implement evidence into practice: a systematic approach using the Theoretical Domains Framework. *Implement Sci.* 2012;7:38.

4.8 Appendices

Appendix 4.1: Strategy for MEDLINE (OVID)

Ovid MEDLINE(R)

#	Searches	Results
1	vignette*.tw.	4928
2	Narration/	4463
3	1 or 2	9362
4	(narrative* adj3 (individual or patient* or personal or illness or people*)).tw.	1053
5	(testimon* adj3 (individual or patient* or personal or illness or people*)).tw.	160
6	(anecdote* adj3 (individual or patient* or personal or illness or people*)).tw.	64
7	(story or stories or storytelling* or story-telling*).tw.	17111
8	4 or 5 or 6 or 7	18161
9	(peer* adj2 (worker* or group* or support* or training* or trainer* or educator* or education* or mentor* or listening or discussion* or counsel* or leader* or coach* or influence* or intervention* or advisor* or candidate* or partner*)).ti,ab.	6340
10	(lay* adj2 (facilitator* or advisor* or worker* or educator* or trainer* or mentor* or tutor* or leader*)).ti,ab.	499
11	(community adj2 (representative* or advisor* or worker* or educator* or trainer* or mentor* or promoter*)).ti,ab.	2877
12	(promotora* or health advocate*).ti,ab.	545
13	(diabetes buddies or diabetes buddy or fellow patient* or patient navigator*).ti,ab.	241
14	(peer led or peer delivered or peer initiated).ti,ab.	386
15	(experience* adj2 (illness or shared or peer* or participant* or patient*)).ti,ab.	51492
16	expert patient*.ti,ab.	132
17	(self-help group* or support group*).ti,ab.	5237
18	(group adj2 (session* or meeting* or discussion* or consultation* or care* or visit* or education* or class* or dsme or diabetes self management or self management or management or learning or program* or intervention* or training)).ti,ab.	38514
19	(group based adj (session* or meeting* or discussion* or consultation* or care* or visit* or education* or class* or dsme or diabetes self management or self management or management or learning or program* or intervention* or training)).ti,ab.	188
20	cluster visit*.tw.	3
21	(shared medical appointment* or group medical appointment*).ti,ab.	47

22 (self help support* or social support*).ti,ab.	18679
23 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22	120237
24 3 or 8 or 23	145137
25 (education* adj2 (program* or intervention*)).ti,ab.	31741
26 (self-management* adj2 (program* or intervention* or education*)).ti,ab.	1662
27 (diabetes adj2 education).ti,ab.	1607
28 25 or 26 or 27	34106
29 (class* or meeting* or workshop*).ti,ab.	798289
30 (online or internet or web).ti,ab.	75210
31 (culturally or culture).ti,ab.	368087
32 (video* or cd-rom*).ti,ab.	62441
33 (social learning or social cognitive).ti,ab.	3494
34 29 or 30 or 31 or 32 or 33	1272727
35 28 and 34	6539
36 24 or 35	150504
37 exp Diabetes Mellitus/	245842
38 diabet*.ti,ab.	314714
39 37 or 38	350225
40 36 and 39	5624
41 randomized controlled trial.pt.	333594
42 controlled clinical trial.pt.	68869
43 randomized.ab.	245077
44 placebo.ab.	132344
45 clinical trials as topic.sh.	132801
46 randomly.ab.	174343
47 trial.ti.	95893
48 41 or 42 or 43 or 44 or 45 or 46 or 47	743485
49 exp animals/ not humans.sh.	2929808
50 48 not 49	681089
51 50 and 40	1641
52 limit 51 to english language	1579

Appendix 4.2: Characteristics of included studies

Reference	Type of intervention including shared patient experience components	Study design	Study population in IG/CG	Treatment group(s) including shared patient experience	Extent of shared patient experience components integrated in treatment group(s)	Shared patient experience intervention (length/frequency of intervention; CG)	Location / Setting of intervention	Length of follow-up
Wilson / 1987	Peer support	Three-arm RCT	IG-1 = 19 IG-2 = 32 CG = 28	IG-2	b	IG2-b: 8 weekly sessions (9th and 10th classes held during week 12 and week 16) **CG:** not reported	USA senior centres & nutrition sites	4 months
Anderson-Loftin / 2005	Culturally-competent DSME	Two-arm RCT	IG =49 CG = 48	IG	a+b	IG-a: 4 weekly (1.5hour each) classes + IG-b: 4 monthly (1hour each) sessions **CG**: received routine treatment	USA primary care practice sites	6 months
Rygg / 2012	DSME	Two-arm RCT	IG =73 CG = 73	IG	sole focus of the intervention	IG: 3 weekly or biweekly (15hour in total) sessions **CG:** was placed on a waiting list to receive the intervention programme later	Norway hospitals	1 year
Maxwell / 1992	Social support	Two-arm RCT	IG =111 CG = 93	IG	sole focus of the intervention	IG: 4 weekly (each 75min) and twice a month for 2 month (3 months in total) sessions **CG**: received other type of intervention	USA diabetes outpatient training and education centre	7 months
Lujan / 2007	Promotora-led diabetes	Two-arm RCT	IG = 75 CG = 74	IG	a	IG-a: 8 weekly (2hour each) sessions **CG:** received routine treatment	USA catholic faith–based community clinic	6 months

Lorig / 2008	DSME	Two-arm RCT	IG = 219 CG = 198	IG	sole focus of the intervention	IG: 6 weekly (2.5 hour) sessions **CG:** received routine treatment and were placed on a waiting list to receive the intervention programme later	USA community settings	6 months
Long / 2012	Peer support	Three-arm RCT	IG-1 = 39 IG-2 = 40 CG = 39	IG-1	sole focus of the intervention	IG-1: once a week sessions **CG**: received no intervention	USA veterans affairs medical Centre	6 months
Philis-Tsimikas / 2011	Culturally-sensitive peer-led diabetes education	Two-arm RCT	IG = 104 CG =103	IG	a	IG-a: 8 weekly (2hour each) sessions **CG**: received routine treatment	USA community health centres	10 months
Holtrop / 2002	HB	Two-arm RCT	IG = 67 CG = 65	IG	sole focus of the intervention	IG: 6 weekly (1.5hour each) sessions **CG:** received routine treatment and were placed on a waiting list to receive the intervention programme later	USA primary care clinics	6 months
D'Eramo Melkus / 2010	Culturally-relevant DSMT	Two-arm RCT	CG = 52 IG = 57	IG	a	IG-a: 11-weekly sessions **CG:** received other type of intervention	USA primary care centre	2 years
Aghamolaei / 2005	HE	Two-arm RCT	IG = 40 CG = 40	IG	a	IG-a: 4 weekly (2hour each) classes **CG:** received routine treatment	Iran diabetic clinic	4 months

De Weerdt / 1989	HE	Three-arm RCT	IG-1= 172 IG-2 = 183 CG = 203	IG-1 IG-2	a a	IG-1a: 4 weekly (3hour each) sessions + IG-2a: 4 weekly (3hour each) sessions **CG:** received no intervention	Netherlands out-patient clinic of the local hospital	7 months
Lorig / 2010	DSME	Three-arm RCT	IG = 491 CG = 270	IG-1 IG-2	b b+f	IG-1b: 6 weekly sessions IG-2b: 6 weekly sessions + IG-2f: 6 weekly sessions **CG:** received routine treatment	USA using a computer platform conducted in a home setting	6 months
Glasgow / 2003	DSME	Three-arm RCT	n = 320 IG-1 = N/R IG-2 = N/R CG = N/R	IG-1	a+b	IG-1a: online (anytime access) + IG-1b: online (anytime access) **CG:** received other type of intervention	USA using a computer platform conducted in a home setting	10 months
McKay / 2002 Barrera / 2002	DSME	Four-arm RCT	IG-1 = 40 IG-2 = 40 IG-3 = 40 CG = 40	IG-1 IG-3	a+b a+b	IG-1a: online (anytime access) + IG-1b: online (anytime access) IG-3a: online (anytime access) + IG-3b: online (anytime access) **CG:** received other type of intervention	USA using a computer platform conducted in a home setting	3 months
Wu / 2011	Self-efficacy	Two-arm RCT	IG = 81 CG = 77	IG	a	IG-a: 4 weekly (60min each) sessions **CG:** received routine treatment	Taiwan not reported	6 months

Liebreich / 2009	Counselling	Two-arm RCT	IG = 25 CG = 24	IG	b	IG-b: 11 weekly sessions **CG:** received other type of intervention	Canada using a computer platform conducted in a home setting	3 months
McKay /2001	HB	Two-arm RCT	IG = 38 CG = 40	IG	d+e	IG-d: online (anytime access) + IG-e: online (anytime access) **CG:** received other type of intervention	USA using a computer platform conducted in a home setting	8 weeks
Chaveepojnkamjorn / 2009	Peer support	Two-arm RCT	IG = 80 CG = 84	IG	sole focus of the intervention	IG: 5 sessions (2hour each) sessions **CG:** received routine treatment	Thailand hospital	7 months
Carter / 2011	DSME	Two-arm RCT	IG = 26 CG = 21	IG	c	IG-c: online (anytime access) **CG:** received routine treatment	USA using a computer platform conducted in a home setting	9 months
Bond / 2010	DSME	Two-arm RCT	IG = 31 CG = 31	IG	b	IG-b: 6 weekly sessions **CG:** received routine treatment	USA using a computer platform conducted in a home setting	6 months
Baradaran / 2006	Culturally-appropriate HE	Two-arm RCT	IG = 59 CG = 59	IG	sole focus of the intervention	IG: 3 (1.5hour each) sessions in 3 months **CG:** received routine treatment	UK GP's surgeries	6 months

Anderson / 2005	DSME	Two-arm RCT	IG = 125 CG = 114	IG	a	IG-a: 6 weekly (2-hour each) sessions **CG:** was placed on a waiting list to receive the intervention programme later	USA community-based locations	6 weeks
Daly / 2006	HB	Two-arm RCT	IG = 51 CG = 51	IG	a	IG-a: 3 monthly sessions **CG:** received other type of intervention	UK diabetes centres	3 months
Cohen / 2011	Shared medical appointments	Two-arm RCT	IG = 53 CG = 50	IG	b	IG-b: 4 weekly (1hour each) sessions **CG:** received routine treatment	USA not reported	6 months
Agurs-Collins / 1997	HB	Two-arm RCT	IG = 32 CG = 32	IG	a+b+d	IG-a: 12 weekly (60min each) sessions + IG-b: 12 weekly (30min each) sessions + IG-d: 6 biweekly (90min each) sessions **CG:** received other type of intervention	USA urban hospital in the African-American community	6 months
Adolfsson / 2007	DSME	Two-arm RCT	IG = 50 CG = 51	IG	a	IG-a: 4- 7 sessions (2.5hour each) within 7 months **CG:** received routine treatment	Sweden primary care centres	1 year
Gagliardino / 2013	Peer support	Two-arm RCT	IG = 93 CG = 105	IG	c	IG-c: 12 monthly sessions **CG:** received other type of intervention	Argentina houssay centre (which is a referral centre for the education of both people with diabetes and health professionals)	1 year

Sinclair / 2013	Culturally-adapted DSME	Two-arm RCT	IG = 48 CG = 34	IG	sole focus of the intervention	IG: 12 (1-h each) sessions **CG:** was placed on a waiting list to receive the intervention programme later	USA community health centres and community centre	3 months
Naik / 2011	DSME	Two-arm RCT	Number analysed: IG = 44 CG =41	IG	a	IG-a: 4 (1hour each) sessions **CG:** received other type of intervention	USA clinic	3 months
Khan / 2011	HE	Two-arm RCT	IG = 67 CG = 62	IG	a	IG-a: 5 lessons (30min each) **CG:** received other type of intervention	USA clinic	3 months
Samuel-Hodge / 2009	Culturally-competent-DSME	Two-arm RCT	IG = 117 CG = 84	IG	b	IG-b: 12 biweekly sessions (90 - 120min each) **CG:** received other type of intervention	USA African American churches in central North Carolina	1 year
Hornsten / 2005	Person centred	Two-arm RCT	IG = 44 CG = 60	IG	a	IG-b: 10 (2-hour each) sessions **CG:** received routine treatment	Sweden primary health care centres	1 year
Samaras / 1997	Peer support	Two-arm RCT	IG= 13 CG = 13	IG	a	IG-a: 6 (1-h) monthly sessions **CG:** received routine treatment	Australia leisure centre run by a local council	1 year

White / 1986	DSME	Two-arm RCT	IG = 20 CG = 21	IG	sole focus of the intervention	IG: weekly, biweekly (initially) and then monthly (1hour each) sessions **CG:** received other type of intervention	USA not reported	6 months
Greenhalgh / 2011	Culturally-competent DSME	Two-arm RCT	IG = 79 CG = 78	IG	sole focus of the intervention	IG: 12 biweekly (2hour each) sessions **CG:** received routine treatment	UK diabetes Centre	1 year
Ridgeway / 1999	HE/HB	Two-arm RCT	IG = 28 CG = 28	IG	a	IG-a: 6 monthly (1.5hour) sessions **CG:** not reported	USA primary care clinic	1 year
Sarkadi / 2004	DSME	Two-arm RCT	IG = 39 CG = 38	IG	sole focus of the intervention	IG: 12 monthly sessions **CG:** was placed on a waiting list to receive the intervention programme later	Sweden pharmacies	2 years
Murrock / 2009	Peer support	Two-arm RCT	IG = 24 CG = 22	IG	sole focus of the intervention	IG: 2 times a week (60min each) classes for 12 weeks **CG:** received no intervention	USA community based outpatient clinic	1 year
Trento / 1998, 2001, 2002, 2004	Group-visit	Two-arm RCT	IG = 56 CG = 56	IG	a	IG-a: 4 yearly (for 1-5 years) sessions **CG:** received routine treatment	Italy hospital diabetes outpatient department	1 year, 2 Years, 4 years, and 5 years

Trento / 2008	Group-visit	Two-arm RCT	IG = 25 CG = 24	IG	a	IG-a: 3-4 yearly (40-50 min each) sessions CG: received routine treatment	Italy hospital diabetes outpatient department	2 Years
Brown / 2002	Culturally-competent DSME	Two-arm RCT	IG = 128 CG = 128	IG	a+b	IG-a: 12 weekly meetings + IG-b: 14 biweekly meetings **CG:** received routine treatment and were placed on a waiting list for the intervention programme	USA hospital diabetes outpatient department	1 year
IG = Intervention group; CG = Control group; DSME = Diabetes self-management education; DSMT = Diabetes self-management training; HE = Health education; HB = Health behaviour; GP = General practitioner; USA = United State of America; UK = United Kingdom								

Appendix 4.3: Components of shared patient experience

Reference	Extent of shared patient experience components integrated in treatment group(s)	Description of shared patient experience	Mode of delivery in shared patient experience						Roles (and contents*) of shared patient experience		
			Facilitator(s)	Remote	Face-to-face	Individual	Group	Role model	Emotional	Informational	Unclear
Wilson / 1987 Pratt / 1987	IG2-b	Peer support facilitator (non-patient) sought to foster **peer interaction, focusing on group behaviours critical to self-help groups**	x **peer support facilitator (non-patient)**		x		x			x	
Anderson-Loftin / 2005	IG-a	Participants were taught to make healthy, low-fat food choices according to the Diabetes Food Pyramid, practical and culturally competent strategies for reducing fats, and individualized, mutual goals. Teaching methods, such as demonstration, **story-telling, vicarious experiences, and role-modelling are used** because learning occurs primarily by experiential methods	x **local registered dietician**		x		x	x		x	
	IG-b	Participants were provided professional group education with **peer discussion**. The peer-professional approach facilitates cultural translation of content, culturally competent learning methods, and **emotional support from peers** and family and is the preferred group structure of southern African Americans	x **nurse case manager**						x	**x**	
Rygg / 2012	IG sole focus of the intervention group	HCP-led DSME **discussion group was structured around the patients' experience** and questions arising in the group. In addition, there are long breaks, purposefully included, to give participants time to interact with each other	x **diabetes nurses**		x		x			x	
Maxwell / 1992	IG sole focus of the intervention group	HCP-led support group was described to patients as an opportunity to come together **to share experiences and support with other persons with diabetes for the purpose of improving life and developing new coping skills.** Patients were encouraged to express how they felt when they were diagnosed	x **psychiatrist & diabetes nurse specialist**		x		x		x	x	
Lujan / 2007	IG-a	Promotra (non-patient)-led DSM classes where members were frequently invited to **contribute personal anecdotes or experiences that were relevant to the class topics**	x **promotra (non-patient)**		x		x			x	

Lorig / 2008	IG sole focus of the intervention group	Peer educator (patient)-led Spanish DSM program **focused on modelling** (by having Spanish-speaking peer educators), and **social persuasion (by asking participants to systematically report on their successes and problems in the group). By doing this, they receive support and encouragement from the group and course leaders to continue working on their action plans**	**x** **peer educator (patient)**		**x**		**x**	**x**	x*		
Long / 2012	IG-1 sole focus of the intervention group	**Patients were matched to a peer mentor (patient)**: **mentors were encouraged to draw on their own experiences, talk with his or her mentee to learn his or her background, understand his or her motivations, help identify the differences between his or her behaviours and goals, and help identify a realistic plan for goal achievement** within 1 to 3 weeks. Mentors were given the telephone number of their mentees and informed that they would receive $20 per month if the mentees confirmed that they talked at least once per week	**x** **peer mentor (patient)**	**x** **phone**		**x**				x	
Philis-Tsimikas / 2011	IG-a	Peer educator(patient)-led DSME classes were interactive, **providing opportunities for patients to discuss personal experiences** and offer support and empathy to other group members	**x** **peer educator (patient)**		**x**		**x**		x		
Holtrop / 2002	IG sole focus of the intervention group	Lay health advisor (non-patient)-led discussions were on behaviour management skills. Each session included "how ya doing?" time **to discuss participants' thought about their progress**	**x** **lay health advisor (non-patient)**		**x**		**x**			x	
D'Eramo Melkus / 2010	IG-a	Throughout HCP-led DSM group sessions, participants **discussed personal and cultural influences on their body images** and identified ways and means of reaching diabetes self-care and weight management goals, emphasizing cultural reinforces as well as barriers	**x** **nurse, clinical psychologist , and/or psychiatric mental health nurse**		**x**		**x**			x	
Aghamolaei / 2005	**IG-a**	Patients actively participated the education sessions. All the information is derived and analysed on the basis of patients' knowledge and experience. Patients were encouraged to ask questions, **interject their own experiences and receive feedback from other patients** and instructors	**x** **health educator & nurse**		**x**		**x**			x	

De Weerdt / 1989, 1991	IG1-a	Peer (patient: guide each session, to answer questions and to lead the group discussions)-led group education classes **used video film** which directed the course of each session: it prompted participants to take part in group discussions. The video also had a motivational function. **The film showed seven patients telling about their positive experiences with active self-care.** These patients were chosen so as to form an average reflecting Dutch society. Each participant could recognize himself or herself in one of the people, and this could motivate them	**x peer (patient)**	**x video film**	**x**		**x**			x*	
	IG2-a	same as above									
Lorig / 2010	IG1-b	**Peer(patients: assisting participants by modelling action planning and problem-solving, o**ffering encouragement, providing each participant personalized responses during each weekly session)-led DSM discussion group where each week, participants are asked to reply to a question such as "What problems do you have because of your diabetes?" and to make a specific action plan. The questions and action plans posted on bulletin boards can be seen by all participants	**x peer (patient)**	**x online**			**x**	**x**	x	**x**	
	IG2-b	same as IG1-b									
	IG2-f	The discussion group was intended to reinforce any benefits of the program by **providing peer support**									**x**
Glasgow / 2003,	IG1-a	The conference was a peer-directed (but professionally monitored) forum for participants to interact with one another in a safe, supportive setting where **participants were encouraged to express their concerns, successes, and frustrations with their day-to-day coping with diabetes.** Group members posted messages that other members could read and answer	**x peer (patient)**	**x online**			**x**		x*	x*	
	IG1-b	The conference was more topic-oriented than the Diabetes Support Conference. The research staff introduced specific diabetes-related topics to **stimulate peer group discussion.**	**x research staff**								**x**

McKay / 2002, Barrera / 2002	IG1-a	The conference was a peer-directed (but professionally monitored) forum for participants to interact with one another in a safe, supportive setting where **participants were encouraged to express their concerns, successes, and frustrations with their day-to-day coping with diabetes.** Group members posted messages that other members could read and answer	x peer (patient)	x online			x		x*	x*	
	IG1-b	The conference was more topic-oriented than the Diabetes Support Conference. The research staff introduced specific diabetes-related topics to **stimulate peer group discussion**	x research staff								x
	IG3-a	The conference was a peer-directed (but professionally monitored) forum for participants to interact with one another in a safe, supportive setting where **participants were encouraged to express their concerns, successes, and frustrations with their day-to-day coping with diabetes.** Group members posted messages that other members could read and answer	x peer (patient)						x*	x*	
	IG3-b	The conference was more topic-oriented than the Diabetes Support Conference. The research staff introduced specific diabetes-related topics to **stimulate peer group discussion**	x research staff								x
Wu / 2011	IG-a	The sessions used 10 min **DVD** to provide the participants with a vicarious experience by **showing a person with type 2 diabetes ("Uncle Asparagus") successfully carrying out self-care activities in order to prevent** the occurrence of acute and chronic complications. Uncle Asparagus **described** the number of years since the initial diabetes diagnosis, what he did to help himself, **the worst part of the experience and how he dealt with his worst times, the best part of the experience** and what he would like to tell others going through treatment for the illness, and how the experience of diabetes influenced his family or life **Persons with type 2 diabetes who were using self-care activities successfully in order to prevent the occurrence of acute and chronic complications in this group were used as a role model.** The patients who were a role model were selected by the participants in this group and **shared their experience of how they dealt with their worst times, as well as the best part of the experience, which provided peer support**	x nurse	x DVD	x		x	x		x*	

Liebreich / 2009	IG-b	Study coordinator posted weekly topics based on the social cognitive construct featured that week. Participants could respond and view postings at their leisure. This allowed participants a forum in which to **exchange ideas and receive support from other study participants**	x research staff	x online			x		x	x	
McKay /2001	IG-d	This area allowed group members the opportunity **to share information and provide emotional encouragement and support for engaging in their program** by posting messages		x online			x		x	x	
	IG-e	This area was available for focus topics, where specific physical activity-related topics (e.g., "PA Barrier Busters") of potential interest were posted by research staff, and participants were encouraged to **post comments and share their thoughts on the topic(s)**	x research staff							x	
Chaveepojnkamjorn / 2009	IG sole focus of the intervention group	Active learning (exploring, reflecting, **sharing experiences with others,** choosing personal solutions) was stimulated			x		x			x	
Carter / 2011	IG-c	The module linked all intervention participants so that they were able **to exchange coping strategies, pose questions, and share preferred educational resources or any other information relative to losing weight and adopting a healthy lifestyle**		x online			x			x	
Bond / 2010	IG-b	The group **promoted peer support and social interaction through sharing of each person's personal experiences in dealing with their diabetes.**	x nurse, social worker, & psychologist	x online			x			x	
Baradaran / 2006	IG sole focus of the intervention group	Patients were asked to **discuss some of their experiences and problems**	x bilingual podiatrist & dietician		x		x			x*	

Anderson / 2005	IG-a	At the beginning of group session, patients were invited to reflect on their experience of working on their self-selected goals and talk about what they had learned and how it could be applied in the future. During each session patients were encouraged **to discuss emotional experience of living with diabetes (Living with diabetes raises emotional issues related to relationships, work, family, economic circumstances, overall health, physical functioning, and other life dimensions)**	**x nurse & dietitian**		**x**		**x**		x		
Daly / 2006	IG-a	**The sessions provided general support from both peers** and professionals.	**x various health-care professionals**		**x**		**x**				**x**
Cohen / 2011	IG-b	**The sessions** allowed for **open discussions about each individual's risk factor control, obstacles, and solutions**	**x clinical pharmacist (diabetes educator)**		**x**		**x**			x*	
Agurs-Collins / 1997	IG-a	**The group provided social interaction and peer support**	**x registered dietitian & exercise physiologist**		**x**		**x**				**x**
	IG-b	same as above									
	IG-d	The sessions provided additional information and **support in a format with less didactic instruction and more sharing and problem solving among participants** than the initial weekly sessions								x	
Adolfsson / 2007	IG-a	1) The patients were encouraged to identify problems related to their diabetes. The facilitator supported this process by actively involving all the patients and by inviting each of them to **talk about their own specific problems.** 2) The introduction to the different themes started with an open question, i.e. "What do you know. . .?" "What do you think about. . .?" . 3) The patients were encouraged **to share their experiences with each other.** 4) After the first session, each session began with a **discussion of what the patients had experienced** and reflected upon since the last session. Support for and barriers to making behavioural changes were discussed	**x physicians & diabetes specialist nurses**		**x**		**x**			x*	

Gagliardino / 2013	IG-c	Group calls among peers were conducted to **share experiences, difficulties and alternative solutions implemented**		x **phone**		x				x*	
Sinclair / 2013	IG sole focus of the intervention group	Peer educator (non-patient) read a story to develop discussions. Participants **shared personal experiences with diabetes, discussed successes and challenges to achieving their goals**	x **peer educator (patient)**		x		x			x*	
Naik / 2011	IG-a	Divided into several teams. Each team decides which of 3 case patients was at greatest risk for suffering long-term complications from diabetes based on their behaviours. After each team made their decision, they revealed their choice to the other teams, and facilitated a discussion. During the intra-team discussion, team members **had space to share insights and experience with each other**	x **general internist**		x		x			x	
Khan / 2011	**IG-a**	Online lessons used video story. Individual patient watched **video which recorded difference testimonials from various diabetic patients talking about diabetes self-care, emphasizing barriers to care, challenges, and personalized solutions they or family members had encountered**		x **online video**		x				x*	
Samuel-Hodge / 2009	IG-b	Peer counsellors (patient) and HCPs led the group. During the monitoring sessions and the group discussions, participants **shared successful strategies they had used to make progress toward goals, shared their struggles with efforts to change behaviours**	x **pharmacist, dentist, social worker, podiatrist & peer counsellor (patient)**		x		x			x*	
Hornsten / 2005	IG-a	Discussions in the group session were **based on the patient's personal** understanding, **thoughts and concerns related to living with diabetes** and being patient initiated by questions such as: "Why do I feel craving for sweets even though I have high blood sugar?; I know how to take my self-tests, but why do I need to take them?; My doctor talks about the benefits of exercise, but how can I exercise with arthritis?; . The areas of the discussions were not predetermined, since they emanated from the patients understanding and **covered experiential,** practical as well as theoretical points of **view**	x **diabetes nurses**		x		x			x*	
Samaras / 1997	IG-a	To overcome barriers: building self-esteem and motivation and **providing** professional and **peer support** in a group	x **physician, dietician, or nurse educator**		x		x		x		

White / 1986	IG sole focus of the intervention group	Patients were encouraged to interact and assess their own and their peers' progress toward managing their diabetes by **sharing ideas, advice, and support with one another.** Also in a small-group problem-solving format, patients **shared ideas and provided mutual support** for dietary change and increased exercise levels	**x** **clinical psychologist**		**x**		**x**		x	x	
Greenhalgh / 2011	IG sole focus of the intervention group	1) Sessions must **involve spontaneous, informal story sharing** without an imposed format (i.e. participants are encouraged to **tell whatever stories they want about their condition, in whatever order**, with no stipulation of what is 'important' or 'legitimate') - the intervention was intentionally unstructured and informal; 2) They are asked **to bring personal stories** on the agreed topic next time, and also asked whether they would like a health professional (dietician, exercise specialist, diabetes nurse, etc) to come and respond to their stories; Process: On arrival, participants have 10–15 minutes 'social time' before being asked to get into 'buzz groups' of 2-3 and share their stories. After about 20 minutes, the facilitator invites them to regroup in a plenary format and asks 'does any group have a good story to share?'. Informal discussion on this story is encouraged, with a focus on the practicalities and moral challenges that the story raises. the generic design for the group session is around the 'told story'	**x** **health advocates**		**x**		**x**		x	x	
Ridgeway / 1999	IG-a	Patients were encouraged to ask questions, **interject their own experiences,** and receive feed back from other patients and the instructors.	**x** **nurse & dietician**		**x**		**x**			x	
Sarkadi / 2004	IG sole focus of the intervention group	1) The self-monitoring **diaries of participants were shared with the group and comprised an important foundation for discussions**; 2) The guiding pedagogical principle throughout the group sessions was that any questions raised should be solved by the group rather than by the group leader	**x** **pharmacist**		**x**		**x**			x	
Murrock / 2009	IG sole focus of the intervention group	1) During the first week of the dance classes, each woman **chose a personal goal for improving 1 diabetes outcome and shared it with the group**; 2) After each class, the women had the opportunity **to share their progress of working toward their goals, share tips for eating** at upcoming weddings and family reunions, and discuss other concerns related to living with diabetes			**x**		**x**			x	

Trento / 1998, 2001, 2002, 2004	IG-a	Each group session included interactive learning; **discussion of some of the patients' experiences.** To induce positive group dynamics, the facilitators helped each patient identify and s**hare his/her problems and successes with the other members.** The patients were encouraged to report their personal experiences, if they so desired. If patients related examples of unintentionally incorrect behaviour, this was not criticized but was used as a source of positive learning for the group. The emergence of group leaders was encouraged, while maintaining the full involvement of all other members. Less extroverted patients were helped, but never forced, to participate during all phases. To reinforce cohesion and interpersonal relationships, the same patients and facilitators took part in the same groups over time	**x physicians & health educator**		**x**		**x**			x*	
Trento / 2008	IG-a	Each group session included interactive learning; **discussion of some of the patients' experiences.** To induce positive group dynamics, the facilitators helped each patient identify and s**hare his/her problems and successes with the other members.** The patients were encouraged to report their personal experiences, if they so desired. If patients related examples of unintentionally incorrect behaviour, this was not criticized but was used as a source of positive learning for the group. The emergence of group leaders was encouraged, while maintaining the full involvement of all other members. Less extroverted patients were helped, but never forced, to participate during all phases. To reinforce cohesion and interpersonal relationships, the same patients and facilitators took part in the same groups over time	**x nurses & dieticians**		**x**		**x**			x*	
Brown / 2002	IG-a	HCP and community workers (patient) used Spanish-language diabetes education videotapes (15 min each) , which conveyed information and interviews with local physicians, nurses, dietitians, and people with diabetes (**peers talking on the videotapes about diabetes and how they had learned to manage their diabetes effectively**) - some patients even recognized friends and relatives 1) An informal approach was fostered to encourage open discussion of problems and questions. 2) Focused on success (improving blood glucose levels rather than weight loss; participants perceived they had failed at weight loss many times in the past)	**x bilingual nurse, dietitian, & community worker (patient)**	**x Video film**	**x**		**x**			x*	
	IG-b	1) Sessions provided opportunities for patients and family members/friends to meet in an informal atmosphere **to discuss their problems in managing diabetes, express feelings about the impact of diabetes on the family, ask questions in a nonthreatening environment,** review previously learned information and skills, and participate in cooking demonstrations; 2) Individual participants **discussed their concerns and problems, and members of the group assisted each other in solving problems**; 3) Participants helped one another with diabetes-related problems, and most individuals in the groups actively participated in discussions. Individuals also compared results of their glucose self monitoring and encouraged one another to monitor							x*	x*	

HCP = Healthcare professional; DSME = Diabetes self-management education; DSM = Diabetes self-management; * = Interventions describing specific kinds of peers' experiences stories

Appendix 4.4: Effects of interventions

	Psychosocial outcomes												Knowledge outcome
Author	Quality of life	Social support	Psyhlogical distress	Illness perception	Outcome expectation	Locus of control	Self-efficacy	Treatment satisfaction	Normative belief	Motivation to comply	Intention to behaviour		Diabetes Knowledge
Wilson / 1987		(x)											
Anderson-Loftin / 2005													
Rygg / 2012	x		x					x					x*
Maxwell / 1992			x			x							x
Lujan / 2007							x ↄ						x*
Lorig / 2008	x		x*				x*						
Long / 2012													
Philis-Tsimikas / 2011													
Holtrop / 2002							x*						
D'Eramo Melkus / 2010	x*	x*	x*				x						x
Aghamolaei / 2005	x												x*
De Weerdt / 1989			x			x*			x*	x*	x*		
Lorig / 2010	x		x				x*						
Glasgow / 2003		x*	x										
McKay / 2002	x		x										
Barrera / 2002		x											
Wu / 2011					x*		x*						
Liebreich / 2009		x	x		x		x*						
McKay /2001			x										
Chaveepojnkamjorn / 2009	x*												
Carter / 2011	x*												x
Bond / 2010		x*	x*				x*						
Baradaran / 2006				x									x

	Psychosocial outcomes												Knowledge outcome
Author	Quality of life	Social support	Psyhlogical distress	Illness perception	Outcome expectation	Locus of control	Self-efficacy	Treatment satisfaction	Normative belief	Motivation to comply	Intention to behaviour		Diabetes Knowledge
Anderson / 2005				x			x						x*
Daly / 2006													
Cohen / 2011	x						x						
Agurs-Collins / 1997													x
Adolfsson / 2007	x						x						x*
Gagliardino / 2013			x	x									x
Sinclair / 2013			x										x*
Naik / 2011													x*
Khan / 2011							x						x
Samuel-Hodge / 2009	x*												x
Hornsten / 2005			x					x					
Samaras / 1997	x												
White / 1986						x							x
Greenhalgh / 2011	x						x						
Ridgeway / 1999	x												x
Sarkadi / 2004													
Murrock / 2009													
Trento / 2001	x*												x*
Trento / 1998	x												x*
Trento / 2002	x*												x*
Trento / 2004	x*												x*
Trento / 2008	x*		x			x*							x
Brown / 2002	x	x		x									x*

( ) = reuslt not reported
* = statistically significant improvement
❯ = statistically significant deterioration

	Clinical outcomes							Health service utilization outcomes	
Author	HbA1c	Systolic blood pressure	Total cholesterol	HDL	Weight	BMI		Primary care, clinic, and/or emergency room visits	Hospitalisation
Wilson / 1987	(x) colorimetric method				(x)				
Anderson-Loftin / 2005	x RIAIM		x colorimetric method	x	x	x*			
Rygg / 2012	x Laboratory measurement	x	x Laboratory measurement	x	x	x		x	
Maxwell / 1992	x AC		x	x					
Lujan / 2007	x* finger-stick procedure								
Lorig / 2008	x* BIOSAFE kits					x		x	
Long / 2012	x*								
Philis-Tsimikas / 2011	x* Laboratory measurement	x	x Laboratory measurement	x	x	x			
Holtrop / 2002	x					x			
D'Eramo Melkus / 2010	x	x	x	x	x				
Aghamolaei / 2005	x colorimetric method								
De Weerdt / 1989									
Lorig / 2010	x* BIOSAFE kits							x	
Glasgow / 2003	x turbidimetric immunoinhibition		x	x					
McKay / 2002	x Bio-Rad Micro Column Test								
Barrera / 2002									
Wu / 2011								x*	x*
Liebreich / 2009									
McKay /2001									
Chaveepojnkamjorn / 2009						x			
Carter / 2011	x	x			x	x			
Bond / 2010									
Baradaran / 2006									

	Clinical outcomes							Health service utilization outcomes	
Author	HbA1c	Systolic blood pressure	Total cholesterol	HDL	Weight	BMI		Primary care, clinic, and/or emergency room visits	Hospitalisation
Anderson / 2005	x	x	x	x	x				
Daly / 2006	x	x	x	x*	x*				
Cohen / 2011	x*	x*	x	x	x			x	
Agurs-Collins / 1997	x* Bio Rad Diamat System	x		x	x*	x*			
Adolfsson / 2007	x HPLC & MSER					x			
Gagliardino / 2013	x	x	x	x		x		x	x
Sinclair / 2013	x* DCA 2000 analyzer	(x)	(x) Cholestech analyzer	(x)	(x)				
Naik / 2011									
Khan / 2011	x phlebotomy following NGSPS	x							
Samuel-Hodge / 2009	x HPLC	x			x				
Hornsten / 2005	x* HPLC	(x)	(x)	x*	x	x			
Samaras / 1997	x*		x ACOPM	x	x	x			
White / 1986	x* AC & colorimetry				x				
Greenhalgh / 2011	x	x	x	x		x			
Ridgeway / 1999	x AIGHA		x CEHOPM	x	x				
Sarkadi / 2004	x*					x			
Murrock / 2009	x* Variant II Turbo Analyzer	x*			x				
Trento / 2001	x* HPLC		x	x*	x	x			
Trento / 1998	x HPLC		x	x	x	x			
Trento / 2002	x HPLC		x	x	x	x			
Trento / 2004	x* HPLC		x	x	x	x			
Trento / 2008	x* HPLC	x	x	x	x				
Brown / 2002	x*		x	x	x	x			

HDL = High-density cholesterol
HbA1c = Glycated haemoglobin
BMI = Body mass index
( ) = reuslt not reported
* = statistically significant improvement
☽ = statistically significant deterioration

HPLC = high performance liquid chromatography
RIAIM = Roche integra automated immunoturbidimetric method
NGSPS = National glycohemoglobin standardization srogram standards
AC = Affinity chromatography
MSER = Mono Sion-exchange resin
AIGHA = Abbott IMX glycosylated hemoglobin assay
ACOPM = adaptation of the cholesterol oxidase/peroxidase method
CEHOPM = cholesterol ester hydrolase oxidase/peroxidase method

	Health behavioural outcomes									
Author	Physical activity	Self-monitoring of blood glucose	Diet	Foot care	Smoking activity	Medication adherence	Amount of medication consumed/ prescribed	Insulin use	Communication with physicians	Behaviours related to home blood glucose monitoring
Wilson / 1987										
Anderson-Loftin / 2005			x*							
Rygg / 2012			x	x*		x				
Maxwell / 1992										
Lujan / 2007										
Lorig / 2008	x	x						x	x	
Long / 2012										
Philis-Tsimikas / 2011										
Holtrop / 2002	x		x*							
D'Eramo Melkus / 2010										
Aghamolaei / 2005										
De Weerdt / 1989	x	x*	x					x*		x*
Lorig / 2010	x									
Glasgow / 2003			x							
McKay / 2002			x							
Barrera / 2002										
Wu / 2011										
Liebreich / 2009	x*									
McKay /2001	x									
Chaveepojnkamjorn / 2009										
Carter / 2011	x		x	x						
Bond / 2010										
Baradaran / 2006										

	Health behavioural outcomes									
Author	Physical activity	Self-monitoring of blood glucose	Diet	Foot care	Smoking activity	Medication adherence	Amount of medication consumed/ prescribed	Insulin use	Communication with physicians	Behaviours related to home blood glucose monitoring
Anderson / 2005										
Daly / 2006			x ☽							
Cohen / 2011	x	x	x	x	x	x	x*			
Agurs-Collins / 1997	x		x							
Adolfsson / 2007										
Gagliardino / 2013	x	x					x			
Sinclair / 2013										
Naik / 2011										
Khan / 2011	x ☽	x	x	x	(x)	x	x*	x		
Samuel-Hodge / 2009	x*		x							
Hornsten / 2005										
Samaras / 1997	x		x							
White / 1986									x*	
Greenhalgh / 2011										
Ridgeway / 1999										
Sarkadi / 2004										
Murrock / 2009										
Trento / 2001										
Trento / 1998										
Trento / 2002										
Trento / 2004										
Trento / 2008										
Brown / 2002										

( ) = reuslt not reported
* = statistically significant improvement
☽ = statistically significant deterioration

Appendix 4.5: Risk of bias in included studies

Author	Sequence generation	Allocation concealment	Blinding outcome assessors	Completeness of outcome data	Selective reporting
Wilson / 1987	unclear	unclear	unclear	unclear	unclear
Anderson-Loftin / 2005	low	unclear	unclear	unclear	low
Rygg / 2012	low	high	unclear	low	low
Maxwell / 1992	unclear	unclear	unclear	unclear	unclear
Lujan / 2007	unclear	unclear	unclear	unclear	unclear
Lorig / 2008	unclear	unclear	unclear	unclear	unclear
Long / 2012	low	low	unclear	unclear	low
Philis-Tsimikas / 2011	low	unclear	low	unclear	unclear
Holtrop / 2002	unclear	unclear	unclear	unclear	unclear
D'Eramo Melkus / 2010	low	unclear	unclear	unclear	unclear
Aghamolaei / 2005	unclear	unclear	unclear	unclear	unclear
De Weerdt / 1989	unclear	unclear	unclear	unclear	unclear
Lorig / 2010	low	unclear	unclear	unclear	low
Glasgow / 2003	unclear	unclear	unclear	unclear	unclear
McKay / 2002	unclear	unclear	unclear	unclear	unclear
Barrera / 2002	unclear	unclear	unclear	unclear	unclear
Wu / 2011	low	unclear	unclear	unclear	unclear
Liebreich / 2009	unclear	unclear	unclear	LOW	unclear
McKay /2001	unclear	unclear	unclear	unclear	unclear
Chaveepojnkamjorn / 2009	unclear	low	unclear	unclear	unclear
Carter / 2011	low	unclear	unclear	unclear	low
Bond / 2010	unclear	unclear	unclear	unclear	unclear
Baradaran / 2006	unclear	unclear	unclear	unclear	unclear

Author	Sequence generation	Allocation concealment	Blinding outcome assessors	Completeness of outcome data	Selective reporting
Anderson / 2005	unclear	unclear	unclear	unclear	unclear
Daly / 2006	unclear	unclear	unclear	unclear	unclear
Cohen / 2011	unclear	unclear	unclear	unclear	unclear
Agurs-Collins / 1997	unclear	unclear	unclear	unclear	unclear
Adolfsson / 2007	unclear	low	unclear	unclear	unclear
Gagliardino / 2013	unclear	unclear	unclear	unclear	unclear
Sinclair / 2013	low	low	unclear	unclear	unclear
Naik / 2011	unclear	unclear	unclear	unclear	unclear
Khan / 2011	low	unclear	unclear	unclear	unclear
Samuel-Hodge / 2009	low	low	low	low	unclear
Hornsten / 2005	unclear	unclear	unclear	unclear	unclear
Samaras / 1997	unclear	unclear	unclear	unclear	unclear
White / 1986	unclear	unclear	unclear	unclear	unclear
Greenhalgh / 2011	low	unclear	unclear	unclear	unclear
Ridgeway / 1999	unclear	unclear	unclear	unclear	unclear
Sarkadi / 2004	low	unclear	unclear	unclear	low
Murrock / 2009	low	unclear	unclear	unclear	unclear
Trento / 1998	low	unclear	unclear	unclear	low
Trento / 2001	low	unclear	unclear	unclear	low
Trento / 2002	low	unclear	unclear	low	low
Trento / 2004	low	unclear	unclear	unclear	low
Trento / 2008	low	unclear	unclear	unclear	unclear
Brown / 2002	unclear	unclear	unclear	unclear	unclear

Chapter 5. Analysis of existing sources of qualitative evidence exploring patients' attitudes, experiences, information/support needs in relation to the initiation of insulin therapy

Introduction

While the systematic review in chapter 4 provided promising evidence to inform the potential use of shared patient experience to improve diabetes-related health in adults with type 2 diabetes, the evidence was not specific to the context of the decision-making process in starting insulin therapy. There are still many uncertainties about the evidence to support the design and development of an intervention based on shared patient experience.

As noted in chapter 2, while past research has highlighted psychological factors involved in the reluctance toward/refusal of the initiation of insulin therapy, it is crucial to gain a more in-depth understanding about patients' attitudes and beliefs toward the initiation of insulin therapy, including the views of those who have already begun insulin therapy. Simultaneously, it is crucial to understand patients' attitudes and experiences in relation to information/support needs and, in particular, support through shared patient experience in the context of decision-making about starting insulin. Qualitative data may be able to clarify these uncertainties, and provide complementary evidence to inform a possible pilot design of a future intervention. To help build the evidence base, two linked pieces of work were conducted, namely a narrative literature review of qualitative studies (chapter 5- part 1), and a secondary analysis of an existing collection of qualitative interviews (chapter 5- part 2). By using available sources of qualitative evidence, two studies reporting complementary perspectives were pulled together to assess the following research question.

Aim

The two studies aimed to answer the following research question:

- What does a non-systematic narrative review of the existing literature say (chapter 5- part 1) and what is known (chapter 5- part 2) about patients' attitudes and beliefs toward the initiation of insulin therapy as well as their attitudes and experiences in relation to information/support needs (in particular, support through shared patient experience) in the context of the decision-making process to commence insulin therapy?

Chapter 5 – Part 1. Narrative literature review of qualitative studies: Methods, Results, and Strengths/Limitations

5.1.1 Methods

5.1.1.1 Narrative literature review

There has been growing interest in developing systematic reviews of qualitative studies. Nevertheless, there are some concerns for the 'appropriateness and feasibility' of attempting to conduct a systematic review of qualitative studies[1]. Techniques for synthesizing qualitative studies are still in their infancy compared with the synthesis of quantitative studies, and obstacles include a lack of guidance on how to develop suitable search filters, little consensus on how to synthesise the evidence,[1,2] and disagreement over how to ensure the quality of the studies[1-4]. There is also concern over the risk of a systematic review artificially reducing the complexity and interpretive nature of qualitative research[1]. For this reason, a narrative literature review was undertaken.

5.1.1.2 Literature search and study selection

Five databases [EMBASE (1974 - present), PsycINFO (1967 - present), Medline & Medline in process (1946 - present), CINAHL (1980 - present), and Social Science Index (1956 – present)] were searched from database start date to *May 2014*, together with reference lists of review articles. Reference lists of primary articles found from initial searches were also searched manually. The search terms were developed for each database by combining search terms relating to type 2 diabetes (e.g. *diabetes, type 2, non-insulin dependent, late/adult onset)*, insulin therapy *(e.g. insulin commencement/start)*, and qualitative study *(e.g. research, interview, focus group, narration, observation*). The strategy for the Social Science Index is presented as an example in Appendix 5.1. The Social Science Index strategy was tailored to the other databases. Papers were included if they consisted of qualitative research (using qualitative data and analyses) which explored patients' attitudes and beliefs toward the initiation of insulin therapy, and patients'

attitudes and experiences in relation to information/support needs (in particular support through shared patient experience) in the context of the decision-making process in starting insulin therapy, and were published in the English language. Studies where qualitative data and analyses were embedded within larger mixed methods studies were included only if the qualitative data were extracted. Limiting searches to studies conducted in the United Kingdom (UK) and other European countries that have a similar medical system to the UK was considered. After further discussion, however, it was anticipated that people's concerns, emotions, and feelings about insulin therapy might not necessarily be affected by medical systems, and that there might be a possibility of finding only a few studies if limiting the search to these specific locations. Thus, it was agreed not to restrict the search to the specific locations. However, during the analysis close attention was paid to the potential impact of medical systems. Conference abstracts and dissertations were excluded.

5.1.1.3 Data synthesis

One reviewer extracted data on study characteristics and context from included studies using Excel. After familiarization with the findings of individual studies, initial themes were developed and the reviewer assigned sections of findings to these themes. Initial themes were then discussed and revised with supervisors (a senior qualitative researcher and a primary clinician) in order to develop ideas, and confirm interpretations of themes and assigned sections. Revised themes were then grouped into main themes and sub-themes. The data were identified and synthesised from study findings, including participant responses as well as authors' summaries and interpretations.

5.1.1.4 Quality assessment of included studies

As noted above, there has been considerable debate among researchers about how best to assess the quality of qualitative research (reliability and validity), and indeed, whether it can or should be assessed at all[2,5-7] given the very different epistemological basis of qualitative research[8]. To date, no consensus has been reached regarding how the quality of qualitative research should be

judged (e.g. difficulty in capturing range of study designs in a single set of quality criteria)[2-4,7,9,10], and carried out (e.g. doubt about whether a ''checklist'' approach can capture the nuances and intricacies of data)[9]. Despite these issues, '*there is agreement that some way of distinguishing high-quality studies from poor [-quality] is desirable*'[5]. The development of criteria for assessing qualitative research provides practical guidelines for the weighting of studies within a synthesis of the research evidence[2], and transparency in the peer reviewing of research papers[9]. This is an important way to help researchers and practitioners who are unfamiliar with qualitative research identify studies which provides the strongest basis for action[4,9], and support qualitative research to have some clear implications for policy and practice[4].

The judgement of quality assessment approaches/criteria needs to reflect the purposes of the narrative review, whose own aims were to understand patients' attitudes, experiences, and information/support needs in relation to the initiation of insulin therapy, and to produce evidence that can be translated into implementation of a trial based on shared patient experience. In order to reflect these purposes, Daly's assessment approach[9] was considered appropriate, since it was developed to appraise the quality of studies (mainly interview studies) with regard to their capacity to provide evidence-for-practice or policy, by prioritising 'study design producing transferable evidence, evidence that is generalizable beyond the setting where the study is conducted'[9]. This approach uses four levels of a qualitative hierarchy to judge the strength of qualitative evidence that reflects 'the reliability of study conclusions for decisions made in clinical practice and health policy'[9]: *generalizable studies* (studies using conceptual frameworks to derive an appropriately diversified sample with analysis accounting for all data); followed by *conceptual studies* (studies that analyse all data according to conceptual themes but may be limited by a lack of diversity in the sample); *descriptive studies* (studies that may provide helpful lists of quotations but do not offer detailed analysis); and *single case studies* (the least likely studies to produce good evidence-for-practice)[9].

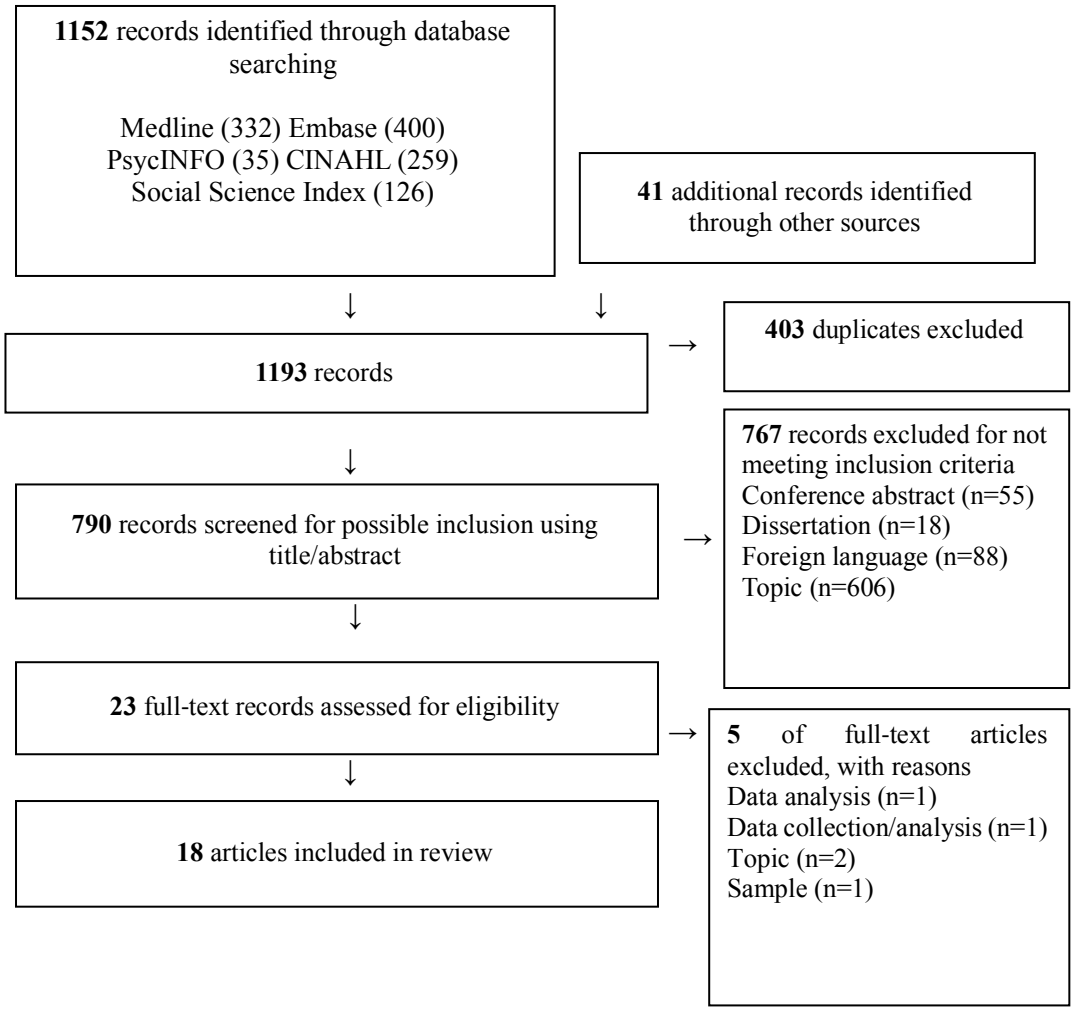
The assessment of the studies included in the narrative review suggests that they appear to be largely categorized into *descriptive studies*, the third highest of four levels in the qualitative hierarchy of evidence-for-practice. Whether and how poor-quality studies should be included in the synthesis remains contested[5]. However, given that there are no accepted or empirically tested methods for excluding qualitative studies from syntheses on the basis of their quality[2,9,11], and that even poor quality studies potentially include interesting data[9], all the studies in the review were included regardless of their quality.

5.1.2 Results

5.1.2.1 Search results

Figure 5.1 illustrates the flow of papers at each stage of the review process. An initial literature search identified 1193 references, from which 403 duplicate papers were excluded. The remaining 790 papers were reviewed using titles and abstracts and 23 papers were identified as relevant based on specified inclusion/exclusion criteria. The full-text articles of the 23 papers were then retrieved and read to confirm the relevance of each. Five papers were considered not relevant. The final review included 18 articles, which demonstrated the examination of patients' attitudes and beliefs toward the initiation of insulin therapy, and patients' attitudes and experiences in relation to information/support needs (in particular support through shared patient experience) in the context of decision-making in insulin therapy.

Figure 5.1 Flow chart of review of qualitative studies



5.1.2.2 Characteristics of included studies

The characteristics of included studies are summarised in Appendix 5.2. 18 included studies consisted of samples ranging in size from five to 45[12-29]. Eight studies took place in Europe [Romania (n = 1)[13] and the UK (n = 7)[14,18,22,23,25,27,28]]; seven studies took place in North America [the United States of America - USA (n = 3)[19,20,24] and Canada (n = 4)[15-17,26]]; two studies took place in Asia [Malaysia (n = 1)[12] and Singapore (n = 1)[29]]; the rest were conducted in New Zealand (n = 1)[21], and Brazil (n = 1)[16]. Moreover, the studies represented a variety of settings including diabetes centre/clinic (n = 5)[13,17,21,22,25], private setting (n = 4)[18,26-28], primary care clinic (n = 2)[12,29],

community/public clinic (n = 2)[17,20], scenarios where the setting was not clear (n = 2)[14,15], hospital (n = 1)[16], community centre (n = 1)[23], and medical university (n = 1)[24]. Three were published between 1996 and 1997[15,20,24], and the rest were published between 2004 and 2013[12-14,16-19,21-23,25-29]. Six studies used data obtained from semi-structured interviews[13,17,18,21,25,26]; six used data from focus groups [15,19,23,24,27,29]; four used data from one-to-one/in-depth interviews[14,20,22,28]; two used data from in-depth individual interviews or focus groups[12,16]. Of the analytic strategy papers, three studies used thematic analysis[12,18,22]; three used framework analysis[14,16,17]; three used the interpretative phenomenological approach[21,25,28]; three used grounded theory[15,26,29]; two used thematic content analysis[23,27]; two used content analysis[19,20], one used contextual analysis[24]; one used the phenomenological approach and content analysis[13]. 14 studies examined attitudes/experiences of patients only[12-14,16-18,20,21,23-28]; two examined attitudes/experiences of patients and healthcare professionals[22,29]; one focused on attitudes/experiences of patients, their family members, and significant others[19]; and one focused on attitudes/experiences of patients, their family members, community leaders, and elders[15].

Socio-demographic information about study participants was described in most of the studies (e.g. ethnicity, gender), while a few lacked such details as gender[15] and ethnicity[26,28,29] of participants. Only one study recruited female participants only[24] and all others recruited both female and male participants. Studies varied according to which treatment stage participants had reached: seven included a combination of those who had already initiated insulin, and who had not been recommended to initiate insulin by healthcare professionals and had not initiated insulin[14,16,18-20,26,27]; six studies included only participants who had already initiated insulin treatment[12,17,21,22,25,28]; one included only those at the point of moving onto insulin but had not initiated insulin[13]; one included only those deemed necessary to initiate insulin by healthcare professionals but had refused to initiate insulin[23]; one included only those who had not been recommended to initiate insulin by healthcare professionals and had not initiated insulin[24]; one included a combination of those who had refused insulin initiation, and who had already initiated

insulin[29]; one study did not report such details[15]. Studies of certain ethnic/racial groups provided specific information about the experience of a particular group. This enabled comparison of the groups between the studies, in which the majority of the studies (13 out of 18) recruited only participants belonging to ethnic minority communities in the country in which the studies were conducted[14,15,17,19,20,23,24,27], or only those belonging to the dominant community in the country in which the studies were conducted[12,13,16,18,22]. While two studies[21,25] recruited participants from an ethnic minority as well as dominant communities in the country in which the studies were conducted, no attempt was made to explain their results on the basis of ethnicity.

Analysis of the results of studies included in this paper revealed three headings regarding patients' attitudes and beliefs toward the initiation of insulin therapy, and patients' attitudes and experiences in relation to information/support needs (in particular support through shared patient experience) in the context of the insulin decision-making (see table 5.1). The first heading (Attitudes/beliefs about potential insulin therapy) examines patients' initial responses to insulin in a context of managing disease with non-insulin treatment prior to the initiation of insulin, which were explored below under three main themes: *punishment, threat, or failure*; *fears;* and *impact of peers' experiences in forming initial responses to insulin therapy*. The second heading (Actual decision to move onto insulin treatment) explores how peers' experiences function in a context of decision-making about starting insulin, under two main themes: *impact of peers' experiences in making decisions about starting insulin therapy;* and *other triggers to accept insulin therapy.* The final heading (Actual experiences of insulin management) observes how patients' initial responses to insulin change in the process of managing insulin, under three main themes: *better than anticipated; as anticipated;* and *impact of peers' experiences in managing insulin therapy*.

Table 5.1 Headings, main themes, and sub-themes

Headings	Main themes	Sub-themes
Attitudes/beliefs about potential insulin therapy	**Punishment, threat, or failure**	Punishment or threat
		Failure
	Fears	Fear of disease severity/mortality
		Fear of risk to health
		Fear of insulin injection/technology
		Fear of leading restricted life
		Fear of discrimination
		Fear of the unknown
	Impact of peers' experiences in forming initial responses to insulin therapy	
Actual decision to move onto insulin treatment	**Impact of peers' experiences in making decisions about starting insulin therapy**	
	Other triggers to accept insulin therapy	
Actual experiences of insulin management	**Better than anticipated**	
	As anticipated	
	Impact of peers' experiences in managing insulin therapy	

Attitudes/beliefs about potential insulin therapy

Studies reviewed for this paper identified some initial responses to insulin often shared in the accounts of non-insulin treated patients talking about their future insulin treatment as well as the accounts of insulin treated patients talking about their retrospective views of the initiation/decision. These are explored below under three main themes including punishment, threat, or failure; fears; and impact of peers' experiences in forming initial responses to insulin therapy.

Punishment, threat, or failure

Some patients considered insulin as a form of punishment or threat, which in turn, seems to reinforce their sense of personal failure when they rationalise the need to start insulin.

Punishment or threat

Insulin was often described as a form of 'punishment'[25,28], a 'penalty for non-adherence'[13], or 'punishment for not controlling lifestyle'[29]. Such perceptions seem to be present in different cultural contexts including those of the UK, Romania, and Singapore. While the data comparing gender differences in such perceptions were limited, one study conducted in the UK suggested that women tended to see insulin as a form of punishment, while men were more likely to see it as a form of treatment that would be beneficial to them[25]. A number of studies identified for review also suggest that one factor resulting in insulin being represented as 'punishment' is a perception that healthcare professionals used insulin as a 'threat'[13,20,24,27] by intimating to patients that their potential need for insulin would be a consequence of their not having conformed to earlier advice (e.g. poor diabetic control, lack of adherence to diet, exercise, or tablet regimens)[17,27,28]. One patient reported:

> '*I know several times the doctor told me your sugar is up, your sugar is up and he said it has to come down or else we put you on the insulin. I've been dreading that*'[27].

These studies show the association of 'scare tactics' perceived to be used by healthcare professionals and patients' views of insulin as a form of punishment (this is patient-reported perception – it may not reflect actual behaviours of healthcare professionals. Yet, the perception is nonetheless important).

Failure

The perception of insulin as 'punishment' may also relate to the way in which patients rationalised the need to start insulin treatment, where patients from different cultural contexts (e.g. Romania, the UK, Canada, and the USA) saw insulin commencement as a result of personal failure in regard to past treatment[13,17,18,20,25,27,28] including failure to adequately self-care[17,20] or failure to control glucose levels[27]. In one study, one patient looked back at the time when s/he was advised to initiate insulin and expressed feelings of guilt and self-blame, perceiving that the need for insulin was due to his/her lack of diligence and adherence to past regimens:

> '*I failed to manage it on my own. So now I have to go on insulin ... and ... it's not so much about giving yourself a needle; it's about failure. I failed to manage it, and it's the 'why me' thing. Why me? But you know, I have to do it. I didn't manage to do it. I couldn't do it. I didn't try hard enough*'[17].

Although one study in the UK reported that patients rarely associated a sense of personal failure with their disease self-management when advised to initiate insulin[22], studies in this review identified that this was indeed often expressed among patients.

Fears

Fear was another central aspect of initial responses to insulin reported by patients. A synthesis of the studies identified different elements associated with insulin that contribute to feelings of fear, including fear of disease severity/mortality, fear of risk to health, fear of insulin injection/technology, fear of leading a restricted life, fear of discrimination, and fear of the unknown.

Fear of disease severity/mortality

Patients' fear that insulin is a marker of disease severity was one of the major concerns expressed in a significant proportion of studies, where patients perceived that insulin is reserved only for very serious and advanced stages of disease[12,14,17,19-21,23,25,27-29], that insulin is a treatment to be used as a last resort [19,23,25,27,29], that insulin means getting closer to death[12,20,21,29], or that insulin represents a death sentence in itself[27]. Comments included:

> '*Well, what I've heard about insulin is that when you have to use insulin it means that your diabetes is very advanced'*[19].
>
> *'I felt like once you hit insulin you are on a slide to.... you know death'*[21].

These phenomena were particularly apparent in studies conducted with patients from ethnic minority groups including Chinese patients in Canada, Maori patients in New Zealand, African Caribbean patients in the UK, and Hispanic and Mexican American patients in the USA.

While patients often vented their concerns for insulin as a marker of disease severity or proximity to death, some studies presented the opposite view of insulin, crediting insulin with prolonging or saving their lives[13,20,29]. One patient stated that insulin represented his/her '*only chance for survival'*, a crucial '*step towards the ... future'*, offering the patient '*a chance'*[13], while another patient commented:

> '*I think if you take insulin, that means that I can preserve my organs and I can live longer'*[29].

Fear of risk to health

In the studies reviewed, patients often expressed their beliefs in the risk of insulin to health and the body, such as anxieties that insulin could cause diabetes complications including blindness[20,28], kidney damage[12,19,20], and heart attacks[20], as well as side-effects, such as weight gain[14,20,23,29] and hypoglycaemia[16,23,27,29]. Patients expressed their concerns about the risk to health in the following terms:

> '*When the doctor prescribed insulin, I was terrified of detrimental effects of insulin on*

the kidneys. I was afraid that insulin might ruin my health'[12].

'The frightening thing is that you gain weight. On the other hand, you go into hypo [hypoglycaemia]. That is quite frightening ... my fear is that hypo is very dangerous. We won't be able to control our own body anymore when we go into a coma. I do not know how I am able to manage this insulin"[29].

Some patients from non-Western cultural backgrounds also expressed concerns associated with the risk of insulin to health which are unique to their own cultures[14,17,27]. African Caribbean and African patients in the UK, as well as Chinese patients in Canada displayed distrust for Western medicine, and raised concerns about the chemical nature of insulin[14] and insulin's unnatural constitution, which they believed to cause allergic reactions in their body[27] or upset the balance in their body, resulting in more significant health problems[17]. One African Caribbean patient foresaw future risks of insulin to health:

'*Well just this general concern of injecting yourself and the residue that it leaves in your body. I mean because is it a hormone or something like that?'*[14]

Such fears toward insulin outnumbered positive views, although a few studies reported patients' beliefs in insulin as being beneficial for their health[12,13,29]. Some patients commented that insulin improves health, maintains good glycaemia control, prevents complications, makes them feel healthier/more energetic, and/or is natural to their body. One such patient commented:

'Insulin is identical to what my body used to produce before, when it was healthy'[13].

Fear of insulin injection/technology

A number of studies reported the 'technology' attached to insulin as a key concept, where patients were often apprehensive about mastering the proper technical skills necessary for the performance of insulin therapy[12,13,17,20,25,27]. For instance, one patient raised some concerns about the technique necessary to gauge his/her insulin dose:

'*Maybe I'll go into a coma if once I do it wrong. What if I won't be able to learn the procedure? What if it gets blocked up somehow and I inject less than I need?'*[13]

Some patients also worried about negative consequences on health owing to a failure to operate insulin properly[13,25]. Apart from such concerns over insulin technology, the actual insulin injection was another significant concern shown by many studies, including fear of needles[12,23,25,27,29], fear of pain associated with administration of injection[12,16,17,29], and fear/discomfort of self-injection[12,14,16,20,21,23,25-27]. Comments included:

> '*There is no way I will start insulin, I cannot inject myself, I feel terrified just to think about the injections*'[16].

> '*I never had anything against insulin but I could not see myself injecting insulin*'[12].

Some patients reported severe needle phobia[12].

Many patients raised such feelings of fear toward insulin injection/technology, whereas absence of such fears was also reported by a small number of studies[13,29]. Comments by some patients included:

> '*I am not afraid of injections; I've been injected many times before in my life*'[13].

> '*There are a few different types of pens. They come in very handy, so it's not a problem. There shouldn't be a problem*'[29].

Fear of leading a restricted life

Patients often believed that insulin would be a source of inconvenience and could cause a loss of control over their lives[13,20,23,29]. Studies reported patients' concerns about inconvenience in the use of insulin when away from home[13,29]. For one patient there was a concern over where one needs to go to perform injections if one finds oneself on the street or at work:

> *'I was thinking [about other people with diabetes] – where do they go to do the injection, if, for instance, they are on the street or at work? Do they go to the toilet or where?'*[13].

One patient also expressed concern over how to refrigerate insulin while travelling:

> '*for tablets, I can put [store] them anywhere. I don't want to carry ten needles if I go overseas. I have to put it in the fridge. Am I going to bring a fridge everywhere I go? If you can find a way to store the insulin easily…*'[29].

Other studies described patients' concerns about the inconvenience of using insulin when living alone. One patient for instance, exhibited his/her concern at not being able to cope should s/he experience a hypoglycaemic episode[23]. Patients who live with their caregivers also foresaw future inconvenience in using insulin should their caregiver support diminish (e.g. if the caregiver moves away)[23,29]. Such a concern was described by one patient as follows:

> '*What if my daughter gets married? [Do] I go to her house everyday [for the insulin injection]?*'[29].

On the other hand, none of the studies reported patient views to the effect that insulin would not be a source of inconvenience in their lives.

Fear of discrimination

A number of studies identified patients' fear of discrimination attached to insulin, where they expressed concerns that the need to inject in public may cause feelings of social rejection, and that they may be affected by the negative connotations associated with the use of insulin injections[13,17,18,23,27]. For instance, patients did not want people to know they had diabetes[21,23,27]. For some, it was the anxiety of what others might think, where the use of needles was often identified with either '*drug addicts*'[13], '*bad diabetics*'[18,23], or sometimes seen as a '*handicap*'[13,17], which was cited by one patient:

> '*Only bad diabetics have insulin*'[23].

The extent of such perceived discrimination may also be influenced by a patient's cultural context. A study of Chinese patients in Canada[17], as well as studies featuring Maori patients in New Zealand, Bangladeshi[23], and African Caribbean and African[27] patients in the UK, all reported that insulin use is usually associated with strong stigma and taboo in their societies, so patients wanted to hide their injections in order to prevent people knowing they use insulin. One Bangladeshi patient reported his/her concern that insulin use may reduce marriage prospects[23].

While numerous accounts of fear of discrimination were reported by patients, one study foresaw future fear of discrimination in a more positive way. This was expressed by one patient as follows:

> '*There's nothing to be ashamed about [insulin]. People like us who are already diabetic, we just have to admit we are diabetic. In fact, when you take oral [medication] in front of people, they will ask you what [disease] you have. We have to be very truthful and tell them I'm on medication for diabetes'* [29].

Fear of the unknown

In some studies, patients raised concerns over a lack of understanding about insulin, for example often posing questions over whether or not insulin treatment would be necessary in the future[13,20]. Some studies also reported patients' concerns that healthcare professionals often did not elaborate on the role of and the need for insulin in the management of early stage diabetes[18,27,29]. One of the patients stated:

> *'I've got to say it's [discussing insulin therapy is] very rare. It wasn't spoken about as a subject, it was always diabetes, sugar and food and diet control... not so much of what insulin was, what insulin can do. In that sense, whenever the doctor spoke about insulin injection, it is always something quite dangerous, quite serious... If insulin is a subject by itself right from the start, I think it would have made a lot of understanding'* [29].

In order to mitigate these fears, a few studies also recommended healthcare professionals bringing up the subject of insulin from the early stages of the disease [23,29].

Impact of peers' experiences in forming initial responses to insulin therapy

Such initial responses to insulin therapy (e.g. fears) may be influenced by the stories/observations of other people with diabetes, which people may encounter by chance in their everyday lives.

Patients often recounted observing others/hearing a story of others who had or were perceived to have had negative experiences with insulin. For instance, one patient connected insulin with impending death (fear of mortality) as follows:

> '*There was a lady with diabetes and she would inject herself with insulin and she died'* [19].

Based on observation of a person who initiated insulin, one patient connected insulin with advanced illness (fear of disease severity)[14]:

> '*... she just brushed it to one side because it wasn't, she wasn't on insulin straight away ... when she went onto the insulin that's when everybody thought oh this is serious'.*

Moreover, witnessing people experiencing a hypoglycaemic episode[27] or hearing a story of others perceived to have gone blind through using insulin[20,28] seemed to influence patients' beliefs that insulin had some risks to their health (fear of risk to health). Observing others or hearing a story of others who were scared of needles[25,29] also triggered patients' fear of insulin injection, as one of the patients stated:

> '*... I talk to one of my friends; her husband is using insulin. He has been using insulin for more than three years... up till now the husband is still scared of the needle... if I jab, how am I going to overcome that?* '[29].

Peers' experiences also affected patients' understanding about future insulin treatment (fear of the unknown). In one study, patients spoke of knowing other people who ended up on insulin despite being highly compliant in their self-care, and others who never had to take insulin although they were always very noncompliant, which raised a question over whether the decision to prescribe insulin is purely arbitrary[20].

While papers identified for review provided no data to link experiences of other people with patients' positive attitudes toward future insulin therapy, these findings indeed suggest that patients, implicitly, use other people's experiences with insulin when forming initial responses to insulin therapy.

A few studies reported patients' views toward the use of peers' experiences in a context of managing disease with non-insulin treatment prior to insulin. In one study of Mexican patients in the USA, patients raised questions over the credibility (e.g. perceived trustworthiness of the experiences patients observe and/or hear) and authenticity (e.g. truthfulness of the experiences patients hear) of experiences of other people who have diabetes, which have the potential to mislead, as stated by one of the patients:

> *'People have told me: 'Don't take insulin. You're going to go blind like my grandmother, or my father, or my brother.' Well, that makes you nervous about insulin. Who wants to lose their eyesight? And I've seen it too. But I don't know if it's from the insulin or the disease. I couldn't say it's the insulin'*[20].

The authenticity and credibility may mediate the impact of peers' experiences on patients' initial responses to insulin therapy. In contrast to this, in a study of African Caribbean and African patients in the UK, non-insulin treated patients showed strong interests in using peer educators (especially those who have been on insulin) in order to increase their understanding about upcoming insulin treatment[27], and encourage honest information sharing:

> '*They'll [peer educators] welcome you more because they will see you as one of theirs and you're not likely to lie to them, you know ....*'.

Actual decision to move onto insulin treatment

Analysis of the interviews identified several factors which may affect patients' decisions to accept/refuse the initiation of insulin therapy, notably the direct experience of other people who have initiated insulin and patients' concerns over the actual presence of physical symptoms. This is explored below under two main themes, namely impact of peers' experiences in making decisions about starting insulin therapy, and other triggers to accept insulin therapy.

Impact of peers' experiences in making decisions about starting insulin therapy

Although papers identified for review contained little about these data, the accounts of patients talking about peers' experiences encountered by chance in their everyday lives suggest that patients make the decision to accept or refuse insulin partly based on stories/observations of other people with diabetes.

For example, one study reported that patients accepted insulin after observing their relatives for whom insulin had a beneficial impact on their health[12]. Comments included:

> '*After I saw my husband had better sugar control with insulin, I accepted insulin'*.

'*How could I refuse insulin? My father and older brother are on insulin. My brother's health was better after he took insulin'*.

In another study, watching others such as elderly people successfully managing insulin prompted one patient to have self-confidence in managing insulin, which in turn, made her/him accept insulin:

'*Many people are taking insulin ... talking to them helped me. Even older people can do it, those with bad eyesight, and very young children also'*[13].

These accounts of others with insulin may increase patients' positive perceptions toward insulin, by encouraging them to believe that insulin is beneficial for their health (mitigating fear of risk to health), or raising their self-confidence in managing potential insulin by mitigating fear of insulin injection/technology, fear of leading a restricted life, or fear of discrimination.

One patient's decision to accept insulin was motivated by the experience of a non-insulin using relative who was perceived to have failed to manage illness and died through using oral medicines only:

'*My dad had diabetes and the pills dragged him into the grave'*[13].

Experiences of this kind may raise awareness of the limited benefits of current (non-insulin) treatment and reinforce patients' representations of insulin as protection against death or the progression of a worse-case scenario (reduction of fear of risk to health).

However, peers' experiences could also influence patients in their decision to 'refuse' insulin. For example, in one study patients refused insulin after observing perceived health problems or death associated with insulin[23]. Comments included:

'I have friends who have collapsed after insulin injections and ended up in hospital'.

'My uncle had diabetes for many years. He always refused to go on to insulin, until he went into hospital with a heart attack. He started insulin there and died within a year'.

These findings suggest that such stories/observations of other people may trigger feelings of fear such as fear of risk to health, which in turn, may influence patients' decisions to refuse insulin. Likewise, not only the experiences of people who have been on insulin, but also those who have not been on insulin contributed to patients' decisions to refuse insulin. For instance, in one study a patient's reason for refusing insulin is attributed to observing a neighbour who did not have to take insulin although she had been diabetic for a long time:

'We have a neighbour – she has had diabetes for 15 years and she's still on tablets'[13].

Such experiences among peers may influence patients' understanding about the necessity of upcoming insulin treatment, which in turn, may make them refuse insulin.

Overall, these findings suggest that patients draw on other people's experiences when making decisions about starting insulin therapy, whether consciously or not.

Other triggers to accept insulin therapy

Although this was not a focus of this review, the analysis of the papers suggests several key determinants other than peers' experiences which may play an important role when patients decide to accept insulin. One of the most prominent determinants is patients' concerns over the actual presence of physical symptoms (e.g. uncontrollable blood sugar levels, intolerable side effects of oral medicine, and complications).

For instance, in one study, several insulin treated patients recalled their experiences of not having been able to control blood sugar levels, which made them decide to move onto insulin[12]:

> *'I accepted insulin because the pills were not effective anymore. Pills are not effective in…controlling diabetes… not effective anymore'.*
>
> *'I know after a while, oral medication cannot bring down blood sugar. I took insulin because the pills were not working anymore'.*

Concerns over side effects of oral medicines, and complications (e.g. neuropathy) may also lead to a faster acceptance of insulin therapy[13]. Some non-insulin treated patients described this as follows:

> *'When I've seen what the pills were doing to me... And I know that the pills are destroying the kidneys as well'.*
>
> *'I've seen that I became worse lately – I was already feeling my legs numb; it really made me think twice'.*

These findings may suggest that patients are more likely to make the decision to accept insulin if they experience some physical symptoms that reinforce their concerns about the limited benefits of non-insulin treatment (e.g. oral medicine) or their perceptions that the disease has progressed.

Actual experiences of insulin management

Studies in this review revealed that some fears attached to insulin, which were often anticipated by patients before the initiation, were expressed in a more positive light and/or became a reality when patients actually experienced insulin management. This was observed 1) by comparing the accounts of non-insulin treated patients who talked about their current perceptions that insulin would result in fears, with those of insulin treated patients talking about their current experiences of insulin management; 2) by comparing the accounts of insulin treated patients who talked retrospectively about their views toward insulin associated with fears prior to the initiation, with those of (other) insulin treated patients talking about their current experiences of insulin management; 3) by observing one account of an insulin treated patient talking about his/her own retrospective view of insulin prior to the initiation by comparing it with his/her current experiences of insulin management.

Better than anticipated

The review found a discrepancy between patients' anticipations about future insulin treatment and their actual experiences of managing insulin. Some fears attached to insulin (fear of risk to health, fear of disease severity/mortality, fear of insulin technology, fear of insulin injection) were expressed in a more positive light when patients actually experienced insulin therapy.

While numerous accounts about the fear of risk to health were expressed by patients before the initiation of insulin, a number of studies identified that insulin treated patients often talked about beneficial effects of insulin on their current health condition[12,16,19,20,25,27,28]. For example, some patients reported that insulin was natural to their body[12] or described how insulin made them feel much healthier and more energetic[12,16,19,20,25,28], controlled their blood glucose levels[16,20,25,27], prevented complications[16,20], and/or decreased symptoms of headache and fatigue[20]. Also, in some studies, patients cited superior effects of insulin in terms of current improved health in comparison with their health condition before the initiation[12,19]. One of the patients described it as follows:

> *'I felt very bad before insulin. But since I started using insulin I feel well because I've had diabetes for seven years and I have never gone to a hospital'*[19].

Such positive experiences attached to insulin management outnumbered negative attitudes, where some patients reported several insulin-related health problems that they experienced while managing insulin, including hypoglycaemia[16,21,26,28,29], weight gain[19,29], and/or complications[16,28].

Second, while patients often expressed a fear of disease severity/mortality prior to the commencement of insulin, none of the studies reported such fear in the accounts of insulin treated patients talking about their current experiences of managing insulin. Instead, patients often perceived insulin as prolonging or saving their lives[16,27]. One of the patients stated:

> *'The main reason I take insulin is because it's what keeps me alive, and if I don't take it, my diabetes will complicate and I don't want that'*[16].

In one study, some patients explicitly compared their current feelings with their past views and reported decreased fear of disease severity/mortality. They stated that although before initiation they thought insulin meant death, their feelings had now chnaged[27].

Third, contrary to the fear of insulin technology often expressed by patients before insulin, none of the studies reported such fear in the accounts of insulin treated patients talking about their everyday experiences of managing insulin. Instead, many patients reported that the technology attached to injection was not difficult to use[19,20,25,27,28]. They cited the ability to actually administer the injections themselves[19,25,27] or to adjust the insulin doses themselves[25]. For some, injection was considered easy to control[19,20]. One of the patients expressed his satisfaction with using insulin as follows:

> '*I have used insulin for five years. I don't feel bad. I inject myself every day'*[19].

One patient contrasted the ease of use with his fear before starting insulin:

> *'Let people realise that having insulin is just as easy as having the tablet. Before, I did not think that'*[27].

Finally, a number of studies identified accounts of insulin treated patients reporting that insulin injection was not as painful as expected[19,20,25,27], although a few patients reported their strong negative feelings about injections[15,16].

As anticipated

An analysis of the literature identified that some of the fears toward insulin that were anticipated by patients before initiation (fear of leading a restricted life, fear of discrimination) became a reality when patients actually experienced insulin management.

As anticipated by patients before initiation, insulin treated patients from different cultural contexts often descried several aspects of using insulin that they perceived to be inconvenient[12,16,19,25-27].

For instance, one study conducted in Canada and Brazil, and another in Malaysia, reported patients saying it was difficult to find a place to perform the injection when in public places, such as when they are out shopping, at a party, or eating out with friends[12,16], as one person explained:

> *'Like when I go to a party, or a gathering, I have to go to a certain place, or even in front of the public, open up my shirt, and do the insulin, and, I didn't like to do it, those kind of things like the insulin with the public, but sometimes I have no choice, and there is no place to go to do it'*[16].

In relation to this, patients in the UK and the USA also reported the inconvenience of performing/carrying insulin while travelling[16,19,25], as described by one of the patients in the following terms:

> '*I'm doing my best to take my insulin on time, every day. But sometimes I do forget, and sometimes I'm not home at the right time to do my insulin. It causes some inconvenience sometimes, specially when I travel. You know, I cannot be on time for my insulin, and it's a trouble, even the transportation sometimes'*[16].

Concern among patients about the inconvenience of taking insulin when living alone was raised by one study:

> '*I think it's rather dangerous for a diabetic to be on his or her own you know, because I find that when I go into hypoglycaemic, sometimes it's a struggle to maybe get to the kitchen'*[27].

Patients in Canada and Brazil also expressed their concerns about following the strict schedule to administer insulin injections[16,26]:

> '*For me, what I don't like about insulin is the inconvenience. Having to stick to that strict regimen of taking it early in the morning, and having breakfast, and then having to take it at 5 o'clock, and having supper. I don't like that strict regimen. That's about the biggest thing for me. More convenience, not having such a regimented schedule would be nice'*[16].

While a few patients expressed positive attitudes toward insulin leading to a better quality of life[12,16,27], the experience of leading a restricted life was often reported among this population.

Second, as anticipated by patients prior to the initiation of insulin, the experience of discrimination was also raised by a number of insulin treated patients such as those from Singapore, Malaysia, the UK, and New Zealand, where they reported experiencing social rejection and embarrassment in their everyday life surrounding managing insulin[12,21,28,29]. For

instance, some patients expressed not wanting people to know they had diabetes[29], while others showed anxiety over what other people might think, where the use of needles was identified with 'drug addicts'[12,21]:

'[I am] embarrassed to give needle in public… just like a drug addict'[21].

Others also expressed shame for exposing their bodies in public[12,21], which was recounted by one of the patients:

'It is not easy when people watch you injecting insulin. It is embarrassing'[12].

In addition, one study conducted in the UK reported the different forms of discrimination that patients came across which they felt resulted from their insulin use, including discrimination when hiring a car, renewing their driving licence, applying for holiday insurance, and being made redundant from work[28]. Such experiences of discrimination were often reported amongst patients currently managing insulin, although a patient in one study perceived no shame in using insulin in public[27].

Impact of peers' experiences in managing insulin therapy

Analysis of the studies suggests that stories/observations of other people with diabetes may have an impact on people's experience of managing insulin.

For instance, one study conducted in the UK reported that patients who started managing insulin in a group setting experienced great encouragement from other group members, which in turn increased their self-efficacy to manage insulin[28].

5.1.3 Strengths and limitations

This chapter fills a gap in the evidence by reviewing a number of existing qualitative studies in order to explore patients' attitudes, experiences, information/support needs (in particular, support

through shared patient experience) in relation to the initiation of insulin therapy. Second, although the quality of the papers was assessed, all the studies were included regardless of their quality for the reasons mentioned above. This in turn allowed identification and confirmation of the commonly occurring concepts across various settings and sample characteristics based on a larger pool of studies. Third, while this is not a systematic review, a comprehensive and systematic search strategy was used to minimize bias in selecting the studies. Finally, in order to reduce interpretation bias, the reviewer discussed the main/sub-themes with supervisors to reach consensus prior to finalizing the themes. In this process efforts were also made to minimize the risk of participants' quotes being interpreted differently from how they were intended.

The results of this review also need to be examined with an understanding of some limitations. The fact that the data obtained from this review are what others have already interpreted only allowed the reviewer to see the data through someone else's interpretation and choice of data extracts. Second, about half of the studies included were conducted using patients who had been on different types of treatment (e.g. oral medicine only, insulin, or diet/exercise). Some of them, however, did not always specify the types of treatment patients receive when using interview quotations. This made it difficult to interpret how this sample's characteristics affect patients' responses to insulin. Discussions of age and gender were also absent in most of the studies. Third, the result of the quality assessment suggests that the conclusions presented are largely drawn from studies of lower hierarchy in their capacity to provide evidence-for-practice, and hence the findings of this review need to be interpreted cautiously. Finally, owing to time and resource restrictions, only English language papers were included for this review, potentially limiting the number of relevant papers identified.

Chapter 5 – Part 2. Secondary analysis of an existing collection of qualitative interviews: Methods, Results, and Strengths/Limitations

5.2.1 Methods

5.2.1.1 Secondary qualitative analysis

Secondary analysis aims to find answers to new research questions that were not the primary focus of the original research to pursue a new perspective on the original question, or to explain an issue in more depth[30,31]. Chapter 5 - part 2 presents a secondary analysis of an existing collection of qualitative interviews collected for an original study, which set out to explore what it is like living with type 2 diabetes. Patients were invited to talk about issues such as symptoms, diagnosis, controlling diabetes and its impact on lifestyle. The purpose of this secondary analysis was to explore patients' attitudes and beliefs toward the initiation of insulin therapy, and patients' attitudes and experiences in relation to the information/support needs (particularly support through shared patient experience). Following Heaton's (2008) five types of secondary analysis, it is suggested that this study falls into the category of 'supplementary analysis' in that 'more in-depth analysis of an emergent issue or aspect of the data, that was not addressed or was only partially addressed in the primary study, is undertaken'[31]. In other words, insulin therapy was included in the original study, but only formed part of it. Strengths as well as limitations of secondary analysis are considered later (section 5.2.3).

5.2.1.2 Data source

The secondary analysis was carried out using the interview collection on diabetes from the archive held by the Health Experience Research Group at the University of Oxford. The data were obtained through 'formal data sharing'[31], where the secondary analyst had access to datasets deposited in the institutional archives, and re-used data collected independently by others. The

data have met the necessary ethical and legal requirements for being shared with other researchers[31].

The data were collected in 2007 from 40 patients with type 2 diabetes. Participants were recruited through various routes including general practitioners (GPs), hospital consultants, support groups, newsletters, advertising in the press, on websites, in social media and by word of mouth. Recruitment packs (containing a 'study information sheet', introductory letter, reply slip, and stamped addressed envelope) were handed out by doctors and nurses to potential participants aged over 16, who could contact the researchers if they were interested in the study. Anyone with type 2 diabetes was eligible to take part. The study method aimed for a diverse, maximum variation purposive sample, including 13 non-insulin treated and 27 insulin treated patients, living throughout the UK, and representing various ethnic backgrounds. Further information about the samples is provided in table 5.2.

The interviews were usually carried out in the homes of the participants, and conducted with participants on their own, but occasionally a partner or friend was present during the interview. All the interviews were conducted by experienced qualitative researchers fully trained in the research process with a detailed handbook for further reference. The interviews lasted 90 - 120 minutes on average, and were audio-taped or video-recorded if the participants consented. Following an uninterrupted account of participants' experiences from when they first began to suspect there was a problem, the interviewer used semi-structured prompts to explore specific topics and issues raised by the interviewee.

The interviews were fully transcribed, and checked for accuracy, and the transcript was returned to the interviewee for review (sections of the interview which participants preferred not to be used were removed from the final version). Following review of the transcript, the interviewee was asked to sign a form granting copyright to the University of Oxford, which allowed the interview

to be used for research, teaching, and broadcasting publication on a website (http://www.healthtalk.org/). Ethical approval for the original study was granted by the Eastern Multi-Centre Research Ethics Committee (ref 03/5/016).

(The methods of the original study have been described in detail elsewhere: http://www.healthtalk.org/)

Table 5.2 Information about samples

Participants (n=40) demographic, biographic, and interview details	
Age at diagnosis (N)	20-30 (6)
	31-40 (8)
	41-50 (10)
	51-60 (9)
	61-70 (6)
	71-80 (1)
Length of disease in years (N)	1-10 (28)
	11-20 (7)
	21-30 (3)
	31-40 (2)
Insulin treatment (N)	Non-inuslin treated (27)
	Insulin-treated (13)
Sex (N)	Male (22)
	Female (18)
Ethnic origin (N)	White/British (23)
	Asian (8)
	White (2)
	Jamaican (2)
	Zimbabwe (2)
	Black/British (1)
	White American (1)
	White Canadian (1)
Marital status (N)	Married (28)
	Divorced (3)
	Single (3)
	Long term partner (3)
	Widowed (1)
	Separated (1)

5.2.1.3 Analytic procedure

[i] This DPhil project was developed with the aim of producing evidence that can be translated into an intervention to be tested in a trial based on shared patient experience in type 2 diabetes. Consisting of five work streams, the project addressed this aim by using complementary strategies (qualitative and quantitative research methods), where the secondary analysis (chapter 5 – part 2) and the primary qualitative work stream (chapter 6) both posed key research questions to examine in the data. In conducting the secondary analysis and the primary qualitative work stream, ensuring 'a suitable "fit" between the research methods used and the research questions posed' was considered to be more important than 'the degree of philosophical coherence of the epistemological positions typically associated with different research methods'[32]. Emphasis was thus placed on choosing the most appropriate research methods that might answer the research questions posed rather than 'focusing too much on philosophical assumptions underlying different methods'[32].

Since both qualitative work streams not only had some specific issues to explore, but also aimed 'to leave space to discover other unexpected aspects of the participants' experience'[33], a thematic analysis using a framework method was considered appropriate. Thematic analysis is a method for identifying, analysing, and reporting patterns (themes) across a dataset that provide an answer to the research question being addressed[34]. This method allows a combined approach since it has no commitment to either inductive or deductive approach[35]. The framework method is a flexible tool that can be adapted for use in thematic analysis, and is considered appropriate for thematic analysis of textual data, particularly interview transcripts[33]. The framework method provides a structured data analysis procedure by using a matrix of cases, codes, and summarised data, and enables analysis of the data thematically (for each theme across all participants) as well as case by case (for each participant across all themes)[33,36]. The method is also considered suited for

[i] The data analysis applied for a secondary analysis of the qualitative study (chapter 5 – Part 2) was similar to the one applied for a primary qualitative study (chapter 6).

studies with specific research questions[33,37]. Some disadvantages have also been pointed out (e.g. a lack of theoretical foundation; the possibility of missing some themes which were not included in a pre-determined 'framework')[33].

The process began by reading the transcripts and field notes several times to identify patterns and to get a sense of each interview as a whole before breaking it into parts. At this stage, summaries of the content within each interview were also produced for each participant, which informed some recurring inductive themes and ideas. Based on the list of these themes, an initial framework was developed to ensure no obvious areas of overlap and to clarify the concepts/themes in the framework[38]. Here, themes that emerged from the data were 'described in terms that stay close to the language and terms used in the data set'[38]. The initial framework was applied to the data, and refined (supervisors also read some original materials, and discussed refining some of the themes in the framework). Consideration for maintaining 'a balance between reducing the data on the one hand and retaining the original meanings and "feel" of the interviewees' words on the other' was also borne in mind during this process[33].

In the process of developing the framework further, the main themes to be used were chosen (including both inductive and deductive themes), and more abstract concepts were generated. Deductive themes were informed by the research objectives, a review of the relevant literature on what is known about the initiation of insulin therapy (see chapter 2), and particularly the previous qualitative work stream (see chapter 5 – part 1). The framework was applied to the data using NVivo. To check whether a code is appropriately assigned, the findings within each code were compared[36], which in turn, helped to refine existing codes, and to add new codes.

After all the coding was done, a central chart was produced to build a picture of the data as a whole, which included codes, field notes, and demographic data for all participants. The chart was read within cases, and across all cases within the themes, to see whether there were any

patterns unique to particular subgroups[38]. The chart was used in the process of analysis (see chapter 5 - part 2, section 5.2.2 and chapter 6, section 6.4). The chart was also used at a later stage (see Discussion section) to pull together the results in chapter 5 and analyse them as a whole.

The main themes such as fears, avoidance or acceptance, technology, consequence, and knowledge emerged in response to the data. While the data in relation to two of the main themes, use of/views toward peers' experience under the first (Attitudes/beliefs about potential insulin therapy) and second (Actual experiences of insulin management) headings were limited, since they were integral to the research question they were imposed on the data by the researcher and added as a part of the framework.

5.2.2 Results

Analysis of the accounts of non-insulin treated patients and insulin treated patients is presented under two main headings (see table 5.3). The first heading (Attitudes/beliefs about potential insulin therapy) examines patients' initial responses to insulin in a context of managing disease with non-insulin treatment prior to the initiation of insulin, which were explored below under three main themes: *fears; use of/views toward peers' experience;* and *avoidance or acceptance.* The second heading (Actual experiences of insulin management) observes how patients' initial responses to insulin change in the process of patients actually managing insulin therapy. This was examined under four main themes: *technology; consequences; knowledge;* and *use of/views toward peers' experiences*. Not surprisingly, many of the themes identified are similar to those in the narrative review (chapter 5 – part1), but with some differences in content and emphasis.

Table 5.3 Headings, main themes, and sub-themes

Headings	Main themes	Sub-themes
Attitudes/beliefs about potential insulin therapy	**Fears**	Fear of insulin injection/technology
		Fear of disease severity
		Fear of risk to health
		Fear of leading a restricted life
		Fear of discrimination
		Fear of the unknown
	Use of/views toward peers' experiences	Impact of peers' experiences in forming initial responses to insulin therapy
		Patients' views on the use of a support group in a context of managing disease with non-insulin treatment prior to insulin
	Avoidance or Acceptance	
Actual experiences of insulin management	**Technology**	Adjusting insulin doses
		Injecting insulin
	Consequences	Impact on health
		Impact on social life
	Knowledge	
	Use of/views toward peers' experiences	Impact of peers' experiences in managing insulin therapy
		Patients' views on the use of a support group in a context of managing insulin therapy

Attitudes/beliefs about potential insulin therapy

This section explores patients' initial responses to insulin therapy by focusing on three main themes, including fears, use of/views toward peers' experiences, and avoidance or acceptance.

Fears

As observed in the narrative review, fear was again a central feature of the initial responses to insulin and often featured in the accounts of patients. Different elements associated with insulin that contribute to feelings of fear are described in the following six sub-themes, which include fear of insulin injection/technology, fear of disease severity, fear of risk to health, fear of leading a restricted life, fear of discrimination, and fear of the unknown.

Fear of insulin injection/technology

Fear of insulin injection was one of the major concerns for many patients, including fear of needles (patients 20, 22, 27, 35), needle phobia (patient 4), fear of pain associated with injection administration (patients 22, 28), and fear/discomfort of self-injection (patients 7, 12, 13, 19, 32, 36, 38). Such fear is illustrated by the following comments:

> '*I can't bear the thought of injecting myself. I mean, when they take blood out I know I can't look. I have to look so, yeah' (patient 38).*
>
> *'I'm needle phobic so nothing's going to prepare me for that' (patient 4).*
>
> '*I don't relish the idea of injections much. But I guess one gets used to it' (patient 13).*

Apart from fear of insulin injection, patients were also apprehensive about mastering proper techniques involved in insulin therapy (fear of insulin technology) such as adjusting insulin doses (patient 36). Negative consequences for health owing to a failure to administer insulin correctly were also raised as a concern (patient 8).

On the other hand, a few insulin treated patients reported that such fear was not an issue from the beginning (patients 17, 34). This suggests that a minority might not have had concerns over fear of insulin injection/technology before the initiation of insulin.

Fear of disease severity

Fear of disease severity was another significant concern for some patents, where they perceived

that insulin is reserved only for very serious and advanced stages of disease (patients 2, 7, 8, 17, 26, 27, 29, 31, 32, 36, 38). Comments included:

> '*you know, you perhaps go onto insulin if you get bad enough' (patient 36).*
>
> '*I'm thinking that that [insulin] is the downside of it, that's where we could end up' (patient 7).*
>
> '*Yeah, I mean knew somebody who was diabetic but they just still carried on eating the food they loved eating so in the end, they're now on insulin' (patient 38).*

One factor possibly leading to the perception of insulin being reserved only for very advanced stages of disease seems to be the perceived attitudes of healthcare professionals. Some healthcare professionals were perceived to present the possibility of starting insulin as a result of exhausting all other possible treatments, or the disease having progressed, although not in a way to threaten patients as observed in the narrative review (patients 4, 8, 12, 17, 21, 28, 31, 38). Accounts of some patients included:

> '*I've been told that it [diabetes] is progressive and, and eventually I might have to go onto tablets and, eventually might even have to go onto insulin' (patient 12).*
>
> *'They [healthcare professionals] said that [insulin] would be a last resort' (patient 17).*

Many patients raised such feelings of fear toward disease severity, whereas some patients did not mention their views either way.

Fear of risk to health

Beliefs in the potentially harmful effects of insulin on health and the body were expressed by some patients. One patient, for instance, saw insulin as poisonous (patient 8):

> '*I've always been, "I don't want to go onto insulin"… I just don't want to put poison like that, what I consider poison, into my body without absolutely having to'.*

Some patients harboured anxieties around possible side-effects of insulin including hypoglycaemia (patients 14, 16, 19, 20) and weight gain (patient 17), which was expressed by patient 17 in the following terms:

'I then went on to try various different diabetic tablets over the course of the next few years but I didn't, it wasn't very controlled very well… they [healthcare professionals] said it [insulin] was a fat-producing product… So I sort of went, I mean I was fine with that because I thought, well that makes sense, I don't want to be putting on weight'.

Such fear toward insulin was more common in the data than positive views, but a few patients pointed to the benefits of insulin. Some patients, for instance, argued that insulin would improve health by maintaining good glycaemia control (patients 5, 13, 27):

'I will be put on insulin, which I gather is a more effective, more efficient, control' (patient 13).

For one patient who was concerned about the side effects of oral medicine, insulin was also represented as a form of protection against such side effects:

'I'm on five different tablets, which can cause kidney problems. You can't just keep taking tablets all the time… Obviously with insulin I know that doesn't affect your kidney or liver function' (patient 14).

Fear of leading a restricted life

One major worry for patients was that insulin would be a source of inconvenience restricting their lives and could even cause loss of control over the disease. In this context, some patients described concerns over inconvenience in the use of insulin whilst away from home (patients 4, 5). Patient 4, for instance, was relieved at not needing to carry insulin while travelling:

'Interviewer: Do you ever try to take your medicine in your hand luggage so you don't get separated? And has that ever given you any difficulties?
No. Because I don't do insulin and I don't have to inject, it's just tablets and they just show up on the x-ray machine... I've been asked to take them out and show them what they are, and they're just prescription ones and that's it'.

Adhering to the strict insulin regime in daily life (patients 8, 27) or when flying across time zones (patient 14) was another worry anticipated by some patients:

'It was more coming back, with all the travelling, with all the stopovers and delays and diversions. I couldn't remember if, you know, a) if I'd taken the last tablet or, when we'd eaten last. So, but luckily I suppose, that's where a problem with, if I was on insulin, you know, that can be more of a problem (patient 14)'.

Inconvenience in performing injections at work was also a concern for patient 8:

'But, if you're in a meeting, you'd have to inject and... I mean that's quite hard, difficult to, at some of the meetings I go to, that would be quite a statement. You know, it would be quite difficult to, to do. You'd have to sort of explain beforehand what you were doing and why you were doing it, why you'd have to leave'.

Also, for patient 8 who is proud of his ability to control his disease through diet and oral medicine rather than relying on insulin, his nurse's advice to take insulin for convenience by allowing more flexible food intake paradoxically meant that he would lose control over the disease:

'Talking about it [insulin] with the nurse a little bit afterwards, it's about if you go onto insulin people can eat what they like. So it's being able to eat the trifle or the cake or the bar of chocolate as and when you choose. Whereas I wanted to actually improve my eating. My way of eating. What I ate. So I think for me it was sort of there was something about trying to take control of it for me, rather than using a drug to control it'.

While fear of this kind was commonly expressed by patients, one non-insulin treated patient expressed positive views to the effect that insulin would not be a source of inconvenience in her life since insulin is now packaged for portability (patient 19).

Fear of discrimination

Fear of discrimination attached to insulin was a source of distress for some patients, where they were concerned about being affected by the negative connotations associated with the use of insulin. Some patients were worried about possible driving restrictions (e.g. car insurance, driving licence eligibility) (patients 8, 12, 20). This was expressed by patient 20 as follows:

'You get ripped off by the insurance companies. The minute I go onto insulin I lose my 'Class 1, Heavy Goods'. Right… You lose your heavy goods licence, an Arctic lorry. You can't drive Arctics. You've got to inform your insurance company. You've got to have a medical every three years to renew your driving licence. And there's things like that annoy me… They say, "Oh you might go into hypo". How do you know? How do they know how insulin will affect me, or how it will affect you? *What right have they got to say that it [insulin] will affect everybody the same?'*

Fear of the unknown

Some patients raised concerns over a lack of understanding about insulin (patients 3, 4, 8, 12, 23, 25, 30). Questions about insulin raised by patients included when insulin needs to be initiated

(patient 8), what might happen if they have to initiate insulin in the future (patients 3, 38), why insulin needs to be injected when there are tablets available (patient 25), and what insulin is made of (patient 30). Moreover, some patients believed that transferring from non-insulin treatment (e.g. oral medicine) to insulin therapy means that one's type of diabetes changes from type 2 to type 1 (patients 4, 12, 23, 30). Patient 12, for instance, commented:

> '*I eventually might even have to go onto insulin. It might develop into type 1 diabetes… I haven't had time to sort of go through the diet bit, the tablet bit and then we might get to the type 1, where, where I have to be injecting'.*

Patient 8 was also shocked when she discovered that insulin therapy is required not only for type 1 but also for type 2 diabetes.

While there could be a number of reasons for such uncertainty including patients being unable to recall or misinterpreting the information given them, some explicit accounts by patients (as observed in the narrative review) suggest that such uncertainty could be a result of gaps or inconsistencies in information about insulin treatment provided by healthcare professionals in the management of early stage disease (patients 3, 8, 38). For patient 8, for instance, her confusion was to do with receiving conflicting advice from her GP and nurse about the timing of starting insulin:

> *'When I first went onto the medication, it was quite a while before… and I certainly remember the nurse saying very early on, "Oh, you might be best to go onto insulin because you can, it's much easier. Once you learn how to, to use it, it's much easier." And my doctor, my GP was saying, "No, you don't want to go onto insulin unless you really need to." So there was a slight mixed message there'.*

Use of/views toward peers' experiences

Analysis of the interviews identified several sources that have the potential to affect patients' initial responses to insulin (e.g. fears). As observed in the narrative review, one such source is hearing about the experience of other people with diabetes. In addition, while the narrative review contained little about these data, the analysis of interviews provided patients' views on the use of peers' experiences through a support group in a context of managing disease with non-insulin

treatment prior to insulin. This is explored below under two sub-themes, namely impact of peers' experiences in forming initial responses to insulin therapy and patients' views on the use of support groups in a context of managing disease with non-insulin treatment prior to insulin.

Impact of peers' experiences in forming initial responses to insulin therapy

The accounts of patients talking about peers' experiences encountered in their everyday lives suggest that patients may form initial responses to insulin based on stories/observations of other people with diabetes.

Observing other patients/hearing the stories of others who had negative experiences with insulin seems to contribute to a range of fears including fear of leading a restricted life (patient 5), fear of insulin injection (patient 12), fear of insulin technology (patients 20, 36), and fear of risk to health (patients 8, 16, 19, 20). For example, observing an insulin-using relative who had initiated insulin and collapsed owing to hypoglycaemia gave patient 16 the impression that insulin could be a risk to his health (fear of risk to health):

> '*I remember my father having it and he used to have injections. I remember him having hypos, passing out, and my mother sort of catching him and pushing him into a chair and I thought, you know … so I was very concerned when I had been diagnosed [with diabetes]... So, for the first two or three months I was probably very worried, thought about it a hell of a lot and perhaps felt a bit sorry for myself'.*

Helping other patients to manage insulin treatment (e.g. adjusting insulin doses, injecting insulin, balancing glucose levels and the prescribed insulin doses) seems to trigger patients' fear of insulin technology (patients 20, 36). The account of patient 5, who reported observing an insulin-using husband that avoided travel because of concerns over potential inconvenience in carrying injections, also appeared to strengthen her fear of leading a restricted life:

> '*I've not been on holiday, I've never gone on holiday. Because my husband [who has been on insulin] feels like, "Why should I bother carrying my tablets around, and take my insulin everywhere", and then you have to change your needles, this and that. He doesn't like that'.*

On the other hand, the analysis from the secondary analysis suggests that testimonies of people who have had positive experiences with insulin could contribute to patients' positive attitudes toward future insulin, such as patients' beliefs that insulin could be beneficial for their health (patients 5, 14, 27), that insulin could induce a better quality of life (patient 14). Comments included:

> *'Those that have gone onto insulin generally say, oh, they feel a lot better, you know, because they don't get the highs and the lows. As long as you control it right, they seem to, you know, have a better lifestyle once they're on the insulin' (patient 14).*

Watching another person in the media who made the decision to initiate insulin in the early stage of the disease, well in advance of insulin being considered absolutely necessary, also appears to have increased patient 18's awareness about the option to initiate insulin early thus reducing their fear of the unknown:

> *'I have just thought of Steve Redgrave, who is a type 2 diabetic… His choice to go on insulin well before he needed it was an interesting one'.*

Overall, these findings suggest that patients draw on other people's experiences with insulin when forming initial responses to insulin therapy.

Patients' views on the use of a support group in a context of managing disease with non-insulin treatment prior to insulin

The accounts of patients talking about peers' experiences suggest a great deal of variation in terms of whether and why patients valued support groups in a context of managing disease with non-insulin treatment prior to insulin.

Some patients preferred not to join a support group, and raised several reasons for this. A common objection was related to the perceived non-usefulness of support groups, both in terms of providing information and addressing emotional issues. For instance, patient 4 perceived a lack of useful information/advice from other group members, which kept him/her away from the group.

For patient 14, his/her reason for not joining a group was a desire to avoid seeing others experiencing less fortunate effects:

> *'I find support groups one of the most depressing experiences I've ever come across, because it is full of people who are very depressed, for one, and can't see a way out of the morass for another'.*

Practical issues (e.g. lack of time) were also common reasons for avoiding support groups:

> '*I am so committed to my parents… And I still don't have the time to commit to it, when I give half a day every day of my life to my mother and father. That's, I wouldn't like to let anybody down' (patient 9).*

Patient 12's reason for avoiding the group was having a sufficient support network provided by his family members. Cultural considerations were also raised as a reason for not participating in groups by patient 26:

> *'I don't know of any support group who talk about diabetes or whatever, people don't talk about this sort of thing. It is a taboo to some people. When they are diabetic or whatever, especially, Afro Caribbean, some of these people they keep it to themselves. They don't mention it. And even though they have tablets or medication, they keep it to themselves'.*

In contrast, some patients derived positive value from attending a group. The main benefit of joining was a perceived usefulness in terms of information/advice. Patient 20, for instance, was pleased to discover that the group provided him with resources that he felt would not be available from healthcare professionals:

> *'Doctors can't tell you too much, because the doctors haven't got too much experience of it, unless they are a diabetic themselves… You've got to go and talk to a person who has got it. And you'll find if you do go to a diabetic meeting it will open your eyes a lot. How it's affected people's lives. And how they have controlled it and how they advise you on things you can do, and what you can't do. And it, it is a good thing'.*

A similar experience was described by patient 16:

> '*It is useful to chat to other people, and the more you speak to other people, the more you learn. So I found that beneficial to me as I say attending the meetings and chatting to others in many ways'.*

Others also expressed hopes that the group might provide them with the opportunity to 'know more things about the disease' (patients 19, 21), 'get the most practical advice' (patient 28), and 'gain help/information from peers' (patients 38, 39). Patient 28, for instance, commented:

> *'Join a support group. If there is such a thing, that would be really helpful. Talking to other people…, that's where you'll get most practical advice. People need to talk to other people about how it impacts on their life. And well I've tried this, and this worked very well, I tried that, it was terrible, you know, and that's the sort of thing. And you listen to other people'.*

Other than information/advice, some patients described perceived usefulness in terms of emotions, where they derived reassurance and encouragement from joining a support group (patients 14, 20). A sense of social solidarity (feeling that 'he is not alone') by being with other people who have similar problems to him was expressed by patient 14:

> *'I went [to a local support group] for a couple of years and [found it] very interesting… Sharing experiences, realising that you're not on your own… I'm sure the problems that one person has got, everybody's got, you know. So it's just a feeling that you're not on your own…and to meet other people with diabetes that have got all the problems you've got. So you, you think, "I'm not alone here"'.*

Avoidance or Acceptance

Although the data available from the narrative review did not say much about this, the data available from the secondary analysis suggest that patients seem to respond to feelings of fear in a variety of ways.

Some patients expressed a sense of acceptance at the idea of being put on insulin in the future, or appeared to try to persuade themselves that there was no other choice than to accept insulin in the future despite having hopes of avoiding it altogether (patients 12, 18, 19, 20, 26, 28, 30, 31). This was illustrated by patient 18 in the following terms:

> '*If I have to take insulin I have no choice, I would have to learn how to do it' (patient 18).*

Others added:

'*I don't think I'd be one to adapt to insulin… But I think you've got to have the initiative yourself to accept these things and to live with them. Because what do you do otherwise?' (patient 19).*

'People come to terms with these things [insulin]. And I'm sure it won't be, well, if it ever did come to that, you'd come to accept it, and get on with it. Because it would become part of your life and a necessary part of your life to keep going' (patient 12).

While most people's sense of acceptance was expressed as a sense of resignation, patient 14 welcomed the idea of future initiation of insulin:

'Interviewer: So how do you feel about the possibility of being put on insulin?
No, not worried about it at all. As I said, it might be perhaps the best way to go because of the amount of tablets I'm taking'.

On the other hand, the hope of avoiding insulin was expressed by some patients (patients 4, 8). Comments included:

'*Everything else I think is under control. I'm trying to convince myself that with all these tablets I'm taking, I'm actually now going to be better off than before… I'm probably going to live longer than I would have done, and I don't want to be injecting… I'm not going to say, 'God I'd rather not', but I just want to put that off. I don't want to face that' (patient 4).*

'*I said to him [the healthcare professional] in January, "I want one last try to get these under control." And he said, "Okay, but you've said that before." And I said, "No, I really mean it this time. I will, and then if I don't get it under control, I will start insulin. And you can put that on my card, that I will do that." And he let me do that… It's been negotiated. The increase of medication has been negotiated' (patient 8).*

Likewise, the experience of patient 20 suggests that such a response to the idea of potential insulin may vary over time:

'Interviewer: I mean do you, if, if it came to insulin then how would you feel?
I wouldn't be happy, but, over the years of having the diabetes I've probably come to the thing if it happens, it happens. There's nothing I can do about it. If it does come to insulin, then I've got to take insulin. I wouldn't have been happy ten years ago… I probably would have kicked. Gone screaming and kicking before they give me insulin, but now… I have had it [diabetes] for so long now… Yes, fine if it does [if it comes to insulin], it does. I have got to take it. I can't do nothing about it'.

Actual experiences of insulin management

As observed in the narrative review, changes in patients' initial responses to insulin (e.g. fears) in the process of them actually managing insulin were also reported in the secondary analysis. This is explored below under four main themes, namely technology, consequences, knowledge, and use of/views toward peers' experiences.

Technology

In the process of managing disease with insulin, patients are required to master several technical skills in order to administer insulin. Some aspects of these technical skills are identified in the following two sub-themes, namely adjusting insulin doses (including *stabilising insulin doses* and *matching insulin doses with food intake*) and injecting insulin. While patients often reported their concerns over these technical skills before starting insulin (fear of insulin injection/technology), such concerns evolved in several ways at the stage of actual insulin management.

Adjusting insulin doses

Patients' experience of adjusting insulin doses is an evolving process of learning complex calculation skills to *stabilise insulin* by determining appropriate doses that better control blood glucose levels and/or *match insulin doses with food intake*.

Regarding ***stabilising insulin doses***, as anticipated by patients before initiation, patients (in the middle of the learning process) were often especially apprehensive about the technical skills necessary to stabilise insulin dose according to blood glucose levels. For patient 37, her worry was about calculating the number of units relative to glucose levels:

> *'Our people would not understand... how to take insulin, the number of units to take may be difficult… How they would know…'.*

For some patients, their concerns were about getting used to adhering to the regime necessary to stabilise their insulin dose:

'*It was quite a lot, quite a juggling act when I first went on it [insulin]. More so than the one I originally went on because that was two injections a day, and on this insulin you have to be much more accurate with your blood sugar readings. You have to be much more aware of taking them [insulin], yeah' (patient 17).*

'*It [following regime] doesn't come naturally at the moment. I have to think about it… And I've been known to forget… to have the evening jab' (patient 2).*

Although patient 15 reported feeling that the technology attached to stabilising insulin doses was user-friendly, such a concern was indeed often expressed among patients.

However, accounts of patients who have already successfully stabilised their insulin dose, suggest that such a concern may be reduced over time as they adjust the regime to their everyday life with a healthcare professional's support. Comments included:

'*You wouldn't up your levels [of insulin dose] willy nilly and just 'cause you felt like it, you work on a ratio of what you have got to take, which is consulted with your diabetic nurse, or normally with your GP or your diabetic specialist in the hospital and then work from there then… When I was given 10/10 it didn't suit me and I had to increase it, increase it, increase it. But I done it in stages, with the supervision of people… And I've been on the level that I am taking now for the best part of two, maybe three years and it, suits me'(patient 24).*

'*I'm in a routine.. I tend to take my insulin first thing in the morning… so you know it's located in parts of the day. And with a routine it's more difficult to forget. If your routine is haphazard it can be easily forgotten. If you have got a regular routine it's less difficult to forget. You've got to manage it and I think the sooner you learn to manage it [adjusting the regime to routine], the easier it will be' (Patient 15).*

As anticipated by patients before initiation, ***matching insulin dose with food intake*** remained a worry for many patients. Those who are in the initial stage of this process often worried about mastering the arithmetic skills needed:

'*It's all about knowing how much insulin you [take] but… there's still things that I'm still learning. So, how to, how much, how much do I take? I've eaten, you know, that big plate of whatever, how much, how should I you know, I'm still learning about those things but it's something I find quite difficult. But the last time I went to see the nurse group, that's what we discussed' (patient 40).*

'*Originally I didn't [match insulin doses with food]. But later on I did that myself. But, I don't think all people can do that. They haven't got the ability to balance one with the other and I think some people need to be told and shown how to do that' (patient 15).*

However, accounts of patients who are more experienced in the technical skills necessary to match insulin doses to food intake, suggest that such concern could be mitigated over time as patients gain experiential knowledge and learn through trial and error:

> *'If you know you're going to have steak and kidney pie, which will have, involve pastry…, you have a rough idea how much extra you're going to be having over a normal lunch. So you just say, "Right, better put another extra six units in."..* *And then when you get home and you check, if you find you're a little bit low, you realise you've put too much [insulin] in or you've done too much activity after lunch. And if you're a little bit on the high side, it means that you didn't put enough [insulin] in at lunchtime. And you can counteract that at teatime by putting a bit more [insulin] in. So it's a case of checks and balances… And, you gradually learn by trial and error'* *(patient 11).*

Injecting insulin

Starting insulin involves a process of getting used to the technology associated with injecting, which includes learning how to administer injections and preparing injections.

Contrary to patients' anticipations prior to initiation, patients in general reported having little trouble with the technology associated with injecting (e.g. searching for and selecting injection sites where patients feel comfortable to inject, cleansing the injection site, and shaking the injection), and felt that healthcare professionals' advice and recommendations were easy to follow (patients 1, 10, 11, 15, 22, 34).

Mastering such technology may also lead to reduced pain associated with injection administration. Patient 11 for instance, shared his unique way of rotating injection sites to avoid discomfort:

> '*I have to work out what date it is. And if it's an odd date I do it on the left-hand side, because odd and left are short words. If it's an even date it's a longer word, so I do it on the right-hand side because it's a longer word. So I do either side of the navel with the evening one. And the day ones, there are four in the day, I tend to use one leg for about a month and then I swap over to the other leg, just to keep it even'.*

By contrast, some patients still raised occasional concerns over injection pain (patients 15, 22), fear of needles (patient 35), and the idea of self injection (patients 15, 24, 32). This was described by patient 22:

> '*It's just sometimes, I mean, sometimes when you stick your insulin into one of the sites, your stomach, your thigh, your stomach or, you know, the inside of the legs… It's if you hit a nerve, and instantly it's your reaction, it's pain, it's exactly the pain, you know, you go and you pull it back out and it's a case of, wow, … if there was another way I'd do it'.*

Consequences

Insulin can have several impacts on patients' wellbeing as well as their social life. While patients often anticipated the negative impact of insulin on their wellbeing and social life (fear of risk to health, fear of leading a restricted life, and fear of discrimination) before initiation, such concerns evolved in several ways at the stage of insulin management. This is explored in the following two sub-themes, namely impact on health and impact on social life.

Impact on health

As anticipated by patients before insulin, fear of risk to health in relation to hypoglycaemia became a reality at the stage when patients had their first hypoglycaemic episode, where they often described the experience as being accompanied by a sense of panic or even death (patients 2, 10, 15, 24). This was described by patient 2 as follows:

> *'I was driving home from shopping and I suddenly felt like death and I started to feel trembly. The problem is that I didn't know what was happening, because I'd never had it before… I was feeling giddy. I was totally unsafe on the road, but I didn't have the sense to stop and wait for it to wear off, because I, I had no experience of it'.*

Yet, accounts of those who have experienced several hypoglycaemic episodes suggest that such a worry diminishes over time as patients develop a sense of empowerment by gaining experiential knowledge. For instance, this was described by patients 11 and 24 as follows:

> '*Now, I know when one [episode of hypoglycaemia] is coming on because the symptoms… my own symptoms are I start to get a little bit dizzy, I perspire a lot, my legs go weak. And I think, "Ah, ah" and I run across to the machine, do a quick check and of course, "Oh, blimey, it's you know, 3.7. Where's the Lucozade?" And I just drink it, come back to this chair, sit down ten minutes, then I'm as right as rain' (patient 11).*

> '*The only time I have ever lost consciousness, was on the plane [the first hypoglycaemic episode], but no other than that, because you are experiencing…say about a month ago, I was training. I came back in and I showered, but instead of drying I was still wet, so I knew that my sugar levels were down, so I sat down on the bench in the changing rooms, I had my Kit Kat, went back for another shower and I was okay… But it's just, it's just learning to cope and adapt' (patient 24).*

Gaining experiential knowledge not only enabled patients to quickly spot the symptoms and cope with them when it happens but also allowed them to prepare themselves for potential hypoglycaemia, such as by carrying glucose tablets in their pockets, keeping sweets in their car, or storing glucose in the fridge, which in turn seems to strengthen patients' sense of empowerment, enabling them to control and manage hypoglycaemia (patients 2, 10, 11, 15, 24).

Equally anticipated by patients before insulin, some insulin treated patients raised their concerns over weight gain in the process of managing insulin (patients 2, 32, 35, 37, 40). For example, patient 2 expressed frustration with insulin not allowing him to lose weight despite his commitment to healthy eating:

> *'It just is much more difficult to lose weight now I'm on the insulin. So that's one of the drawbacks… I love cabbage and we have carrots, tender sweet. We just eat properly here, and it's not fair that I'm fat. I shouldn't be. I ought to be normal. I suppose I put this down to insulin. It's certainly not overeating'.*

In order to avoid weight gain and minimise such fears, patient 32 took active steps by simply omitting to take insulin:

> '*When I had my insulin more weight piled on. I couldn't lose it in the end once I had the insulin. So that is why now and again I just wouldn't take my insulin for about two or three months…And I could lose [weight]. I lost ten stone in six months without taking my insulin... But when I started taking the insulin again…, then it just piled back on again'.*

There was also puzzlement over how to reconcile healthcare professional advice to lose weight with the prescription of insulin which might cause them to gain weight:

'There's a sort of conflicting thing. Okay, so, you have to lose weight but we [healthcare professionals]'re going to give you this, that makes you, put on weight, and makes it difficult for you to lose weight. You know, so what do you do, you know?' (patient 40).

'*Insulin does put on the weight… They [healthcare professionals] can't just say that you have got to control your food, when I control my food and why does it [insulin] put on weight' (patient 32).*

Although a few patients reported not having experienced insulin-related weight gain, analysis of the accounts of patients identified that this was indeed often experienced.

Other than impact of insulin on hypoglycaemia and weight gain, many patients felt insulin was beneficial for their health in general (patients 1, 2, 10, 11, 17, 22, 24, 32, 34, 35, 37). Some patients also reported less itchy feet (patients 10, 11), better eyesight (patient 34), a diminished desire to eat sweets (patient 37), or reduced tiredness (patient 32) as a result of insulin treatment, while others commented on how insulin controlled their blood glucose levels. Comments included:

'Interviewer: So you know how initially they changed your medication from tablets to insulin, then how did you feel?
Um. Well… it's been good for me. Because I used to have heat inside my feet, what do you call it?
Interviewer: Itching?
Itching, and my feet would become really hot. Sometimes when I'd be asleep at night, it would be very warm. It would be very hot. In the mornings, for about one hour I would walk around, and after that it would be okay. But since using insulin, that is fine, now that doesn't happen' (patient 10).

'*If my sugars are wrong I would say now, and I would ring up and say something but, my insulin keeps it pretty normal. I'm glad I stuck to my insulin, I think changing to insulin's the best thing I ever did' (patient 34).*

'I think I should have gone on insulin earlier because as soon as I went on insulin, my sugar levels sort of came down… You still can have high sugar levels but not as high as they used to be on just tablets. So I think I should have gone on insulin, really' (patient 17).

Impact on social life

Findings in 'impact of social life' were similar to those observed in the narrative review. As anticipated by patients before insulin, several aspects of insulin use were perceived to be

inconvenient by insulin treated patients in the process of managing insulin. Some patients mentioned inconvenience in finding a location to administer injections when eating out (patients 2, 10, 11, 15, 22, 24), which was expressed by patient 2 in the following comment:

> *'The only problem is if I go out to dinner at night. And just before I, I eat I go into the gents and give myself my jab'.*

Gauging timings to inject between ordering and receiving food in a restaurant was also a concern for some patients (patients 11, 15, 24, 35). Comments included:

> '*The difficulty is that if you do it [inject] too soon before the meal, your sugar levels could drop so far that you begin to have a hypo before you've eaten. So, I wait until I've read the menu in the place, get some feeling as to how long they are between taking the order and providing the food, and then I get the needle out and stick in what I think is right' (patient 11).*

Others described the inconvenience of using insulin when travelling, which included concerns over carrying injections (patients 24, 35, 40), adhering to a strict regime (patient 17), and storing insulin (patients 11, 17, 24). For some patients, especially younger ones recently diagnosed with insulin, such inconvenience also appears to affect their sense of loss of control over the disease (patient 40) or their perceptions about themselves (e.g. *'I am ill', 'I am a drug addict'*) (patient 35). Comments included:

> '*I check my bag to see if I've got my insulin there, check to see that I've got enough insulin and wherever I go, I carry this blasted thing around with me, and it's just.. I think that you'd like to think that you've got control of your life really… But I'm allowing the diabetes to control me' (patient 40).*

> '*I do feel like I carry [insulin] equipment around. I'm going to put a label on my wrist. 'I am ill'. 'I am perpetually ill'. And that's that really' (patient 35).*

Despite such fear, often older patients with a longer history of using insulin commented that insulin therapy/diabetes did not have a huge impact on their lives:

> *'It does not restrict what I do' (patient 2).*

> *'It affects my life very little' (patient 11).*

> *'It doesn't stop me doing anything I've wanted to do' (patient 15).*

> *'[Insulin] is something that's not going to stop me doing anything' (patient 24).*

As anticipated prior to initiation, the experience of discrimination was also raised by some patients, who reported examples from their everyday lives which they felt resulted from their insulin use. This included discrimination when applying for travel insurance (patients 15, 24, 35), renewing their driving licence (patients 15, 35), and applying for car insurance (patient 35). Comments included:

> '*I'm an insulin dependent diabetic,…I can see there's another financial burden because I'm insulin dependent, because people are concerned I'm going to go unconscious, have a hypoglycaemic attack and crash my car' (patient 35).*

While patients 22 and 24 said that they could understand the rationale for renewing driving licences every three years, the experience of discrimination was often reported among patients.

Knowledge

While fear of the unknown was often expressed by patients before insulin initiation, this receded once they were actually managing insulin. Soon after initiation, patients reported having the support of typical information sources in the form of nurses and diabetic nurses, and were commonly happy that they received enough information about insulin therapy, including on topics such as when to take insulin, how much insulin to take, how to administer injections (e.g. injection sites, device), and/or how to use insulin (patients 2, 10, 11, 15, 22, 35). Patient 35 was pleased to report on the availability of flexible contact with his healthcare professionals when he transferred to insulin:

> '*When I started injecting, I was given a mobile phone number for my diabetic nurse. So if at any point in time I was struggling with anything, I could phone whatever and ask questions, which I found incredibly refreshing'*.

Adequate information and education about insulin, particularly in the initial stages of managing insulin, was also reported by patient 15 as a key factor in the benefits of the treatment. Some patients also independently sought information about insulin therapy/diabetes to fill the gaps in their understanding of insulin treatment, using sources such as the Internet (e.g. Diabetes UK

website, Google), books, and magazines (e.g. Diabetes UK magazine – 'Balance') (patients 11, 22).

Use of/views toward peers' experiences

The preceding sections (technology, consequences, knowledge) explored how patients' initial responses to insulin (e.g. fears) change in the process of managing insulin. In this process, several potential sources that may affect patients' attitudes, beliefs, and knowledge in relation to insulin were identified, one of which (as observed in the narrative review) is the experience of other people who have initiated insulin. In addition, while the narrative review contained little about these data, the analysis of interviews provided patients' views on the use of peers' experiences through a support group in the context of managing insulin therapy. This is explored below under two sub-themes, namely impact of peers' experiences in managing insulin therapy and patients' views on the use of a support group in a context of managing insulin therapy.

Impact of peers' experiences in managing insulin therapy

Analysis of the accounts of insulin treated patients hearing about peers' experiences in their everyday lives suggest that peers' experiences could have both negative and positive impacts on their perceptions/knowledge about managing their own insulin.

Some patients described how observing other patients/hearing the story of others who failed to cope with insulin-related health problems induced their concerns over the risk of insulin to health (patients 34, 37, 40). For patient 34, this was triggered by observing an insulin-using relative passing out owing to hypoglycaemia:

> '*My stepbrother became diabetic, and he was on insulin, and he had a hard time with it, and, he couldn't handle his diabetes... And it made me think, 'oh my gosh, I've seen him pass out so quick, am I going to do that'?'*

Patient 40 also expressed his/her concern over the impact of insulin on weight gain subsequent to observing other people whom s/he perceived as being overweight owing to long-term insulin use.

On the other hand, observing others who coped well with insulin-related health problems seems to mitigate patients' concerns. Observing an insulin-using acquaintance who managed well with a sudden incident of hypoglycaemia reassured patient 24 that such a side-effect is something that people can handle:

> '*I have been with people who have been hypo in a car… he was in the car and he was eating.. a cake in the car, because he was disorientated, so he was trying to eat it, but he was great about it… He was driving and he knew he was going hypo, so he pulled over. So when it happens, the majority of people who are insulin-dependent diabetics, or become insulin-dependent diabetics, experience these things and they cope more or less well with it'.*

Patient 32 also reported how observing other people administering injections strengthened her understanding of the technology attached to insulin injection.

Patients' views on the use of a support group in a context of managing insulin therapy

Patients' reasons for valuing or avoiding support groups in a context of managing insulin are, in general similar to those reported in a context of managing disease with non-insulin treatment prior to insulin (as discussed above). Some people who were already using insulin chose not to use support groups, feeling they would neither gain useful information nor emotional support. For patient 2, his reason for distancing himself from the group was the desire to avoid seeing 'moaning people'. A perceived lack of useful information in relation to insulin management was also mentioned by patient 1. Moreover, perceptions of not being sufficiently depressed to attend (patient 22), or being capable of coping without peers' support (patient 11) were also reported as reasons for not attending a group. For some, a lack of time to attend a group meeting was another factor (patients 1, 24).

Those who chose to attend a group were generally pleased to discover the degree to which they could receive information and advice about insulin/diabetes from other people (patients 34, 40). Patient 34 also reported his satisfaction in imparting insulin/diabetes-related advice to other members in a support group. Perceived usefulness in terms of emotion was also reported by some patients. For patient 15, his experience of joining a group provided him with a sense of reassurance by seeing another person who successfully administered insulin in a context of poorer standards of disease management:

> '*I think of the woman in our group… And she was talking about when she first started with the syringes, they were more like stirrup pumps, than syringes you know, great big needles... And when I looked at the needles I use, I think "By gum, I am a lucky man", in comparison to her'.*

Seeing other people who required insulin treatment also induced in patient 40 a sense of reassurance that her experiences are normal rather than a 'failure' on her part:

> '*That was our first meeting. It's quite interesting. I think what it meant for me, made me sort of relax a little bit because I saw people there that were, have been for twenty-five years, and are still trying to control it. So I thought, well, I am normal, d' you know? Because I was thinking, you know, 'It's another thing you've failed at you know'.*

Interestingly, some of these patients who consciously avoided support groups by expressing a negative opinion of joining the group nonetheless talked about encountering the experiences of other people in their everyday lives, which in turn benefited their perceptions/knowledge of *technology* and the *consequences* of insulin therapy (patients 22, 24). For example, despite the fact that patient 22 showed an intention to avoid joining support groups (because he is not depressed enough), he nevertheless mentioned reading another person's story of successfully managing diabetes using insulin, which seemed to deepen his understanding about the illness and its treatment. Also, while patient 24 reported no interest in joining a support group due to lack of time, he also coincidentally talked about observing others who coped well with hypoglycaemia, which appeared to leave him with a sense of reassurance in thinking that people can cope with such an issue. In contrast, while patient 34 reported her interest in joining a support group, she also talked about observing an insulin-using relative passing out due to hypoglycaemia, which in

turn, appeared to trigger a fear of risk to health in relation to hypoglycaemia. These findings may suggest that patients' preferences over the level of interaction with other peers (e.g. interactive versus passive) may vary over time or depending on the issues patients face.

5.2.3 Strengths and limitations

There are some strengths as well as limitations in using a secondary qualitative analysis of an existing collection of qualitative interviews. The major strength of a secondary qualitative study is cost and time efficiency. Since the original researchers had already collected the data, the secondary analyst did not have to devote resources to this phase of research[39]. Second, 'data fit' between the purpose of the secondary analysis and the nature and quality of the original data was one of the concerns in conducting a secondary qualitative study[31]. Although analysis was limited to the data collected (e.g. specific research questions about use of/views toward peers' experiences in the context of insulin decision-making could not be asked), some features of the original study could minimise the problem related to 'data fit': 1) the use of purposive sampling produced a sample with a broad range of experiences and the demographic details of participants (e.g. geographic region, age, gender, and ethnic group); 2) the use of an initial unstructured interview technique where the interviewers asked the participants for the story of their disease-related experience, with little interruption plus a semi-structured interview design (compared to tightly structured interviews), helped to identify participants' own concerns and priorities that were not linked to a highly focused research interest and made the interviews a rich source for this secondary analysis[40]. Related to this, the breadth, richness, and variety of the data contributed to the generation of new knowledge through the enhancement or expansion of existing analyses. Third, the use of 'supplementary analysis', which enabled the conducting of more in-depth analysis of the data that was only partially addressed in the original study, can contribute to developing cumulative evidence, a lack of which is often cited as a common criticism of

qualitative research[41]. Finally, it has been argued that 'where the secondary analyst was not part of the original research team the approach is best only employed by experienced researchers'[40]. Although the secondary analyst in this case was not an 'experienced researcher', supervision was carried out by a senior qualitative researcher who was part of the original research group responsible for the data collection throughout this study. Also, one of the supervisors who is a primary care clinician specializing in diabetes research, was able to discuss the themes and interpretations from a clinical perspective.

The study also has some limitations. Some of the information that was critical in analysing the secondary data (e.g. information about the use and length of insulin treatment) was not available from the original participants' information sheets. Thus, the secondary analyst had to find this information from the original interview transcripts. However, some of the transcripts did not include data regarding the length of insulin treatment, which occasionally made it difficult to draw conclusions about the potential function of such a factor in patients' attitudes and beliefs toward the initiation of insulin therapy as well as their attitudes and experiences in relation to the information/support needs. Second, an absence of contextual knowledge is another issue in conducting a secondary qualitative study, especially in circumstances where the secondary analyst was not part of the original research team[40,42] (and this was indeed the case). Although the secondary analyst had access to the original data including transcripts and participants' demographics sheets, the secondary analyst had no access to field notes and audio-tapes, though was able to see several patients talking in their online video clips. Consultation with the primary researcher was impossible as she had retired. This might pose some issues including how the data are affected by the lack of contextual knowledge[39]. Third, the patient population consisted of patients in the UK, therefore the results cannot be extrapolated to patients residing in different geographical areas. Finally, as mentioned above, although the use of particular sampling and data collection (unstructured narrative and semi-structured interviewing) methods produced a lot of relevant data, 'there were some occasions where the original interviewer had not followed up on

topics that would have been of great interest to the current research questions'[43]. As such, the available data did not contain all the necessary data to answer all the research questions. For instance, the data provided no specific evidence on patients' use of/views toward peers' experiences in the process of making the decisions about initiation of insulin therapy.

Discussion

The narrative literature review of qualitative studies (chapter 5 - part 1) and the secondary analysis of an existing collection of qualitative interviews (chapter 5 - part 2) provide two different perspectives: the narrative review collates data from a large number of studies from various countries which together constitute a broad knowledge specifically for exploring patients' attitudes, beliefs, and information/support needs relating to the initiation of insulin therapy. On the other hand, the secondary analysis of full interviews conducted in the UK, provides a depth and richness of primary data where patients with type 2 diabetes (including both insulin-treated and non-insulin-treated) talked about various aspects of their illness experiences. Although the interviews were not designed exclusively to ask questions about patients' attitudes and beliefs toward the initiation of insulin therapy, including patients' attitudes and experiences in relation to their information/support needs in the context of the decision-making process in starting insulin therapy, they include a considerable amount of discussion in relation to these topics. By using available sources of qualitative evidence, two complementary perspectives were pulled together to assess the research question (see Aim section), and to explore explanations of why they occurred by detailing explicit (the evidence/explanations that appear overtly in the reasoning of participants) as well as implicit (explanations and interpretations developed by a researcher from patterns across many accounts and sources) accounts[44]. The findings from the narrative review and the secondary analysis are quite consistent and mutually re-emphasising, and lead to the following six broad conclusions:

1. The narrative review and the secondary analysis support the idea that insulin is a high emotional hurdle for many patients to overcome. When interviewed about the idea of potential initiation of insulin, some patients expressed the hope of avoiding insulin by somehow delaying it, while others showed a sense of acceptance despite holding various concerns over insulin therapy. These findings suggest that even if patients recognise insulin

is important or necessary, they may still be unhappy to move onto insulin and hold negative perceptions about it. These results are consistent with previous quantitative studies that explored patients' willingness to start insulin. A survey study of 1400 non-insulin treated patients with type 2 diabetes collected across eight Western nations[45], as well as another survey study of 1267 non-insulin treated and insulin treated type 2 diabetic patients in the USA[46], found that more than half of the patients were not willing, or reluctantly willing to start insulin.

Various psychological reasons that contribute to patients' concerns about moving on to insulin were identified from the narrative review and the secondary analysis, which include fear of leading a restricted life, fear of insulin injection/technology, fear of risk to health, fear of discrimination, fear of disease severity, fear of mortality, punishment or threat, failure, and fear of unknown. Among these, the most prominent types of concerns attached to insulin which are common across diverse countries, include fear of insulin injection/technology and fear of disease severity. A previous quantitative study supports part of this finding and reported that patients most commonly perceived insulin as being reserved only for very serious and advanced stages of disease (fear of disease severity)[45]. On the other hand, while the narrative review reported concerns over insulin including failure, fear of mortality, and punishment or threat, such concerns did not emerge as strongly as themes in the secondary analysis. This may be due to the fact that the secondary analysis was not conducted to provide answers specifically about patients' attitudes and beliefs toward the initiation of insulin therapy, or to do with the country context or cultural background of participants.

2. The narrative review and the secondary analysis explored how patients' initial responses to insulin change over time. The most prominent findings observed were in fear of leading a restricted life and fear of discrimination: as anticipated by patients before initiation, insulin

treated patients often raised several aspects of insulin use that they perceived to be inconvenient as well as the experience of discrimination in the process of managing insulin.

3. The narrative review and the secondary analysis explored how patients recalled being informed about insulin prior to initiation, and found that they could hardly recall communicating about insulin with their healthcare providers. Patients' hopes that healthcare professionals might bring up the subject of insulin from the early stages of the disease was also reported in the narrative review.

4. The narrative review and the secondary analysis explored patients' use of peers' experiences in the sequence of diabetes management, and suggest that patients draw on other people's experiences encountered in everyday life when forming initial responses to insulin prior to the initiation, and managing insulin. Participants from the narrative review also talked about using peers' experiences when making decisions to accept/refuse insulin.

5. The data available from the narrative review and particularly the secondary analysis shed light on patients' views toward the use of peers' experiences (through a face-to-face support group) as a means of supporting disease management with non-insulin treatment prior to insulin as well as insulin management. The data suggest a great deal of variation in terms of whether and why patients valued the group in such contexts. Participants from both of the work streams did not talk much about their views toward the use of peers' experiences to support insulin decision-making.

   Some patients developed a negative opinion of using the group, while others derived a positive value. Their reasons for avoiding or using a support group ranged from cultural, practical, and informational to psychological concerns. Their psychological reasons for avoiding the group included a desire to avoid seeing 'moaning people' and suspicions toward

the authenticity (truthfulness) of information/advice provided by peers. On the other hand, the most prominent reasons for choosing to attend a group included informational and psychological benefits (e.g. a sense of reassurance, a sense of empowerment, a sense of social solidarity by being with peers who have similar problems).

Many of the reasons why the use of a support group is *valued* resonate with other qualitative research conducted in the UK exploring the use of peers' experiences in people facing particular health-related issues[41,47,48]. For instance, a study by Wyke et al. (2011)[48] of people facing decision making in several health topics (e.g. ultrasound scanning in pregnancy, diagnostic testing in pregnancy, terminating a pregnancy, treatment decisions in lymphoma and care for carers of people with dementia), reported that information about personal experiences was thought to be useful in helping the understanding of possible outcomes, and in appreciating that one is not alone, and in promoting hope. Also, a study conducted by Locock and Brown (2010)[41] of patients with motor neuron disease (MND) reported that patients valued peer support for reasons such as perceived usefulness in receiving and sharing information and advice on how to manage the disease, and a perceived sense of confidence and camaraderie from simply being with others who are 'like me'. This may suggest that the psychological reasons for valuing the use of peers' experiences (e.g. a support group) are similar among patients regardless of the type of disease or health conditions people face. On the other hand, psychological reasons for *avoiding* a support group as observed in the narrative literature review and the secondary analysis were slightly different from those reported in other qualitative studies that explored the use of peers' experiences in people suffering from other types of disease, which included HIV positive men[49], women with breast cancer[50], and patients with MND[41]. Some psychological reasons for avoiding peers' experiences, as reported in these studies but not described among patients with type 2 diabetes, included more emotionally extreme reasons, such as feelings of fear over disclosing their disease status owing to resulting stigma and social rejection, a feeling of shock and fear as a

result of exposure to frightening illness trajectories, and emotional overload. This may suggest that psychological reasons for avoiding peers' experiences (e.g. a support group) may depend on the type, severity, the nature of the disease, a patient's personality, or a patient's circumstances at the time.

6. While participants did not report much about their preferences in terms of the format of peers' experiences as a means of supporting insulin decision-making, they often discussed such preferences as a way of supporting general disease management. As discussed above, the data from the narrative review and the secondary analysis suggest that some patients derived a positive value in attending a face-to-face support group. The data from the secondary analysis also suggest that patients' preferences over the level of interaction with other peers (e.g. interactive versus passive) could vary over time or depending on the issues patients face. This finding is consistent with other qualitative research that examined MND patients' views toward the use of peer support[41].

Implications for developing a future intervention

Data available from the secondary analysis have largely reinforced the findings from the narrative review, and provided additional insight and richness in terms of patients' initial responses to insulin, how they change in the process of patients managing insulin, and how patients communicate about insulin with their healthcare providers in the management of early stage disease. This evidence suggests that some kind of support deliverable as a supplement to formal support provided by healthcare professionals could be valuable to ease the process of decision-making about starting insulin. While there is some evidence suggesting the potential use of shared patient experience in the context of insulin decision-making, there were few data specifically exploring patients' views toward and preferences in formats of peers' experiences in the process

of decision-making in starting insulin. The evidence was thus not sufficient from either of the work streams to inform the development of an intervention based on shared patient experience that supports insulin decision-making.

A further primary qualitative study (chapter 6) was therefore designed to fill this gap. It was aimed specifically at patients' views and preferences toward the use of shared patient experience in the context of insulin decision-making, to understand in greater detail what types of peers' experiences could be helpful (e.g. the contents of insulin-related information to share); how this might be done (e.g. group or individual based, face-to-face or remotely); and by whom (e.g. gender, age). This was designed to help in the development of the intervention aimed at supporting effective insulin decision-making.

Conclusion

While there are still some new data needing to be explored in more detail, all the factors discussed in the Discussion section provide some direction to develop an intervention that aims to support effective insulin decision-making. We now have more detailed qualitative understanding of patients' various concerns about potential insulin therapy, and concerns regarding a lack of communication about insulin with healthcare professionals prior to insulin. We can also conclude that some patients at least use other people's experiences when considering whether or not to start insulin. In the next chapter, I build on this evidence with findings from a primary qualitative study that investigated patients' views and preferences toward the use of shared patient experience to support the process of decision-making about starting insulin in type 2 diabetes.

References

1. Sandelowski M, Docherty S, Emden C. Focus on qualitative methods. Qualitative metasynthesis: issues and techniques. *Res Nurs Health.* 1997;20(4):365-371.
2. Dixon-Woods M, Fitzpatrick R, Roberts K. Including qualitative research in systematic reviews: opportunities and problems. *J Eval Clin Pract.* 2001;7(2):125-133.
3. Chapple A, Rogers A. Explicit guidelines for qualitative research: a step in the right direction, a defence of the 'soft' option, or a form of sociological imperialism? *Fam Pract.* 1998;15(6):556-561.
4. Popay J, Rogers A, Williams G. Rationale and Standards for the Systematic Review of Qualitative Literature in Health Services Research. *Qual Health Res.* 1998;8(3):341-351.
5. Garside R. Systematic review and synthesis of qualitative research. In: Ziebland S, Coulter A, Calabrese JD, Locock L, eds. *Understanding and using health expereinces: Improving patient are*. UK: Oxford University Press; 2013:104-116.
6. Popay J. Moving beyond floccinaucinihilipilification: enhancing the utility of systematic reviews. *J Clin Epidemiol.* 2005;58(11):1079-1080; discussion 1081-1078, 1089.
7. Sandelowski M. A matter of taste: evaluating the quality of qualitative research. *Nurs Inq.* 2015;22(2):86-94.
8. Lewis J, Ritchie J. Generalising from qualitative research. In: Ritchie J, Lewis J, eds. *Qualitative research practice: A guide for social science students and researchers*. London: SAGE; 2003:263-286.
9. Daly J, Willis K, Small R, et al. A hierarchy of evidence for assessing qualitative health research. *J Clin Epidemiol.* 2007;60(1):43-49.
10. Greenhalgh T, Taylor R. Papers that go beyond numbers (qualitative research). *BMJ.* 1997;315(7110):740-743.
11. Thomas J, Harden A. Methods for the thematic synthesis of qualitative research in systematic reviews. *BMC Med Res Methodol.* 2008;8(1):45.

12. Abu Hassan H, Tohid H, Mohd Amin R, Long Bidin MB, Muthupalaniappen L, Omar K. Factors influencing insulin acceptance among type 2 diabetes mellitus patients in a primary care clinic: a qualitative exploration. *BMC Fam Pract.* 2013;14:164.

13. Bogatean MP, Hancu N. People with type 2 diabetes facing the reality of starting insulin therapy: Factors involved in psychological insulin resistance. *Practical Diabetes International.* 2004;21(7):247-252.

14. Brown K, Avis M, Hubbard M. Health beliefs of African-Caribbean people with type 2 diabetes: a qualitative study. *Br J Gen Pract.* 2007;57(539):461-469.

15. Grams GD, Herbert C, Heffernan C, et al. Haida perspectives on living with non-insulin dependent diabetes. *Can Med Assoc J.* 1996;155(11):1563-1568.

16. Guimaraes C, Marra CA, Gill S, et al. Exploring patients' perceptions for insulin therapy in type 2 diabetes: a Brazilian and Canadian qualitative study. *Patient preference & adherence.* 2010;4:171-179.

17. Ho EY, James J. Cultural barriers to initiating insulin therapy in Chinese people with type 2 diabetes living in Canada. *Canadian Journal of Diabetes.* 2006;30(4):390-396.

18. Hood G, Huber J, Gustaffson U, Scambler S, Asimakopoulou K. 'With age comes wisdom almost always too late': older adults' experiences of T2DM. *European Diabetes Nursing.* 2009;6(1):23-28.

19. Hu J, Amirehsani KA, Wallace DC, Letvak S. The meaning of insulin to Hispanic immigrants with type 2 diabetes and their families. *Diabetes Educ.* 2012;38(2):263-270.

20. Hunt LM, Valenzuela MA, Pugh JA. NIDDM patients' fears and hopes about insulin therapy: the basis of patient reluctance. *Diabetes Care.* 1997;20(3):292-298.

21. Janes R, Titchener J, Pere J, Pere R, Senior J. Understanding barriers to glycaemic control from the patient's perspective. *J Prim Health Care.* 2013;5(2):114-122.

22. Jenkins N, Hallowell N, Farmer AJ, Holman RR, Lawton J. Initiating insulin as part of the Treating To Target in Type 2 Diabetes (4-T) trial: an interview study of patients' and health professionals' experiences. *Diabetes Care.* 2010;33(10):2178-2180.

23. Khan H, Lasker SS, Chowdhury TA. Prevalence and reasons for insulin refusal in Bangladeshi patients with poorly controlled Type 2 diabetes in East London. *Diabet Med.* 2008;25(9):1108-1111.

24. Maillet NA, Melkus GD, Spollett G. Using focus groups to characterize the health beliefs and practices of black women with non-insulin-dependent diabetes. *Diabetes Educ.* 1996;22(1):39-46.

25. Morris JE, Povey RC, Street CG. Experiences of people with type 2 diabetes who have changed from oral medication to self-administered insulin injections. A qualitative study. *Practical Diabetes International.* 2005;22(7):239-243.

26. Nair KM, Levine MAH, Lohfeld LH, Gerstein HC. "I take what I think works for me": a qualitative study to explore patient perception of diabetes treatment benefits and risks. *Canadian Journal of Clinical Pharmacology.* 2007;14(2):e251-259.

27. Noakes H. Perceptions of black African and African-Caribbean people regarding insulin. *Journal of Diabetes Nursing.* 2010;14(4):148.

28. Phillips A. Experiences of patients with type 2 diabetes starting insulin therapy. *Nurs Stand.* 2007;21(23):35-41.

29. Tan AM, Muthusamy L, Ng CC, Phoon KY, Ow JH, Tan NC. Initiation of insulin for type 2 diabetes mellitus patients: what are the issues? A qualitative study. *Singapore Med J.* 2011;52(11):801-809.

30. Heaton J. *Reworking qualitative data.* London: Sage; 2004.

31. Heaton J. Secondary analysis of qualitative data: an overview. *Historical Social Research/Historische Sozialforschung.* 2008:33-45.

32. Snape D, Spencer L. The foundations of qualitative research. In: Ritchie J, Lewis J, eds. *Qualitative Research Practice: A Guide for Social Science Students and Researchers*. London: SAGE; 2003:1-23.

33. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Methodol.* 2013;13:117.

34. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol.* 2006;3(2):77-101.

35. Vaismoradi M, Turunen H, Bondas T. Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. *Nurs Health Sci.* 2013;15(3):398-405.

36. Pope C, Ziebland S, Mays N. Qualitative research in health care. Analysing qualitative data. *BMJ.* 2000;320(7227):114-116.

37. Parkinson S, Eatough V, Holmes J, Stapley E, Midgley N. Framework analysis: a worked example of a study exploring young people's experiences of depression. *Qualitative Research in Psychology.* 2016;13(2):109-129.

38. Ritchie J, Spencer L, O'Connor W. Carrying out qualitative analysis. In: Ritchie J, Lewis J, eds. *Qualitative Research Practice: A Guide for Social Science Students and Researchers*. London: SAGE; 2003:219-262.

39. Boslaugh S. *Secondary data sources for public health: A practical guide.* Cambridge University Press; 2007.

40. Heaton J. Secondary analysis of qualitative data: An overview. *Social Research Update, University of Surrey.* 1998;22.

41. Locock L, Brown JB. 'All in the same boat'? Patient and carer attitudes to peer support and social comparison in Motor Neurone Disease (MND). *Soc Sci Med.* 2010;71(8):1498-1505.

42. Hammersley M. Can we re-use qualitative data via secondary analysis? Notes on some terminological and substantive issues. *Sociological Research Online.* 2010;15(1):5.

43. Wyke S, Entwistle V, France EF, et al. *Information for Choice: What People Need, Prefer and Use. Report for the National Institute for Health Research Service Delivery and Organisation Programme.* London, UK2011.

44. Ritchie J, Spencer L, O'Connor W. Carrying out qualitative analysis. In: Ritchie J, Lewis J, eds. *Qualitative research practice: A guide for social science students and researchers*. London: SAGE; 2003:219-262.

45. Polonsky WH, Hajos TR, Dain MP, Snoek FJ. Are patients with type 2 diabetes reluctant to start insulin therapy? An examination of the scope and underpinnings of psychological insulin resistance in a large, international population. *Curr Med Res Opin.* 2011;27(6):1169-1174.

46. Polonsky WH, Fisher L, Guzman S, Villa-Caballero L, Edelman SV. Psychological Insulin Resistance in Patients With Type 2 Diabetes: The scope of the problem. *Diabetes Care.* 2005;28(10):2543-2545.

47. France EF, Wyke S, Ziebland S, Entwistle VA, Hunt K. How personal experiences feature in women's accounts of use of information for decisions about antenatal diagnostic testing for foetal abnormality. *Soc Sci Med.* 2011;72(5):755-762.

48. Wyke SA, Entwistle VA, France EFA, et al. *Information for Choice: What People Need, Prefer and Use. Report for = the National Institute for Health Research Service Delivery and = Organisation Programme=0A=*. London, UK=0A=2011.

49. Madiba S, Canti-Sigaqa V. Barriers to participate in support groups for people living with HIV: a qualitative study with men receiving antiretroviral treatment in a HIV clinic in Mthatha, South Africa. *Glob J Health Sci.* 2012;4(6):119-128.

50. Sandaunet AG. The challenge of fitting in: non-participation and withdrawal from an online self-help group for breast cancer patients. *Sociol Health Illn.* 2008;30(1):131-144.

Appendices

Appendix 5.1: Strategy for Social Science Citation Index
– Web of Science, Thomson Reuters – 1956-present

# 7	126	#6 AND #5 AND #4 Indexes=SSCI Timespan=All years
# 6	354,662	**TOPIC:** (qualitative OR interview* OR "focus group*" OR story OR stories OR narration OR narrative* OR discourse OR discursive OR "grounded theory" OR ethnogra* OR phenomenolog*) *OR* **TITLE:** (observation) Indexes=SSCI Timespan=All years
# 5	7,023	**TOPIC:** (insulin) *OR* **TOPIC:** ((insulin* NEAR/5 (start* OR initiat* OR commenc*))) Indexes=SSCI Timespan=All years
# 4	6,473	#3 OR #2 OR #1 Indexes=SSCI Timespan=All years
# 3	702	**TOPIC:** (t2dm OR tiidm OR niddm) Indexes=SSCI Timespan=All years
# 2	54	**TOPIC:** ((("late onset" OR "adult onset" OR "maturity onset" OR "mature onset") NEAR/2 diabet*)) Indexes=SSCI Timespan=All years
# 1	6,290	**TOPIC:** ((("type 2" OR "type ii" OR "noninsulin dependen*" OR "non-insulin dependen*") NEAR/2 diabet*)) Indexes=SSCI Timespan=All years

Appendix 5.2: A summary of characteristics of included studies

Reference number	Primary author (year)	Country	Data collection	Data analysis	Type of participants	Type of treatment	Settings
12	**Abu Hassan 2013**	Malaysia	in-depth individual interviews (n=3) or focus group discussions (n=18)	thematic analysis	T2DM n = 21 (M = 13 / F = 8) Malaysian	patients who had been on insulin for one year or more	primary care clinic
13	**Bogatean 2004**	Romania	semi-structured interviews	phenomenological analysis and content analysis	T2DM n = 18 (M = 11 / F = 7) Romanian	patients at the moment of starting insulin therapy	outpatients at diabetes centre
14	**Brown 2007**	UK	one-to-one interviews	framework analysis	T2DM n = 16 (M = 6 / F = 10) African–Caribbean	patients who had been on: Insulin (n= 6) Tablets (n= 5) Diet only (n= 5)	NR
15	**Grams 1996**	Canada	focus groups	grounded theory	NIDDM n = NR Haida people	NR	NR
16	**Guimarães 2010**	Canada & Brazil	in-depth individual interviews (n = 16) or focus group discussions (n = 16)	framework analysis	T2DM n = 32 (M = 14 / F = 18) Brazilian (n = 17) Canadian (n = 15)	non-insulin treated (n = 15) insulin-treated (n = 17)	hospital in Canada, and a local hospital in Brazil
17	**Ho 2006**	Canada	semi-structured interviews	framework analysis	T2DM n = 5 (M = 4 / F = 1) Chinese	patients who had been on insulin therapy	ambulatory centre for diabetes
18	**Hood 2009**	UK	semi-structured interviews	thematic analysis	T2DM n = 28 (M = 19 / F = 9) white British working class	patients who had been on: Insulin (n= 23) Tablets (n= 5)	participants' homes
19	**Hu 2012**	USA	focus groups	content analysis	T2DM n = 43 (M = 12 / F = 31) Hispanics	patients who had been on: Insulin (31.6%) oral hypoglycaemic agents (68.4 %)	community-supported clinic
20	**Hunt 1997**	USA	in-depth interviews	content analysis	NIDDM n = 44 (M = 22 / F = 22) Mexican American	patients who had been on: Non medication (n = 4) Pills (n = 24) Insulin (n = 14) Pills and insulin (n = 2)	public clinics serving low income patients
21	**Janes 2013**	NZ	semi-structured interviews	IPA	T2DM n = 15 (M = 5 / F = 10) NZ Maori (n=7) or NZ European (n=4) or NZ Maori + NZ European (n=4)	patients who had been on insulin therapy	local diabetes clinic
22	**Jenkins 2010**	UK	in-depth interviews	thematic analysis	T2DM n= 45 (M = 29 / F = 16) white British	patients who had been on insulin	Treating To Target in Type 2 Diabetes (4-T) centres
23	**Khan 2008**	UK	focus groups	thematic content analysis	T2DM n = 36 (M = 20 / F = 16) Bangladeshi	patients in whom insulin therapy was deemed necessary by clinician, but who refused insulin, despite two counselling sessions 3 months apart	local community centres
24	**Maillet 1996**	USA	focus groups	contextual analysis	NIDDM n = 6 (F = 6) black American	patients who had been on Diet or Oral med	medical university
25	**Morris 2005**	UK	semi-structured interviews	IPA	T2DM n= 6 (M = 3 / F = 3) Caucasian (n=4), African Caribbean (n=1), Asian (n=1)	patients who who over the course of the three-month recruitment period transferred from oral to insulin therapy	diabetes centre
26	**Nair 2007**	Canada	semi-structured interviews	grounded theory	T2DM n = 18 (M = 8 / F = 10) NR	patients who were on: diet therapy (n=2) oral medications (n=11) Insulin (n = 5)	location determined by participants
27	**Noakes 2010**	UK	focus groups	thematic content analysis	T2DM n = 13 (M = 5 / F = 8) African–Caribbean (n=8), African (n=5)	patients who had been on: Insulin (n= 6) Tablets (n= 7)	private room in the education centre at NHS trust
28	**Phillips 2007**	UK	in-depth individual interviews	IPA	T2DM n = 8 (M = 4 / F = 4) NR	patients who had been converted to insulin therapy for longer than one year	private setting
29	**Tan 2011**	Singapore	focus groups	grounded theory	T2DM n = 11 (M = 6 / F = 5) NR	poorly controlled diabetic patients who refused insulin therapy despite being on maximum oral hypoglycaemic drugs, and patients who were on insulin therapy	primary care centres

NR = Not reported; NZ = New Zealand; IPA = Interpretative phenomenological approach; NIDDM = Non-insulin depend diabetes; T2DM = Type 2 diabetes mellitus; USA = United States of America; UK = United Kingdom; M= male; F = female

Chapter 6. Primary qualitative study exploring patients' views and preferences toward the use of shared patient experience to support the process of decision-making in starting insulin therapy

6.1 Introduction

The results from the narrative literature review of qualitative studies (chapter 5 - part 1), and the secondary analysis of an existing collection of qualitative interviews (chapter 5 - part 2) identified people's own perspectives on potentially using insulin in type 2 diabetes, including psychological reasons that contribute to patients' reluctance toward starting insulin therapy. Yet, these previous chapters have rarely included evidence for patients' views and preferences toward the use of shared patient experience specifically in relation to decision-making about insulin treatment.

I set out to supplement this evidence through conducting new primary qualitative interviews, to facilitate a more in-depth understanding of patients' attitudes and beliefs in relation to insulin therapy. Also, as noted in chapter 2, the current work stream draws on relevant theoretical perspectives to make sense of how shared patient experience could support the process of decision-making in starting insulin therapy and to optimize design and implementation of the intervention.

6.2 Aim

The main research question this study aimed to answer was:

- How do patients feel about the use of shared patient experience to support the process of decision-making in starting insulin therapy?

The secondary research question this study aimed to answer was:

- What are patients' attitudes and beliefs toward the initiation of insulin therapy as well as their attitudes and experiences in relation to information/support needs (in particular, support through shared patient experience) in the context of the decision-making process?

6.3 Methods

6.3.1 Recruitment

Participants were recruited using purposive maximum variation sampling. Variation was sought across participants' socio-demographic characteristics and specific experiences[1]. 33 male and female participants with type 2 diabetes aged over 18 and who had started insulin (n=12), as well as those who had not (n=21), were selected in the London and South East areas from various ethnic backgrounds. The recruitment methods included advertisements on community notice boards, in local newsletters and newspapers, local and national research groups, on websites, snowballing, and word of mouth (see Appendices 6.1a and 6.1b for advertisement material). Participants who were unable to provide informed consent were not included. Further information about the samples is provided in table 6.1 and Appendix 6.2.

Participants who showed interest in the work stream were provided with a recruitment pack containing information about the research (see Appendix 6.3) and offered a chance to talk to the researchers and ask questions before deciding whether to participate.

Table 6.1 Participants' (N=33) demographic, biographical, and interview details

Age at diagnosis (N)	20-30 (1)
	31-40 (8)
	41-50 (9)
	51-60 (11)
	61-70 (4)
Length of disease in years (N)	1-10 (17)
	11-20 (11)
	21-30 (4)
	31-40 (0)
	41-50 (1)
Age at insulin initiation (N)	31-40 (3)
	41-50 (0)
	51-60 (6)
	61-70 (2)
	71-80 (1)
Sex (N)	Male (23)
	Female (10)
Ethnic origin (N)	White/British (21)
	White/Other (3)
	Asian/Indian (3)
	Black/Caribbean (2)
	White/British/Maori (1)
	White/Native American (1)
	White/Jewish (1)
	Asian/of other origin (1)
Marital status (N)	Married (17)
	Single (11)
	Separated (2)
	Divorced (1)
	Long term partner (1)
	Widowed (1)
Level of education (N)	Secondary school (9)
	Third level (20)
	Other (4) (diploma/technical/college)

6.3.2 Data collection

The interviews were carried out either in participants' homes or in the Nuffield Department of Primary Care Health Sciences, University of Oxford. Participants were interviewed on their own apart from in two cases when a partner was present during the interview[i]. Before the interviews,

[i] A partner was present when the participant so desired.

participants read and signed a consent form (see Appendix 6.4), and answered some demographic questions (see Appendix 6.5). Face-to-face, semi-structured individual interviews were then carried out using a topic guide (see Appendix 6.6) based on results of previous work streams, existing theories, and discussions with supervisors. Individual interviews provide an opportunity for detailed investigation of each person's perspective, for an in-depth understanding of the individual context within which the research phenomena are located, and for detailed subject coverage[2]. Interviews lasted between 60 and 240 minutes, and were audio-taped and transcribed verbatim.

The interviews were structured broadly into three main phases, and started by asking participants broad initial questions, which explored their general experiences of living with type 2 diabetes from the time when they were first diagnosed. Secondly, some focused questions were used specifically to explore their attitudes and beliefs toward the initiation of insulin therapy as well as their attitudes and experiences in relation to information/support needs in the context of the decision-making process in starting insulin therapy. Thirdly, sample vignettes illustrating three formats of 'peers' experiences', which conveyed information about managing type 2 diabetes as well as considering/initiating/managing insulin therapy, were presented to participants to explore their views and preferences toward the use of shared patient experience as a support to help them in the context of insulin decision-making. Participants were asked to discuss their views, preferences, and the usefulness of these vignettes in the context of the decision-making in commencing insulin therapy. The formats of the vignettes included: 1) a laminated print-out of a particular individual's written story surrounding disease/insulin management which was prepared from http://www.diabetes.org.uk/Type-2-diabetes/; 2) a laminated print-out of an online forum where patients exchanged their opinions and experiences about the initiation of insulin which was extracted from http://www.diabetessupport.co.uk; and 3) a laminated print-out of a screen shot of an online curated collection of the filmed narrative interview material containing a large sample of patients speaking about their opinions and experiences surrounding insulin

initiation/management which was extracted from the website http://www.healthtalk.org/ (see Appendices 6.7a, 6.7b, and 6.7c for sample vignettes). While these sample vignettes were prepared from publicly available online information resources, participants were also verbally told that formats of 'peers' experiences' were available in offline formats (e.g. an individual's written story in a magazine, face-to-face support group, face-to-face one-to-one discussion, an offline curated collection of the filmed narrative interview material in DVD format), and were prompted to raise any other formats of presenting peers' experiences to help them make the decision about insulin. The formats and contents of the sample materials were informed from the previous quantitative (see chapters 3 and 4) and qualitative (see chapter 5) work streams. The use of the vignettes provides a basis for discussion in individual interviews, and brings a degree of specificity to the interview, which can be valuable[3]. Follow-up questions were also used to obtain a deeper and fuller understanding of the participants' meanings in their various responses.

All interviews were transcribed by a professional transcriber who was a native speaker of English. The transcriber was asked to note where participants were laughing or using expressions such as 'ums', 'ers', the length of pauses, and repetitions that might affect the interpretation of the transcribed text. At the end of the interview, all participants received payment of £20 and any travel expenses were reimbursed. Following the interview, each participant was sent a personalised thank you note, as well as a reminder that if they had any concerns they should not hesitate to ask their general practitioner (GP) and/or nurse for advice (see Appendix 6.8). Participants who requested results of the work stream were also told they would be sent a copy once the data had been analysed (see Appendix 6.9). Ethical approval for the work stream was granted by the Central University Research Ethics Committee.

6.3.3 Data analysis

Since this qualitative work stream not only had some specific issues to explore, but also aimed 'to leave space to discover other unexpected aspects of the participants' experience'[4], a thematic

analysis using a framework method was undertaken. Thematic analysis allows to carry out a combined approach since it has no commitment to either inductive or deductive approach[5]. The framework method is a flexible tool that can be adapted for use in thematic analysis, and is considered to be appropriate for thematic analysis of textual data, particularly interview transcripts[4]. The framework method provides a structured data analysis procedure by using a matrix of cases, codes, and summarised data, and enables analysis of the data thematically (for each theme across all participants) as well as case by case (for each participant across all themes)[4,6]. The method is also considered to be suited for studies with specific research questions[4,7]. The approach taken was similar to the one described in the secondary analysis of the qualitative study (chapter 5 – Part 2).

The main themes such as avoidance or fatalism, fears, threat, failure, better than anticipated or as anticipated, fear of the unknown, communicating about insulin therapy with healthcare providers, and access to peers' experiences emerged in response to the data. The main themes, including impact of peers' experiences to form initial responses to insulin therapy and other triggers to accept insulin therapy were imposed on the data by the researcher since they were integral to the research question. Roles of peers' experiences and format of peers' experiences arose in response to the data, but also through the previous work conducted by Wyke et al. (2010) (as discussed later)[8].

6.4 Results

A summary of themes is presented in table 6.2. The first heading (Reluctance) examines patients' initial responses to insulin therapy as well as how such responses change in the process of patients actually managing insulin therapy, which are explored below under five main themes: *avoidance or fatalism, fears, threat, failure,* and *better than anticipated or as anticipated*. The second

heading (Being informed about insulin therapy) observes patients' understanding about potential insulin therapy and how patients recalled being informed about insulin therapy from their healthcare providers and peers prior to initiation, under three main themes: *fear of the unknown, communicating about insulin therapy with healthcare providers*, and *impact of peers' experiences to form initial responses to insulin therapy.* The third heading (Making the decision about insulin therapy) explores key determinants other than peers' experiences that have the potential to affect patients' decision to accept the initiation of insulin therapy, under one main theme: *other triggers to accept insulin therapy*. Many of the issues patients raised in the first (Reluctance), second (Being informed about insulin therapy), and third (Making the decision about insulin therapy) headings were consistent with those highlighted in the previous qualitative work streams (see chapter 5 - part 1 and 2). As such, the present work stream aimed to build on the work streams conducted previously by describing how the findings from this work stream relate to the ones from the previous work streams. It should be noted that emphasis is placed on what the present findings add and what is new or distinctive, and thus findings that reinforced the previous findings are not covered in much detail. The fourth heading (Views and preferences toward the use of peers' experiences in the process of decision-making) investigates whether, why, and how patients use shared patient experience in the context of decision-making process about starting insulin therapy, which are explored below under three main themes: *roles of peers' experiences, format of peers' experiences,* and *access to peers' experiences.* The chapter focuses primarily on this as new evidence to fill the gaps left after the narrative review (chapter 5 – part 1) and the secondary analysis (chapter 5 – part 2).

Table 6.2 Headings, main themes, and sub-themes

Headings	Main themes	Sub-themes
Reluctance	**Avoidance or Fatalism**	
	Fears	
	Threat	
	Failure	
	Better than anticipated or As anticipated	
Being informed about insulin therapy	**Fear of the unknown**	
	Communicating about insulin therapy with healthcare providers	
	Impact of peers' experiences to form initial responses to insulin therapy	
Making the decision about insulin therapy	**Other triggers to accept insulin therapy**	
Views and preferences toward the use of peers' experiences in the process of decision-making	**Roles of peers' experiences**	To gain informational advice on insulin therapy
		To recognise a diversity of views and experiences of insulin therapy
		To appraise own approaches to insulin therapy
		To feel camaraderie and self-reassurance
		To gain self-empowerment
		Avoiding peers' experiences
	Format of peers' experiences	Online forum
		Face-to-face support group
		Curated collection of the filmed narrative interview material
		Individual's written story
		Face-to-face one-to-one discussion
	Access to peers' experiences	

Reluctance

Previous work streams found that it was common for patients to be reluctant to move onto insulin treatment, while such a feeling evolved in several ways once insulin had been started. Most of these previous findings were confirmed in the present work stream (all the main themes under 'reluctance' described in table 6.2 are consistent with the previous work streams). Yet, some notable new findings were also identified in the current work stream, in particular, under two of the five main themes: *fears;* and *failure*.

Fears

One notable new finding in the current work stream regards *fear of injection*. Patients in both the current and previous samples commonly saw self-injection as too difficult or complicated, however in the current work stream this was especially evident among those who had preconceived ideas of injection through associations with old-fashioned syringes. One non–insulin treated patient for instance, explained:

> *'The only thing about insulin, I must admit that puts me off about it… it's how on earth you would inject yourself… I think of these syringes and a big bottle that they draw the liquid off [into]. That's what I think of… but for giving an injection I've never actually given myself an injection for any reason. I am happy for someone else to do it. I wouldn't know. It's a fear… fear of actually, how on earth you would actually give yourself this injection' (Patient 10).*

The comments by several insulin treated patients who expressed a sense of relief after discovering that the latest method of insulin injection was far from what they had imagined prior to the initiation, also suggest that they did indeed have preconceived ideas of injection associated with old-fashioned syringes, and that this contributed to their feelings of fear attached to self-injection:

> *'I was pregnant and I had a phial of insulin that I used to have to draw up and this was only in 1996, I had to draw up a syringe and… Now when I was…, second, diagnosed in 2001, I realised that things had moved on the five years it had moved on… I looked at this pen with this tiny little needle and I thought, my goodness me, that's so easy compared to what I had to do… I suppose from a learning point, giving advice point of view for future people, I would say that that needs to be, it needs to be made clear how simple it can be' (Patient 33).*

On the other hand, the current work stream found that for those who had been taking non-insulin injectable medicines, including Glucagon-like peptide-1 receptor agonists prior to insulin, such fear was not part of their concerns from the beginning since they had already overcome such fear while using the injectable medicine:

> *'So, I'm ahead, because I'm actually injecting myself already. Because the Victoza pen is identical to an insulin pen. The needles are exactly the same...Victoza is sort of a stepping-stone between all the other drugs and insulin…to actually do the injection, that's not a problem now, because I've been taking Victoza' (Patient 25).*

> 'Interviewer: Are you worried about needles and pain?
> *No, not now. If I hadn't had the Bieta then I would be. The fact that I can manage with the Bieta and I know that that doesn't hurt, I'm fine with that, not worried about that' (Patient 27).*

Failure

While this was one of the themes raised in the narrative review, *failure* did not emerge as strongly as a theme in this work stream or in the secondary analysis. This was described by patient 5:

> *'I don't think you need to regard it [insulin] as some sort of failure or something if you need to go onto it'.*

As noted in chapter 5 – part 2, the absence of this theme in the secondary analysis may be due to the fact that the data was not collected to find answers specifically about patients' attitudes/experiences toward the initiation of insulin therapy. Yet, this work stream also suggests that such an absence might be a result of recent healthcare providers' awareness of the fact that patients often hold feelings of self-blame and guilt when starting insulin. Such awareness may be due to a recent emphasis in healthcare providers' training on avoiding blame or their use of certain diagnostic tools to assess patients' concerns about insulin (as discussed in chapter 2):

> *'Talking to her [nurse], she was saying that quite a lot probably of type 2s moving onto insulin will feel the fact they had to move onto insulin is an indication that they've failed. That they've failed to look after themselves sufficiently to enable them to continue treating just with tablets. I thought that was an interesting observation (Patient 29)'.*

A comment made by patient 24 below also suggests healthcare providers seemed to be actively and explicitly reassuring patients that starting insulin should not entail any blame:

'The doctor was at great pains to point out that it wasn't my fault, which was great'.

Being informed about insulin therapy

Previous work streams explored how patients recalled being informed about insulin therapy before initiation, and found that while patients commonly recalled talking with peers about insulin or observing peers using insulin, they could hardly recall communicating about insulin with their healthcare providers. Previous work streams also found that patients had concerns over a lack of understanding about insulin therapy prior to the initiation. The present work stream enriched these previous findings with additional new evidence, which is discussed below under two of the three main themes: *fear of the unknown*; and *communicating about insulin therapy with healthcare providers.*

Fear of the unknown

In accordance with the previous work streams, some non-insulin treated patients who were at the early stage of disease management raised concerns over a lack of understanding about insulin: some did not know that insulin is used to treat type 2 diabetes and believed it was only used for type 1 diabetes, while others believed that transferring from non-insulin-based treatment (e.g. oral medicine) to insulin therapy means that one's type of diabetes has changed from type 2 to type 1 diabetes. Strikingly in the present work stream, such a misconception was observed regardless of their educational level or length of time having diabetes. For instance, this was reported by one solicitor (patient 10) and one psychologist (patient 11) who had been diagnosed with diabetes eight years ago and had not been recommended insulin by their healthcare provider:

> *'And when they [healthcare providers] put me onto that and that was what they decided to put me onto, metformin. It was never even suggested [by healthcare providers] that I could use insulin. I always thought it was to do with type 1 diabetes, insulin. I've never been given any information that insulin could be used as a treatment for this version of it… I got it into my head that you could only use insulin for type 1, rather than type 2... In fact, in some respects, if it hadn't been for finding your advert, I would never even have known about the insulin as being a treatment for this type… As I say, I*

wouldn't have known about it otherwise. I always thought it was metformin or amputation. That was a notion that I developed' (Patient 10) [ii].

'[healthcare providers said] "you don't want to become insulin dependent, [the name of interviewee]. You don't want it". I said, "at what point does type 2 diabetes turn into type 1 and how bad does that need to be before you need insulin?"... Is that right? Am I right with that?... Is that what they are saying now? Then again, I am not that well up on it. I am not as educated as I could be with regards to that' (Patient 11) [iii].

Communicating about insulin therapy with healthcare providers

While misconceptions about insulin therapy such as those outlined in the previous section could be attributed to many factors such as patients themselves not listening to or remembering what healthcare providers said about insulin, some explicit accounts by patients suggest that such misconceptions could result from a lack of communication about insulin between healthcare providers and patients. Consistent with the previous work streams, such a lack of communication with healthcare providers was evident at the early stage of disease management, in particular the stage *before* healthcare providers recommended insulin, whereas the current work stream also suggests that this may remain the same even *after* insulin has been suggested by healthcare providers, the time when patients actually need to make the decision.

For instance, regardless of having several months to consider whether or not to move onto insulin since his healthcare provider first suggested it, patient 3 could not recall having had a detailed discussion about insulin during that time:

'The first time he [healthcare provider] suggested [starting insulin] was about six months ago and then again about three months ago. And then, the last time when they suggested it… It wasn't until last Friday really, well, when I was in hospital they explained to me that it's much better for me to go on insulin... But [initially], they just told me that I should go on it… They didn't really explain anything… I was told I should do. I refused...and that was the end of the conversation, really. I carried on with the tablets like that'.

[ii] Although many people did not necessarily report it on tape, when the tape was switched off a striking number of people said that they did not know insulin is used to treat type 2 diabetes before seeing the advertisement for this study.

[iii] During the interviews, I did not correct participants' misconceptions about insulin and type 2 diabetes, but made sure that they had access to the appropriate resources (e.g. Diabetes UK website) after the interviews.

Accounts of a minority who reported having to make the decision to start insulin at the time when it was first recommended by their healthcare providers also suggest that insulin was not communicated by their healthcare providers until the very time that a decision was made:

> *'Making the decision to move onto insulin treatment…It had never been suggested to me...Nobody had said anything to me until it came to that point, until that consultant said, "right, I'm going to put you on insulin"…Nobody has explained anything...I really wasn't given any information' (Patient 30).*

> *'I was, I never considered insulin because I was being treated by tablets…I don't think I was really told anything about it…When the doctor said, "I think you would be better off on insulin", I panicked' (Patient 16).*

In these new qualitative interviews, patients raised several factors that may contribute to a lack of communication about insulin between healthcare providers and patients. For instance, many speculated that it was due to healthcare providers' lack of resources (e.g. personnel and time):

> *'I know more or less what's happened is that there are so many patients now, so many people and they haven't got enough people and staff to deal with everybody quickly…They haven't got enough…resources…not enough staff' (Patient 3).*

> *'They [GPs] should sit down and talk and explain everything [about insulin] …[But] GPs nowadays are cutting all the corners. They haven't got time…They literally haven't got time for their own patient to sit down and talk…My GPs probably haven't told me anything [about insulin], because they haven't got time to explain. They are always thinking what about the next patient outside… I always talk about GPs with my family and say "all GPs are the same. They haven't got much time on their hands"' (Patient 26).*

Some wondered whether healthcare professionals were concerned not to scare patients or wanted to give them time to adjust:

> *'There is sometimes a reluctance on the part of the nurses and the doctors to tell people everything, because they don't want to shock them too much...So they are perhaps told about dietary needs, but not necessarily—I think it maybe that doctors and nurses make assumptions about people, which might not necessarily be well founded. As I say, they don't want to shock them into telling them the reality. So they will talk around the houses and not come up with the full story' (Patient 29).*

> *'At the time I was diagnosed, I was, I hadn't actually got through that process of accepting and I think perhaps and I can understand why the GPs do it [not mention insulin in the early stage of disease], you know. Just give a tablet, because that's easier for that process. I think you have to go through that process of acceptance' (Patient 33).*

Patient 10 assumed such a lack of discussion about insulin was owing to their healthcare providers' judgement that patients do not need to know about insulin at the early stage of disease:

> *'As I say, the impression I am getting is that if I haven't been told that insulin would ever be a feature, again, that's probably maybe because I don't need it at the moment'* .

Patient 30 also expressed the belief that healthcare providers may choose not to discuss insulin because they want to postpone initiation:

> *'He [GP] didn't explain anything [about insulin]. No, because I think they also try and put it off as long as possible before you go on the insulin, if you are type 2'.*

A reason for the lack of communication was also attributed to patients themselves:

> *'It wasn't really explained why I should change to insulin. I was told I should do. I refused. It's my fault as well, because I refused… I was in denial. I didn't want it at the beginning, so I didn't ask why… I just dismissed it and said, "no, I don't want it". They didn't push me' (Patient 3).*

Views and preferences toward the use of peers' experiences in the process of decision-making

The major new findings in this work stream regard the views and preferences toward the use of peers' experiences in relation to decision-making about starting insulin. Evidence on this did not emerge strongly from either the narrative review or the secondary analysis. These were described below under three main themes: *roles of peers' experiences; format of peers' experiences*; and *access to peers' experiences.* Analysis of the data under this heading builds on the work conducted by Wyke et al. (2010) exploring how people view and use different types of information for health-related decision-making[8].

Roles of peers' experiences

During the interviews, participants were asked questions regarding their views toward, use of, and usefulness of information based on shared patient experience *as a supplement to formal support provided by healthcare professionals when making the decision about the initiation of*

insulin therapy. It should be noted that the section draws on comments participants made about information based on shared patient experience in everyday encounters (e.g. informal discussions with other patients) as well as in more formal formats (e.g. support groups) including the formats that were presented during the interview through several sample materials.

With a few exceptions, shared patient experience was seen as valuable when making the decision about insulin. Those patients who valued this type of information saw it as performing various different roles at the time of decision-making, such as helping people gain informational advice on insulin therapy; recognise a diversity of views and experiences of insulin therapy; appraise their own approach to insulin therapy; feel camaraderie and self-reassurance; and gain self-empowerment. Several reasons for choosing not to use shared patient experience information were also reported.

Overall, considerable commonalities in findings about the roles of peers' experiences were observed across the different formats of presenting peers' experiences discussed, and thus this section does not differentiate between the formats except when there is a clear need to do so.

To gain informational advice on insulin therapy

The most notable advantage of shared patient experience in the context of decision-making appeared to be gathering informational advice on insulin. Several kinds of advice were considered crucial to obtain, including: *first-hand experience of insulin therapy that healthcare providers cannot provide; advice that patients felt hesitant to ask of/failed to obtain from their healthcare providers;* and *advice on specific aspects of insulin treatment*. As will be discussed later in relation to Goffman's work on stigma and spoiled identity[9], this may suggest that common experience of physical illness can be a powerful source of motivation for patients to seek such advice from peers.

first-hand experience of insulin therapy that healthcare providers cannot provide

Several participants reported that the use of shared patient experience at the time of decision-making would be/was useful to gain valuable advice beyond what healthcare providers can offer. These people often emphasised that everybody is different in terms of lifestyle, physical response to medicine, and coping methods, but that healthcare providers cannot know all the individual differences and so can only provide patients with standardised, 'one size fits all' advice. They felt that patients themselves can also be another vehicle for supporting their own needs when making the decision.

For instance, when asked about his hypothetical reflection on whether he might have used the sample materials in a context of decision-making, one insulin treated patient described such a role for shared patient experience by using a series of metaphors around learning in a new environment:

> *'You are not going there [support group] looking for factual [information] or statistics... You are going there for advice on how people live in their home with it [insulin] or going out with it… I've always said, people come to this country to learn English and they go to a college or a school. Okay, you can learn the basics almost like a machine. Hello, my name is, Rob, how are you? But in real life to learn the proper language of any country is to go in the street. Nobody speaks the way they teach you… School will tell you the grammar. They will not teach you how people speak in real life, in the real world… You have to learn to be street wise…You go out in the street and it's a different world. It's a different life… Your medical staff will tell you what you should do and shouldn't do. Then you have to put that into practice in the environment… If a doctor tells you, "this is the way to do it" it's because they learned and they have been taught, this is how to do it. But maybe there are different methods of reaching the same target in a different way. You can go to Oxford down the A40 and then the West Way, the quickest way, or you can still get to Oxford by going to Birmingham and come back. You still reach the same target…The GP will guide you in the way they have been taught to guide you. Yes, maybe their way is the most effective. But in real life the most effective doesn't mean it's the easiest for you… Everybody has a different way. Everyone has a different view on what you are trying to achieve. Everyone has got a different method, because everyone's life is different. Everyone's bodies are different. What I take in medicines maybe could kill somebody if their body can't take it if they are allergic to it. If you want to talk to somebody and share your experiences and listen to [experiences of] other people then you are definitely at an advantage' (Patient 3).*

A similar opinion was also heard from one non-insulin treated patient:

'For decision making…in effect, [friend with insulin] probably knows far more than the doctor does. As I said, they are living with it every day… Everybody is different, I suppose is the point. That everybody is going to respond in slightly different ways in the way that all those people, although they had things in common. There were bits that were different about each of them. The GP is not going to know that…They [GPs] can't know everything and they can't know how everybody is going to respond. Reading other peoples' experiences in whatever these forms are is like, okay, I understand that. I can see how that would be [advantageous]' (Patient 13).

Likewise, one insulin treated patient who had been using an online forum since she was diagnosed recalled the time when she was in the process of decision-making, and explained:

'You were talking to people who were doing it [insulin]. They knew. They knew what it was like to start off as well… Because other people have been there and other people have done it. They have got first-hand experience and no doctor can have first-hand experience of every single thing... Everybody is different. I mean, that's the one thing that comes out of anything from forums. Everybody reacts to different situations. Some people can eat Weetabix, I can't' (Patient 24).

Hope of using shared patient experience to gain special '*tips and tricks'* that are not available form healthcare providers was also raised by some non-insulin treated patients even before presentation of the sample materials:

'They [other patients with insulin] have tips and tricks and they have been through it. They have got experience. I can talk to my GP but he's not diabetic. How does he know what it's like? He just signs a bit of paper [3 sec pause]. They have looked through my information and if doesn't apply and not everything would apply to me then I could go on the forum and ask people' (Patient 15).

'The other thing which I think would be very very useful would be to be able to talk to people who are already using insulin. So I could get an understanding on a personal basis as to how people have found the experience and how they cope with it and any issues they have and that sort of thing. I think that would be, if I did have to make that transition, I think that would be a very useful thing for me to do… And the day to day living with it… Does it cause any impediments? Does it cause any inconvenience and if so, how do people deal with it… I try and you know, make the most of contact with people because it's amazing the truth that people can come out with that can feed into your understanding of what's going on. That is why I mentioned it in relation to diabetes and insulin is that to actually talk to someone that's going through it themselves…You get the truth from people in that situation... If I did have to move onto insulin, I would like the opportunity to meet, in advance with other people who are currently using insulin to talk about how it affects them, the practicalities, daily life, yes. How they feel about it... I would like to hear that from someone that's actually doing it, rather than be told by doctors' (Patient 8).

advice that patients felt hesitant to ask of/failed to obtain from their healthcare providers

Shared patient experience could support patients' decision-making by means of gathering advice that patients feel embarrassed to ask healthcare providers or feel that they cannot raise with healthcare providers.

When asked about their views toward the use of sample materials in the hypothetical decision-making scenario, non-insulin treated patients, especially those who have not yet been recommended insulin by their healthcare providers, explained this as follows:

> *'I would look at fellow sufferers' support as more being something…be able to ask a silly question, "by the way if you put marshmallows in a cappuccino, do you get this happening?" or if you don't…I would look at this fellow sufferers' support more as a way of asking questions that I feel I shouldn't really be wasting the doctor's time' (Patient 10).*

> *'Like some questions you can't ask your GP. The GP might not be around. And then, sometimes, to be honest, I find when I go to the GP, I am afraid to ask him something and feel stupid. They make me feel stupid for asking these questions. In a way, GPs, they don't make you feel welcome. They aren't approachable. It's hard to ask the questions. You might have questions, but you don't feel comfortable asking them, in which case something like that [sample materials containing shared patient experience] could help' (Patient 17).*

These comments may reflect patients' concerns about lack of power, fear of revealing ignorance, and pressure to be a 'responsible' user of the National Health Service (NHS).

advice on specific aspects of insulin treatment

There were some examples in this work stream which suggest that shared patient experience could support insulin decision-making by means of gathering advice on specific physical, technical, and more general aspects of managing insulin.

In terms of advice on physical aspects of insulin, non-insulin treated patients often talked of receiving information from peers about the beneficial impact of insulin on health. For instance, one non-insulin treated patient who was in the middle of making the decision talked of receiving

information regarding the positive impact of insulin on blood sugar levels from his insulin-using friends and family members, which he felt could be useful in making the decision:

> *'I have learned a lot from my family and my friends who have got diabetes, who are on insulin and they always tell me that insulin is a better option than a tablet…What they say, because you are on tablet control, you never had the option to control yourself. You are only following a guideline… What they said, in their case, they can lower or increase their dose. They say, if we go to a party or we think we are going to have a little bit of sweet cake or something or we might have a little bit of alcohol. They increase their does themselves, because they know what their body needs to take… and the next morning when they wake up they will take their blood sugar level still as normal, because they control themselves and they are in control of themselves. With tablet control, I think I cannot increase my dose… This only I learned from other people. I haven't learned from my GP' (Patient 26).*

The use of shared patient experience may also support the decision-making by way of obtaining technical advice on insulin. While such a role of shared patient experience was not reported specifically in the context of decision-making, the data from this and previous qualitative work streams reported that people do indeed have concerns about mastering the proper technical skills necessary for the correct administration of insulin (e.g. how to adjust insulin doses, how to manage hypoglycaemia) prior to initiation. Reassurance on this from shared patient experience could aid decision-making. For instance, before the sample materials were presented, one insulin treated patient who had been using an online forum since diagnosis (and who proved to be a rich informant on online forums) recalled a technical difficulty attached to insulin that she had encountered soon after initiation, and commented that getting advice from someone who has been on insulin could have eased her initiation process:

> *'If only they could, each surgery is going to have people who are on insulin. Even if it's a type 1 on insulin just to give advice. Just to give a helping hand. Just to show them how to load the blasted cartridge. The first pen I had when I changed the cartridge, I broke it, because it has a plunger and I could not get that plunger in. I broke it in half. I could not get the plunger in' (Patient 24).*

The same patient (patient 24) also discussed how the online forum was useful at the early stage of managing insulin as a way of obtaining technical advice on insulin (e.g. how to manage hypoglycaemia, what to do when the wrong dose has been injected or when pens have been damaged):

'You will see I've got a hypo wallet over there, behind you, which has got Glucogel inside it. I've got my Gluco Juice on the shelf there and I've got my packet of—I've got these little boxes of jelly babies in every room of the house. I've got one in the car…I picked it up from here [online forum]'.

'All the information is really from the forums, if I've got questions, problems, queries, like, I've just used the wrong pen and I had just injected fifteen units of my long acting when I am meant to do fifteen units of my short acting, what do I have to do now? There is somebody there. Everybody has seen it done it. Injected the wrong one. Knows what to do'.

'He [her husband] boiled some eggs and put them in the usual place, in the top little drawer of the fridge door. Not realising he was putting them on top of my insulin…All my insulin has now been damaged. this [happened when I] was in the caravan so he popped them in a freezer… These things happen. Okay, so you go [to the forum] and say, how dangerous is it? They've only been in there for half an hour. Do I really need to throw them all out? And the answer came back, well, yes, really to be on the safe side, you ought to just, unless you can't get replacements in the short amount of time. The advice was, you are entitled to have an emergency prescription in situations like that. Like telling you, make sure you always carry two pens. Get a spare set. Doctors don't tell you that… They don't actually tell you when you start off, make sure that you have always got your pens and a spare'.

Some participants commented on the value of more general advice on insulin from peers when considering whether or not to start insulin. While most did not mention which kind of general advice they meant, one insulin treated patient (patient 24 as described above) discussed a specific type of advice that she would find valuable in the decision-making process. A non-insulin treated man in an online curated collection of the filmed narrative interview material talking about his needle phobia prompted patient 24 to suggest that patients like that man could obtain reassuring information from the online forum and prepare for making the decision:

'That one on there saying he was a needle phobic, they do have special needles for children who have to inject who are needle phobic. You don't actually see the needle, because it's held up within it. So you've got the barrel and because you don't see the needle, you haven't got that fear sort of hovering over yourself with the needle, no, the thing and you are actually watching the needle go into your arm. So, that makes it better. And that is what they use on children. Now, if he'd have done any sort of question on the forum, that's the sort of thing that I would then say, did you realise, have you asked your doctor, you can have this. That is the sort of thing you can do, you see'.

In a similar vein, after viewing a woman in an online curated collection of the filmed narrative interview material discussing her regret at not starting insulin at an earlier stage of the disease despite problems controlling her blood sugar levels by oral medicine, patient 24 recalled the time

when she was in the middle of decision-making, and reflected that the woman in the material could have received some advice from a forum, so that she could have avoided such regret in making the decision:

> *'There is so many thousands of people out there who are going to be going through it. I had a bad experience, but that's made me stronger. I found out far more about it than a lot of other people who are just, like that woman said, sort of, she didn't ask. She didn't push her own case. If she'd been on a forum and explained what was going on, I'm sure they all would have been saying, I think you ought to go back and discuss it with your doctor. You ought to discuss it with your nurse'.*

Also, before being shown the sample materials, patient 24 described some insulin-related information she actually sought from the online forum during the period between agreeing to begin insulin and actually starting treatment (e.g. what to prepare when travelling abroad, where to administer injections in a public place). Again, while this was not reported specifically in the context of the decision-making process, the data from this and previous work streams reported that people do indeed have concerns over such inconvenience that may restrict their lives. This may suggest that for those who have anticipated *fear of leading a restricted life*, shared patient experience can support their process of decision-making:

> '*Make sure when you get a letter from your doctor if you are travelling by plane that you don't have it time limited. Ask for an open ended one. Silly things like that. If possible get it from your DSN [diabetes specialist nurse], because they don't charge you whereas the doctor will. Maybe more now'.*
>
> *'People will say, I am going away for a weekend and what should I do and what do I need? How do I find out and can I keep my insulin, is it safe to keep it in the kitchen and the freezer in the kitchen of the hotel. Should I ask for something special? It's all these what ifs'.*
>
> *'They [online forum] will answer your questions no matter how simple like… Where do you go in a restaurant for heaven's sake? Where are you going to be able to do your injection? I know you shouldn't inject through your trousers, but I am sorry, I often do'.*

To recognise a diversity of views and experiences of insulin therapy

Shared patient experience could be advantageous for decision-making by prompting people to recognise new aspects or experiences of insulin which they had not previously known or considered.

For instance, an online curated collection of the filmed narrative interview material in which a man discussed his preference for starting an insulin regime that allows him to change the dosage depending on what he eats, rather than taking a fixed number of pills that does not allow any flexibility no matter what he eats, prompted some non-insulin treated patients to recognise new aspects of insulin:

> *'There was another thing that was said.. .Oh yes, you could yourself play around with the amount of insulin. That man said that I didn't know that. I thought once it was diagnosed that that's what he stuck with. That's what I saw with my aunt and it's what I do in Dublin when I am at home' (Patient 11).*

> *'It was interesting what… the second chap was saying about that he had to take the same amount of pills regardless of what you are doing. Whereas with the insulin you can tailor it more, which is something I hadn't considered' (Patient 13).*

Several non-insulin treated patients also described how the same material exposed them to others' positive views of insulin that they had not previously considered:

> *'Interesting, very interesting. One of the things I would say about that is the guy who almost preferred to be on insulin as opposed to taking lots of tablets. Now I found that interesting, very interesting… That's one of the first times I've heard of anybody saying, I'd rather be on insulin than taking all the pills. That I found fascinating. That is an eye opener' (Patent 8).*

> *'That surprises me. I am surprised by the amount of people who don't have an aversion to insulin' (Patient 11).*

In some cases, the sample materials helped some non-insulin treated patients simply to recognise the diversity of insulin-related opinions and experiences that others had:

> *'When you go on this site, so many ideas you get… I would not follow all hundred people there. But, just opening your eyes…it will open my brain probably and I can get more knowledge' (Patient 26).*

> *'This [an online curated collection of the filmed narrative interview material] was really good to hear what they were saying. It really does help. It's like for example, if you go and buy a product like when I go on holiday, I check on Trip Advisor and get all the reviews. This one is like, you are getting all the reviews which are very useful' (Patient 17).*

> *'I think it's better to hear ten different opinions and take the generalisation from that and not just one particular person because…everyone's different and it can affect everybody differently, but you take a little bit from each… Surely the more you know about other people's experiences the less frightening it is when it happens to you [when making the decision], I suppose' (Patient 27).*

This is interesting because it might be assumed that people only look at what supports their opinions whereas in fact these findings suggest that people are willing to seek out a diversity of opinions and advice toward/about insulin from peers regardless of whether or not it supports their own existing perspectives. This will be discussed later in relation to the model of patients' peer-to-peer engagement[10].

To appraise own approaches to insulin therapy

Shared patient experience may support decision-making by helping people clarify their own values in terms of which decision most resonates with them, and reflect their own situation in relation to insulin therapy.

For example, an online curated collection of the filmed narrative interview material offered a non-insulin treated patient who had been considering insulin the opportunity to appraise his own past decision about insulin. The material in question showed an insulin treated patient who discussed not starting insulin at an earlier stage of the disease due to her healthcare providers' refusal to prescribe it regardless of her concerns that tablets were not improving her condition. She also voiced her regret at not starting insulin earlier because insulin improved her sugar control much better than tablets. He reflected:

> *'Interesting comments there. But you know, she obviously should have gone on insulin sooner. But, you know, there again, when I was put onto like the slow release metformin, my control was terrible. And, I suppose, at that time, they [healthcare providers] could have put me on insulin. But it's my insistence on staying on the standard metformin and then with all the other drugs they have been putting in as well has basically kept me off insulin' (Patient 25).*

Also, as observed in the narrative review, accounts of some insulin treated patients explaining how they came to the decision to accept insulin suggest that stories/observations of peers helped them clarify their own values regarding their upcoming insulin decision. Before being exposed to the sample materials, they explained:

> *'A friend of mine or a neighbour, he's been offered it [insulin] and I listened to him and what a difference it had made to him and how he went through, about the injection…*

He said, "It's the best thing that ever happened to me." So I thought, maybe… The next time I went in, to the doctor's, I said, look, can we consider this [initiation of insulin], because I am not under control with this. And, he said, "yes", straight away he said, "You can". He said, "There's not a problem… I thought we'd be there in a few years' time" and he said "but we can transfer you onto insulin"' (Patient 33).

'I got more information…from my friend than I did from the actual medical staff… I have a friend, she's been diabetic from nine years old… She's been on insulin for forty years. She explained to me that when you go on insulin,… you are more free to eat what you want, because insulin is going inside you… And she said also… it should be easier to control the sugar levels with the insulin… She told me that it's very beneficial to be on insulin than tablets… I wanted to see how that works' (Patient 3).

'*The reason I am on this [insulin] is because [name of friend], my friend, they put him on it first. After a week, he phoned me up and he said, for goodness sake, get on this stuff. It is so much better' (Patient 23).*

These findings may suggest that information based on shared patient experience of this kind led patients to perceive that insulin may improve their condition (thereby mitigating their *fear of risk to health*) or allow more flexible food intake (thereby mitigating *fear of leading a restricted life*), which in turn, enabled them to clarify their own values in terms of which decision most resonated with them, and to make the decision to accept insulin. This will be discussed later in relation to the self-regulation model[11].

There were also several examples in the data where shared patient experience helped people reflect on their own situation in relation to insulin. A man in an online curated collection of the filmed narrative interview material discussing his preference for insulin compared to oral medicine (described above) for instance, prompted non-insulin treated patients who have been thinking about initiation to reflect on their own situation through exposure to another's perspective:

'Interesting. So insulin is a better option when you come to think of it?
Interviewer: I can't comment on that.
I mean, like that interview that…gentleman says when you take insulin obviously you learn a lot how to control. With tablets, no matter what you eat and no matter what exercise you do… you take in one go… When you hear this group of people, you draw on your knowledge and you might go and start focusing in the right direction rather than going in a different direction…probably that could help me what to do in the future and which is the right direction for me to go about it… if I have to go on insulin' (Patient 26).

> *'What can insulin do for me? Because like too much metformin sort of gives you, you feel very ill. Yes, so we are moving onto insulin and it will give me a better life and that's what he is saying. I know he hasn't moved onto it, but that's what he's talking about, moving onto insulin because then he can have a better life. Anyway, that was just… I've never heard that before. Obviously, having what these people are saying, that's something I've got to look at' (Patient 25).*

Although patient 13 was still in an early stage of diabetes and she had not yet been recommended insulin by her healthcare provider, a similar scenario was also observed in her comment about an online curated collection of the filmed narrative interview material where a woman talking about her regret at not starting insulin at an earlier stage of her disease (described above):

> *'That was informative. It was her personal experiences, because she was saying, "this is how I was when I was just on pills. This is how it's been since going on insulin. It's much better in lots of ways." I think it does give you something to think about. It makes you think, is this something I should consider talking to my GP about'.*

To feel camaraderie and self-reassurance

The use of shared patient experience could potentially support decision-making, in particular, when patients perceived some similarities with the individual in the sample materials (e.g. common disease experiences, characteristics such as age, ethnicity, and hometown, or stage of disease management) since such perceived personal relevance could allow them to develop a sense of camaraderie and emotional comfort in thinking that *'I am not alone'* in going through this process.

For instance, when asked about their hypothetical reflections on whether they might use/might have used the sample materials in a context of decision-making, some patients (insulin treated and non-insulin treated alike) said that being with someone at the same stage of disease progression and at the insulin decision-making stage can be useful by way of gaining a sense of understanding and comfort:

> *'I think the fact that you are there with people the same as you it probably should make you feel more comfortable that you are not the only one… Maybe there will be people there in the same position as me that will need to start it [insulin]' (Patient 3).*

> *'Like those people who were speaking [in an online curated collection of the filmed narrative interview material] they may have family and friends and whatever, but if they are the only one with this problem [making decision to start insulin], it can feel, you can feel a little bit left out… But if meeting someone who is going through it, it will be able to empathise with you' (Patient 28).*

Before being exposed to the sample materials, one insulin treated patient also recalled her own experience of not having been able to discuss her decision with any of her family members, and expressed her retrospective wish to have had a chance to chat about insulin with someone who is in a '*similar situation'* who also faces making the decision. She felt that this '*buddy system*' could have been beneficial in her own decision-making by preventing her from feeling alone:

> *'It's having somebody like that that is in a similar situation to you and that you can perhaps just have a chat with, I think would be probably the only thing that I would say would improve the situation for me, but I didn't have that. Yes, I had somebody across the road who I could speak to. But I didn't have somebody I could really talk to about it [insulin]… I think going onto insulin that might be a good time to get somebody like a buddy system in. That's just an idea, but for me I think that would be—because you know, I couldn't talk to my, my husband doesn't understand these things. He lives with me, but he doesn't understand these things like I do. And like somebody who is perhaps going through the same things as you are. That's the only thing' (Patient 33).*

This evidence suggests that finding similarities with the individual in the sample materials (although what constitutes 'similarities' varies widely depending on individuals) may prompt people to develop an emotional connection with the individuals, which in turn, may enhance individuals' sense of camaraderie. This will be discussed later in relation to transportation theory[12].

Perceived personal relevance through information based on shared patient experience may also allow people to develop a sense of self-reassurance at the time of decision-making. While reading/watching the sample materials, many participants identified some similarities with the individuals in the materials (e.g. similarities in experiences of managing hypoglycaemia, and/or characteristics such as age, ethnicity, and hometown), and made comments such as *'Exactly the way I described', 'That sounds very much like me'*, or *'All that I still experience'*:

> *'I think they are the same age as me basically that were diagnosed. I did have the tiredness and I did have thirst as well…The sweating, that's another one as well, I had*

that before I was on the medication. It was like dripping sweat on my back basically….Yes, I can understand that light headed feeling, definitely' (Patient 6).

'They [type 1 diabetic people] are the ones that know. They are the ones that deal with it [insulin] every day. Even if you are type 2 and someone else is type 1… It's the same symptoms isn't it, pretty much. They are very closely allied. I get advice from type 1 people anyway' (Patient 13).

To gain self-empowerment

Having confidence in one's ability to manage insulin is an essential first step when facing the decision about the initiation of insulin. Consistent with the narrative review, some participants reported that the use of shared patient experience information could potentially be beneficial in their decision-making by helping them build the self-confidence to manage insulin.

For instance, before being exposed to the sample materials, one insulin treated patient reported how an online forum was useful for her in gaining the confidence '*to handle the problems'* when she faced the decision:

'It's knowing how and why. Why does this happen? Why does that happen? This is where the forum is so useful. It gets to the stage where you get more confidence in yourself in being able to handle the problems that it throws at you' (Patient 24).

Some non-insulin treated patients also emphasised the importance of having self-confidence in the process of decision-making, through observing/hearing stories of other patients successfully managing insulin. Before being exposed to the sample materials, patient 8 reported:

'…and I suppose to give me confidence… What I'd like to hear would be someone to be sitting there and someone who is already on insulin saying, yes, I was a bit worried to start with, but it's all right, you deal with it, it's okay. It's not a big problem. You just carry on with life all the medical stuff then that would help me have a clearer picture of the reasons and benefits of actually moving onto it'.

Similarly, an elderly insulin treated man in an online curated collection of the filmed narrative interview material talking about how he successfully copes with a hypoglycaemic episode prompted one non-insulin treated man to have the self-confidence to contemplate potentially taking insulin as he aged, which he felt could be beneficial in his own decision-making:

'The older men, you know, which I expect with me I would expect to be doing that in their 80s, I think. One was about 69 and the guy in his 80s, I would have thought that's

where I would end up being, I think. And they seem to be quite sort of pragmatic and resigned to the fact, but also the fact that they are actually managing it' (Patient 31).

Sometimes patients found it useful to compare themselves with people they perceived to be in a worse situation than themselves. A non-insulin treated man in an online curated collection of the filmed narrative interview material talking about his needle phobia prompted one non-insulin treated patient who does not have such a phobia to build self-confidence by comparing his own situation with this individual who is in a worse situation:

'Not only has he got to deal with that and lifestyle changes, but he's got to overcome needles as well. He's got two major things there. I suppose in a way it makes you feel, well, actually my situation isn't as bad as that. You could say, well, actually you know, you hear other people's stories and you think your situation isn't very good, but you soon see that other people's is worse' (Patient 20).

These accounts may suggest that the way people develop self-confidence in a context of decision-making is not always achieved by only seeing individuals' success stories of managing insulin. This will be discussed later in relation to self-efficacy theory[13] and the concept of downward comparison[14].

Avoiding shared patient experience

A small number of people showed a reluctance to use information based on peers' experiences at the time of decision-making. One of the reasons for not using shared patient experience was a preference for healthcare providers:

'The only person I can really discuss it [insulin] with is my doctor' (Patient 4).

'Well, first of all, I rely on my doctor to think about these things for me' (Patient 7).

Patients' beliefs in personal relevance in terms of disease experience was also raised by some who felt that no two disease experiences can be the same, and thus others' experiences were not something they valued as a source of information at transition (although it should be remembered that some patients who valued shared patient experience thought such variety was helpful):

'I don't think it [support group] would help me to share my experience or to hear about other people's experience. There is no two people's experience that is the same' (Patient 16).

> *'I could see from this information you have just shown me, there are too many different subjective opinions about what is going on and it makes me realise that for each particular individual there is an individual experience, and that doesn't really help me understand my own experience… Every person's experience is different…We are all different and we all have different reactions' (Patient 1).*

Likewise, patients' perceptions about the seriousness of the disease were connected with non-engagement. Several participants who were suffering from other diseases such as Parkinson's disease and cancer, considered diabetes as a non-serious disease compared to the other diseases they have, and felt less of a need for information based on peers' experiences:

> *'Obviously, if you have something really serious, yes, you do put your health first. I wouldn't put sort of diabetes in that kind of class. [Diabetes is more like] If I had a stomach ache or something like that...I have no psychological worries about diabetes at all…I am more worried about the prostate than the diabetes' (Patient 7).*

> *'The thing is that we don't just suffer from diabetes. Most people as they get old. I am over 70. As we get to that age lots of things start going wrong… I don't want to start chatting to people about diabetes. I want to get on with my life' (Patient 4).*

This may suggest that some patients tend to avoid peers' experiences if they consider diabetes as a normal part of life to be expected as opposed to other diseases they suffer. This will be discussed later in relation to the concept of biographical flow[15].

On the other hand, other people may see diabetes as a serious or even life-threatening disease. The desire to avoid hearing/observing others with a worse condition (linked to the concept of downward comparison[14], which will be discussed later) was expressed by several patients as their reason for avoiding this type of information:

> *'I would find that [support group] a little bit depressing. When I go to the diabetic clinic, there were people there that I've seen that I would say are normal. And then I see that they have got one foot bandaged in a special shoe and then both feet and then they are on crutches, then they are in a wheelchair and I say, you know, I don't know the names of a lot of them, but just to sit and chat in the waiting room. And then, one day, they are not there and I ask someone and they say he died. Well, I guess it's a bit depressing. I'd rather shut my mind to it. Perhaps I have got my head in the sand' (Patient 16).*

One of the patients who saw diabetes as serious also felt that diabetes is not an appropriate subject to share with others:

> '*I can talk quite frankly to my doctor. But I wouldn't like to talk about such personal things with—I would have to know them fairly well…Okay, you talk with somebody who is diabetic and you might say, I had a bit of a hypo the other night or something just like that. Nothing more than that' (Patient 16).*

For one insulin treated patient who used to work as a psychotherapist, her reason for not choosing information based on peers' experiences was due to being *'fed up'* with hearing '*people's sob stories'*. Yet, her comment also suggests that people's value for the use of this type of information may change over time:

> *'I don't really want to hear people's sob stories. But then you see, I had to give up being a psychotherapist… because I got fed up with these people and their angst… I thought, pull yourself together…Get a life... So, I don't really want to hear [others' stories about insulin].*
> Interviewer: For example, if it was twenty years ago, do you think you would have joined [a support group]?
> *Yes, I think so, yes. That's very interesting… It depends on where you are. In your life, yes' (Patient 30).*

Format of peers' experiences

Respondents were asked for their views and preferences for different formats of shared patient experience information including an individual's written story, an online forum, a face-to-face support group, a face-to-face one-to-one discussion, and a curated collection of the filmed narrative interview material. There was a great deal of variation in terms of whether, to what extent (several participants ordered the formats to show the hierarchy of their preferences), and how (e.g. preference for using an online forum just for reading but not for contributing) participants perceived particular formats of information as useful. While a face-to-face one-to-one discussion was the least criticised format, a clear preference was not always expressed by the participants and each format contained both negative and positive comments. Some people also stressed the importance of having the option of different formats when presenting information based on shared patient experience.

Online Forum

The subject of online forums generated the most discussion across the participants, and presented more criticism than positive comments. Many people were concerned about its credibility, and reported their discomfort in communicating with strangers online without knowing their true identities:

> *'There are big problems with online stuff, anyway…People don't know whether it's, they are talking to a young guy or a dirty old man. In real life, it happens' (Patient 8).*

> *'I would dismiss that because I don't know who these people are… I have no idea. Absolutely not' (Patient 17).*

Its reliability was also doubted by people who showed concerns over whether the comments posted on the forum can be taken as *'correct advice'* and whether they are constantly and thoroughly monitored by the organisation to provide accurate advice and information:

> '*It could be a little bit of the blind leading the blind…I don't know if this person actually knows what they are talking about and that's my only concern' (Patient 10).*

> *'How do these people think that they'd be medically qualified to give advice to somebody else? I'm a bit worried about things like that…If there's any totally incorrect advice, dangerous advice, yes, that's right, yes… The more I read this I think, don't want to go down that route, really' (Patient 31).*

> *'Is someone monitoring this to say that the information is correct, is accurate?… I think most people just want to condense what they are saying and then don't say enough and then those that say too much might give you too much of the wrong information' (Patient 21).*

Others felt that a forum would not allow them sufficiently quick and easy access to information. Many thought that there was too much information contained on the forum, and expressed frustration in having to filter and identify specific desired information:

> *'There is so much information. Already I feel depressed. I don't like even look at it. Plus, I am very tired and so… I don't really want to be going onto [forum]… There is too much on there. When I go there I get confused' (Patient 17).*

> '*I think that's why I get a bit overwhelmed, a bit phased by the forum, sometimes. I just feel there's just too much [information] and you don't know what to look at. Filtering all the information is that's what I find, the challenge' (Patient 28).*

> *'Sometimes if you posted [on a forum] and you have to go through all the da, da, da to find the information… You have to go through a lot of information to find anything… You've got to come and go through…whatever to get to what you really want to know' (Patient 23).*

Time to read and type may also inhibit immediate connection to the information they want.

> *'It takes a little bit of a time to read through something and… It might take someone some time to read that' (Patient 13).*

> *'It [online forum] is just like on WhatsApp [iv], you are typing somebody and… I said, this is taking too long… I really don't want to have a conversation and have to be typing each thing that I'm thinking… because you know, the brain is too fast for my fingers. It's not possible to have a conversation on WhatsApp, properly… Not going to have the patience to be sitting there typing and all that' (Patient 28).*

For patient 3, his reason for raising the lack of instant access to information came from the forum's possible delay between a user posting queries and receiving a reply:

> *'If I was on the internet and this guy who had this and I am reading that then I have to go on there and type my own. Maybe they have gone to the toilet and maybe they have gone to the shop. It could be two hours before somebody replies' (Patient 3).*

The different patterns in the use of online support networks between older and younger age groups were also evident. Regardless of whether or not they owned a computer, some older participants self–identified as '*not one to do things like that'*:

> *'I don't like online chat rooms. It's kind of like a chat room. Patients exchanging information. Not my kind of thing' (Patient 14).*

> *'It's not my way of doing things, you know… That's for younger people I think, actually… I'm not a child of the Internet. It's come to me late in life… It could be an age thing… I don't do social media' (Patient 31).*

> *'I don't like forums, the blogs and that sort of thing' (Patient 25).*

While positive comments about this format were rare, some talked about its ability to allow people flexible access to information regardless of time and location:

> *'This could be useful if you tried to get—if there is something bugging you in the mind. In the middle of the night, when something is bugging you. There is no- one to talk to, it could be useful for that. [You can ask] what do you think of this injection?' (Patient 17).*

> '*If you live somewhere where there isn't anything like that, so say, you are stuck maybe in the middle of the countryside or something like that then this acts as a kind of virtual support group' (Patient 13).*

Patient 24 who was very enthusiastic about using an online forum also added:

[iv] WhatsApp is a free messaging application that uses a mobile phone's Internet connection to send and receive messages, calls, photos, videos, documents, and Voice Messages

'What about people who are in the country and five miles away from any doctor, pharmacy or even the surgery. That's what you have to think about. That's why online forums are so important for the isolated people in isolated communities' (Patient 24).

Moreover, several participants who showed an interest in making use of this format commonly expressed their views of using it as a way of receiving information (e.g. just reading posted comments) rather than contributing.

Face-to-face support group

As with the online forum, more criticisms than positive views were expressed for this format. Interestingly, some people who expressed reservations about this format were often those who had joined one previously, or run one professionally. One reason for distancing themselves from the group was due to past experiences of encountering a dominant and arrogant attitude of a group member(s) or group organiser who took over a discussion:

'Maybe it's just because of the experiences I've had. Often, the personalities who are there [in a support group] and not necessarily can't guarantee that you are kind of that you will get on. There are often people who will dominate a group, which was happening a bit on Friday that there was a woman who kind of just basically seemed to talk all the time and it was all about her stuff. Since other people were being really quiet and weren't really saying anything. You are thinking well, what are they getting from this experience?' (Patient 13).

'The only difficulty with groups is you might get one or two people taking over and someone who might be a bit more nervous and not joining in very much. That is the problem with groups' (Patient 8).

'He [healthcare provider] decided which support group I would be appropriate for. I then, the next time went to meet the lady who was in charge of that and that's where it all fell apart. She was very aggressive and said… "if you met somebody from the group in the street you wouldn't speak to them and you would just nod and keep walking and you would be doing this" and I thought, I was a bit tearful… All these restrictions and aggression and I thought, it's better not to waste time that maybe there is somebody who will go along with all of that and help me' (Patient 20).

In relation to this, some expressed concerns over the fluid nature of groups, stating that the quality of a group is influenced by its constituent members:

'In a group you get people who have got all different experiences and the quality of the group varies. Some of them talk more sense than others' (Patient 14).

'Support groups can be a bit kind of hit and miss can't they. It can be a little bit luck of the draw, who you are with' (Patient 13).

Others reported doubts about authenticity surrounding individuals' accounts in a group:

'I always avoid groups, any kind of group things, I always avoid. I have done addiction work and alcohol work and group. The group process brings a different dynamic. People aren't as authentic in a group as they are in the one-to-one situation. I think so. Unless you are completely 100% safe, unless you feel that safeness then people won't disclose' (Patient 11).

For several people, their reasons for not choosing a group was to do with their sense of discomfort in sharing experiences in front of many other people:

'I am not very good with lots of people. If it's just one-to-one like you and me, I'm happy with that. When there's lots of other people around, I shut up. I don't do anything. I let them all carry on. I just go into the background' (Patient 25).

'I am not sure whether that people might hold things back and not put the whole story and I probably would be one of those people if I was doing, I wouldn't want everybody to know about me' (Patient 20).

In contrast with online forums, time and location does matter in this format. Some patients expressed their concerns over lack of flexible access to information, in terms of timing of meetings and access to the location:

'There is a problem there. It depends if that support group fit in my timing then I would not mind. It is not, I mean, coming in my timing better, because as I say, since morning when I get up I've got so many tasks to do at home with everything and raising children, cooking and everything so I don't think I can frequent them. I have to take time off from somewhere which I don't think so. I would not prefer that, no…When you go outside [for the support group] and start going and coming back and staying there probably takes about two hours' (Patient 26).

'If I have to make an appointment and I had to take time off work or travel or—it's not going to be local. I would have to wait three or four weeks before I got to my information session. They don't have them every week' (Patient 15).

Some positive comments for using this format were also made. Several people felt that being able to share the same physical space, hear a real voice, and speak to an individual can have more impact as a way of absorbing the information:

'I gained much more from listening and watching people than reading forums or watching videos [an online curated collection of the filmed narrative interview material]… I could show him what I'm doing and he can show me what I should be doing and that sort of thing. They can reinforce things that you see' (Patient 21).

> *'I personally through work I've always achieved more at face-to-face meetings than conference calls and video conferences and things like that. The camera goes off and you think, damn, I should have, I meant to ask that such and such a question. And the meeting has gone' (Patient 12).*

Some people saw this format as allowing instant access to information by directly asking questions and receiving instant feedback:

> *'I would imagine it's so much better if there is a group and you go there and you talk…and there is instant response' (Patient 3).*

> *'If what they say is perhaps not what they meant to say and what they say maybe too deep or their experience was based on something quite different. You've got the chance to ask them straight away' (Patient 21).*

> *'If we are speaking and then I can oh, but I'm not sure about this. It says here that, blah, blah, blah. I can ask questions. That's why I prefer face-to-face' (Patient 28)*

This is interesting since such 'instant access' is available only when patients are in the group due to the inflexible nature of the format in terms of time and location (as discussed above). Once outside the group, there is no such instant access since patients most likely need to wait a number of days or even weeks until the next group meeting. The online forum, however, was criticised for its lack of ability to provide instant access to information regardless of its ability to convey information beyond time and user location, where some people were critical about the forum's possible delay between a user posting queries and receiving a reply (as noted above).

Furthermore, several people who valued this format reported their preference for having a chair person such as either a lay person who has the necessary skills to facilitate people to express their views openly, or a healthcare provider.

Curated collection of the filmed narrative interview material

Both criticisms and preferences were expressed for a curated collection of the filmed narrative interview material[v]. The most common criticism raised by participants for this material was a lack

[v] As noted in section 6.3.2, during interviews, participants were presented with a laminated print-out of a screen shot of an online curated collection of the filmed narrative interview material containing a large sample of patients speaking about their opinions and experiences surrounding insulin

of instant access to information. Since this material does not allow people to directly '*interact'* with the individual, they felt frustrated at not being able to confirm instantly what had been said, ask questions, and receive feedback:

> *'You can't really interact with video tape [a curated collection of the filmed narrative interview material], can you, really? You are taking in the information and you haven't got the opportunity to say, hold on a minute, what did you say just then? Can we go back to that?' (Patient 11).*

> *'The only problem is, you can't ask questions. They may not cover everything that you want to know. So, that's the only drawback… I think because normally you would have something that would spring to mind, I want to find out what happens, you know, what about if you might want to say something… There were times when I felt like asking him [in an online curated collection of the filmed narrative interview material] a question. But because it's a recorded thing, you can't. You just sort of watch it and say, okay, you know, that's nice, that's nice. But I wanted to ask him… But then you can't' (Patient 28).*

> *'I suppose, if you had something specific to ask, obviously these people you can't interact with them' (Patient 17).*

> *'I don't think a video clip [a curated collection of the filmed narrative interview material], because you are not getting any feedback. I think that's important when you start out [insulin]. Even if it's feedback in the way of that which is saying what I want (Patient 24).*

Concerns over lack of instant access to information, specific to an offline format, were also raised. In an online format, the website had the function of navigating viewers to a specific page, whereas there was no such navigation system in the offline format, which was felt by a few people to be a negative since it prevented them from instantly accessing the specific information they want:

> *'If you have got a toolbar down the side that says, kind of insulin and you can click on it and it will tell you stuff and then you can come and go to other places. That would be nice… It's that kind of navigating your way round a site that you can look where you want to look for what you specifically want to look for' (Patient 13).*

> *'It doesn't seem as instantly helpful, the instant information is not… I think videos [an offline curated collection of the filmed narrative interview material] are more difficult because you have got lots of compounding information there that you have got*

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initiation/management, which was extracted from the website http://www.healthtalk.org/. Participants were told that the website is based on research carried out by a team at the University of Oxford. To illustrate how the website would work in practice, participants were shown a DVD containing recordings of several patients speaking about their opinions and experiences surrounding insulin initiation/management (participants were told that these recordings are available from the website mentioned above) (see Appendix 6.5c for sample vignettes). Participants were also told that a curated collection of the filmed narrative interview material can take an offline format such as on DVD.

to sift through to get to the things that you are wanting… rather than taking the information that I am needing to take out' (Patient 19).

By contrast, some participants reported positive comments for a curated collection of the filmed narrative interview material. For instance, having access to a featured individual's expression, body language, tone of voice led some participants to perceive this material as having greater impact and being more entertaining:

'I think it's all psychology, because when you see video clips [a curated collection of the filmed narrative interview material] probably you think somebody is talking to you, isn't it like one-to-one basically? It's not one-to-one, but that's the cycles on one-to-one basis. We are sharing something… With this one I think is more interesting like you are watching TV and watching this one. You are sharing knowledge. As I say, it sounds like it's a bit of a one-to-one, because you are hearing and you are probably seeing someone or hearing. It's interesting' (Patient 26).

'It was just interesting actually seeing a person talking about their experiences (Patient 27).

'You can see the person and you can see the expressions. There is a whole lot of stuff' (Patient 9).

Positive comments specific to an online format, were also raised. Several participants regarded information developers (e.g. University of Oxford) as trustworthy and felt that information presented by them did not promote particular motives and agendas, but were edited properly to preserve authenticity:

'*I think because they are—if it's going to be on a website like this, it's going to be accurate. It's not just somebody there trying to make a face for themselves and make a name for themselves. It's going to be monitored and it's going to be accurate. I could see the accuracy in all those videos [an online curated collection of the filmed narrative interview material] you showed me. I would agree with that' (Patient 25).*

'I am assuming there is some professional, medical review. Yes, they have got interviews of people and their experiences... You or somebody that knows what the condition is actually edited out of the discussion so that they are actually talking about something—that's why I would be more interested in that… I would probably rather be directed to something like that where there appears to be some border editor' (Patient 10).

'I think if it was something like this, I would trust… Because of the organisation of it, the name behind it, the reputation behind it then I would certainly trust that I was talking to a genuine person' (Patient 8).

'It's probably been monitored more. There will be kind of stories and stories like that, if you see what I mean…That is the kind of thing I would prefer, personally' (Patient 13).

Individual's written story

There were both criticisms and positive comments about an individual's written story[vi]. For instance, people who disliked this material were concerned about the time it takes to read a text:

'Some people don't really have the patience to read' (Patent 17).

'Reading takes a little bit of time to do, doesn't it?… It takes a little bit of a time to read through something… It might take someone some time to read that' (Patient 13).

Also, similar to the criticisms raised in a curated collection of the filmed narrative interview material, not being able to directly '*interact'* with the individual in the story made some people worry about this material not allowing them instantly to ask questions or confirm their interpretation of what had been written in the story - a lack of instant access to information:

'You can't ask questions in a magazine...You just sort, you're given information and you read it and you digest it and you interpret it the way that you interpret it… information is there. But it's trying to digest it and understand it, that's the thing. Because there maybe some aspects of it that you are not sure of. And, what does he mean by that or you know and you can't really, the person can't elaborate on it, because they are not there. You can just read it and say, okay, yeah, all right. But what does that mean and what do you mean by that? How would I know about this and you know, you can't again it's just not being able to, unless I can take this and show somebody and say, okay, can you explain that part to me. Can you explain that? What does this mean? etc. It's good, the information is there. But it's very rigid. It's very rigid. You can't really, it's not the same talking to somebody' (Patient 28).

'If I had some questions, obviously I wouldn't be able to ask that… I can understand that reading that you can say, oh yes, and that happened to them and it's happening to me, but you can't actually ask any questions' (Patient 6).

On the other hand, those who liked an individual's written story perceived its authenticity to provide accurate advice and information:

[vi] As noted in section 6.3.2, a laminated print-out of a particular individual's written story surrounding disease/insulin management prepared from http://www.diabetes.org.uk/Type-2-diabetes/ was presented to participants as a sample vignette of online material (see Appendix 6.5a). Participants were also verbally told that presentations of an individual's written story were available in offline formats (e.g. in a magazine).

'It's been moderated, I suppose and somebody has kind of cherry picked in a way it's the information is much more there' (Patient 13).

Positive comments about the story format, especially when presented in an offline format (e.g. magazine), were also reported by those who felt it is much easier to read compared to an online format:

'Yes. Mainly I find their magazine very good, because I can just sit down and read it…and it's easy to read…I like written information. I can open the pages and look at it. I can then get a pen, if I want to and circle it and look at that later. Whereas, you can't do that on a laptop, on a computer or not easily' (Patient 25).

'It's handy having the stories in a magazine, because I can go back and read them… I can look at the magazine and just sit down with a cup of coffee and just have a read and see what people are doing' (Patient 27).

Face-to-face one-to-one discussion

This format was attractive to many participants, and generated much more positive than negative comments among participants. Some people, for instance, saw this format as enabling the delivery of more personally tailored information that matches an individual's needs:

'That would appeal to me more than a group discussion… This is more personal. It's one-to-one... I feel it is more personal because you are talking one-to-one and you have got a specific thing you are going to talk about' (Patient 14).

'That would be good, I think. That's almost like it's a bit more tailor made towards you rather than support groups' (Patient 13).

'There are tons of people like me who would rather be sitting face-to-face having a discussion like this [the interview]. There is two things that happens there. There is the human connection. The shared information but on a personal level' (Patient 11).

For several participants, being able to have '*eye to eye'* or face-to-face contact with an individual led them to perceive that the information had a greater impact:

'I take in and absorb far more information when I speak to people. I like speaking to people… You are actually looking at the person eye to eye' (Patient 11).

'If someone talks to me now, like you are, I much prefer it than someone typing or you understand?' (Patient 3).

As noted above in the section 'face-to-face support group', the comment made by patient 11 who had less doubt about the authenticity of individuals' opinions presented in one-to-one discussions

compared to a group-based discussion, also suggests that this format allows people to judge the authenticity of the information discussed.

A few participants on the other hand, raised negative comments about this format. Patient 17, for example, felt that this format provides fewer opportunities to see various experiences of others compared to support groups:

> '*Probably a group, because you have got more people to share the experience with. If it's one-to-one, it's one person. With a group, like for example, you showed me the five people and I enjoyed that because there was five different experiences. I think it's better. Everybody has got different feelings and ideas. One person can say that whilst other people could say something else'.*

Patient 21's concern over this format was about having fewer chances to meet someone who is '*exactly like*' oneself compared to in a support group environment:

> *'I'm not so sure about a one-to-one. It depends who that person is, I suppose… So I think face-to-face with people, but in a group, I think, because perhaps groups would be better. Because one-to-one has got to be somebody exactly like yourself, otherwise it's wasted' (Patient 21).*

This may suggest that the degree to which each individual wishes to identify 'similarities' with the person featured in the sample materials varies from individual to individual when using this format.

Access to peers' experiences

As noted above, many valued the use of peers' experiences at the time of decision-making, whereas some participants also said that they were not familiar with or had never heard of information based on shared patient experience prior to the interviews. Several participants raised concerns over how and where they could find this type of information in their everyday lives:

> *'A lot of people don't know about this information… I have not heard of that website [online forum] and not heard of this one [a curated collection of the filmed narrative interview material]… I don't see the doctors handing it out… I've never seen anything at the GP that I go to. Nothing. You go to hospital and you see a lot of things about cancer. You see a lot of things out there about smoking but…when is the last time I saw anything about diabetes?... I go everywhere in the community… [But] I've never seen anything locally that is available' (Patient 17).*

'I work in a library so I'm used to kind of doing that sort of thing. I know where to look… But I do think if I wasn't quite so kind of knowledgeable about that sort of thing, how I would have found out information… You do have to go and look for it… You do have to know about the Diabetes UK website. You have to know then to subscribe to the magazine… You have to actively search by yourself... [You] have to be kind of motivated enough to find the information… They don't have leaflets at the practice or anything like that. It was a bit—you have got this, I want you to go straight onto medication. I think sometimes people don't necessarily get things explained to them' (Patient 13).

'But you have to take the initiative to go on it…[and] make an effort to go to your doctor and say, I want to go on this, please. Can you refer me?... It's not automatic' (Patient 14).

Some participants felt that healthcare providers should take the initiative to distribute sources of such information to patients:

'Only thing is that, who is telling this [shared patient experience information] about… It's very important that a GP or diabetic nurse give you information in advance…then there is the chance that people will go and look at this one… But, if somebody else's telling you then it's very unlikely that they will access this type of information' (Patient 22).

'The GPs should do a lot more. They don't provide anything like there is a support group here and I go to the surgery and I have never seen any leaflets around. They should do something there. I think that's where it starts… More needs to be done by the GPs. They are the first port of call' (Patient 17).

'As I say, just the availability of it, really. It's just like it being advertised, I suppose is the point and saying, this is here. This is a resource, rather than it being kind of like something you might stumble on almost by accident… I suppose your health care professionals, in a way, have to be that first port. They are where you are going to go, because you can go to the doctor because you have for whatever medical reason and then you are diagnosed. You are kind of almost dependent of having kind of like information they can give you straight away' (Patient 13).

'Certainly I will look at this [a curated collection of the filmed narrative interview material] and if my GP said, "look, you are pulling your hair out. You are not controlling your diabetes" and sent you off to a support group then I will go' (Patient 21).

Such a role on the part of healthcare providers, especially for people who do not have access to the Internet, was also considered crucial:

'It's a question of if you don't know where to start… where to look. You were say that chap who is kind of he's 81 [in an online curated collection of the filmed narrative interview material]. He was only diagnosed when he was in his 70s, may not have been as kind of au fait with using the computer… If you don't have the resources like that. If you can't get online, how do you find the information. If you don't have access to the Internet, you are dependent on kind of health care professionals' (Patient 13).

'I think the only concern actually is, how would people that are not able to access the internet for some reason going to be helped… There would have to be some capability for people that don't have internet access to get all that information... I think there should be in every clinic at least half a dozen printed versions of like leaflets for those that do not have computer access' (Patient 10).

6.5 Discussion

6.5.1 Main findings and implications for developing a future intervention

The findings from the primary qualitative work stream have a number of implications for developing a future intervention. These are summarised below under two sections including *patients' attitudes and experiences toward potential insulin treatment*, and *views of and preferences toward the use of peers' experiences in the process of decision-making*, which is divided into three sub-sections, namely *roles and contents of peers' experiences, format of peers' experiences*, and *access to peers' experiences*:

Patients' attitudes and experiences toward potential insulin treatment

The primary qualitative interviews, like the narrative review and the secondary analysis, found that patients were in general reluctant to move onto insulin treatment because of a range of overlapping (not mutually exclusive) concerns toward insulin and lack of information. In some cases, patients who were at the early stage of disease management believed that insulin was only used for type 1 diabetes and not for type 2 diabetes. This was evident regardless of patients' educational attainment or length of time having diabetes. Such a misconception may stem from a lack of communication about insulin between healthcare providers and patients prior to insulin. Patients were rarely able to recall having had detailed discussions about insulin with their healthcare providers at the early stage of diabetes. This remained the same even *after* insulin had been suggested by healthcare providers, the time when patients actually need to make the decision. This evidence suggests that there is currently an unmet need to develop an intervention

to support the process of decision-making about starting insulin which can be delivered as a supplement to formal support provided by healthcare professionals. In particular, an intervention that is designed to mitigate patients' concerns attached to specific aspects of insulin may support the process of decision-making and help prevent delay in the initiation of insulin therapy.

Views of and preferences toward the use of peers' experiences in the process of decision-making

Roles of peers' experiences

The analysis suggests that the use of shared patient experience in the decision-making process has valuable potential to help patients gain informational advice on insulin therapy (in particular, first-hand experience of insulin that healthcare providers cannot provide, advice that patients felt hesitant to ask of/failed to obtain from their healthcare providers, and advice on specific aspects of insulin treatment); to recognise a diversity of views and experiences of insulin therapy; to appraise their own approach to insulin therapy; to feel camaraderie and self-reassurance; and to gain self-empowerment. These findings suggest that the use of shared patient experience may be a useful strategy for some patients to support the decision-making process in starting insulin, and that an intervention based on shared patient experience may be particularly helpful in the decision-making process if it is designed to fulfil these functions.

Several theoretical perspectives from a range of disciplines can be drawn on to make sense of what people said about the way in which shared patient experience supports decision-making about starting insulin, and to inform the intervention design (e.g. selection of some key 'peers' experiences' stories):

The self-regulation model[11] is useful for understanding the mechanism of how shared patient experience prompts patients *to appraise their own approaches to insulin therapy*. The model

assumes that social messages (e.g. in this context, shared patient experience in everyday encounters as well as in more formal formats such as an online curated collection of the filmed narrative interview material where peers talked about the positive impact of insulin on health) develop perceptions about treatment (e.g. in this context, participants developed perceptions that insulin might have improved their condition, thereby mitigated *fear of risk to health*), which in turn enables individuals to perform certain coping strategies (e.g. in this context, patients clarified their own values in terms of which decision most resonated with them and/or decided to accept insulin). These findings suggest that the intervention may be particularly helpful by means of performing such roles if 'peers' experiences' stories are designed to include beneficial impacts of insulin on health.

Self-efficacy theory[13] and the concept of **downward comparison** shed light on the way in which patients *gain self-empowerment* through the use of shared patient experience. The self-efficacy theory suggests that if individuals see a model (e.g. peers) reinforcing the behaviour in ways that appeal to them (e.g. in this context, hearing peers successfully manage insulin by coping with a hypoglycaemic episode), they are more likely to have enhanced self-efficacy (participants developed self-confidence in potentially managing insulin). Yet, the way people develop self-confidence may not always be achieved by merely seeing/hearing others' success stories. In some cases, the sample materials prompted participants to build self-confidence by comparing their own situation with the individual in a worse situation (e.g. patients who have more insulin-related worse health). The mechanism of how such a comparison builds self-confidence is understood through the concept of social comparison, which was defined by Wood (1996) as a 'process of thinking about information about one or more other people in relation to the self'[16]. In particular, one such thought process involved in social comparison – 'downward comparison'[17] – assumes that 'persons can increase their subjective well-being through comparison with a less fortunate other'[14]. These findings may suggest that the intervention could enhance patients' self-confidence if 'peers' experiences' stories are designed to include not only peers' success stories ('upward

comparison') but also stories of peers that provide patients with an opportunity to feel superior about their situation through comparison with others in a worse situation.

Transportation theory helps us to understand why shared patient experience prompts patients *to feel camaraderie* (a feeling of 'I am not alone') in particular, when they found something in common with the person in the sample materials. The theory assumes that individuals identify with or develop strong emotions for the people in the narrative if they perceive similarities with them such as type of experience, age, ethnicity, hometown, or stage of disease management[12,18]. This suggests that an intervention that allows patients to find similarities with the character may contribute to the development of camaraderie.

The application of a **model of patients' peer-to-peer engagement[10]** provides insight into the role of shared patient experience as *recognising a diversity of views and experiences of insulin therapy* (e.g. to recognise new aspects or experiences of insulin which patients had not previously known or considered). The model posits that people tend to seek out others' opinions more if their understanding of the condition resonates with others, and if others' views support their own existing perspective. Yet, the findings from these interviews suggest that people are willing to seek out a diversity of opinions and advice about insulin from peers regardless of whether or not they support their own existing perspectives or understanding of the condition. This suggests that individuals' existing perspectives or understanding of the condition do not need to match those of the characters in the intervention when selecting stories to achieve such a role.

A sociological theory that may be of value is Goffman's work on stigma and spoiled identity, where he tried to understand the idea of stigma and what it is like to be a stigmatized individual[9]. One of the things he identified from observing and talking with people with stigma (e.g. physical deformities of the body, character traits, and tribal identity) is how stigmatized individuals (e.g. people with chronic illness) may use contact with others in the same situation to gain practical

advice or '**tricks of the trade**'[vii]. Such comment on 'tricks of the trade' emphasises the potential of the intervention to support decision-making by means of *gaining informational advice on insulin therapy***.** He reports that individuals who share their stigma (in this context, people who suffer from diabetes and who eventually may need to make the decision/have already made the decision about insulin) know 'from their own experience what it is like to have this particular stigma'. As a result, they can provide the individual with tools in accordance with their shared condition in the form of 'tricks of the trade'[9] (in this context, participants wished to obtain informational advice on insulin from peers). The inclusion of stories that enable patients to acquire: first-hand experience of insulin that healthcare providers cannot provide; advice that patients felt hesitant to ask of/failed to obtain from their healthcare providers; and advice on specific aspects of insulin management (e.g. technical, physical, and general) and in particular, that are designed to mitigate their fears and concerns, may be particularly helpful to support decision-making about insulin. More recent articles such as by Dimond et al. (2015)[19] and Friedner (2010)[20] also describe Rabinow's concept of biosociality, which examines the ways in which people develop new models of relating to each other and fostering relationships based on shared biological characteristics (in this context, people who suffer from diabetes and who eventually may need to make the decision/have already made the decision about insulin). Such theoretical ideas may also inform about the potential of the intervention to support decision-making by means of gaining informational advice on insulin therapy.

The concept of **biographical flow** can be used to understand the way in which comorbidity affects patients' perception about diabetes, which in turn leads them to avoid shared patient experience at the point of decision-making. The concept suggests that 'chronic illness may not necessarily be either positively or negatively disruptive, but may instead be accepted as a biographically anticipated "normal illness"' when certain social indicators (e.g. other health conditions, age, and

[vii] Goffman also talks of the 'circle of lament', which helps us to understand why shared patient experience prompts patients to feel camaraderie (a feeling of 'I am not alone').

social economic status) are taken into consideration[15] (in this context, several participants who were suffering from other diseases such as Parkinson's disease and cancer considered diabetes as a normal part of life to be expected, and felt less need for information based on peers' experiences). This may suggest that the intervention based on shared patient experience may not be well accepted among patients who consider diabetes as a biographically anticipated "normal illness".

Also, the analysis found that, due to the on-going nature of the process of decision-making, the value that patients ascribe to different roles of such information can change over time depending on their stage of disease management (e.g. the stage where healthcare providers have already or have not yet recommended insulin). This suggests that a prospective study measuring the influence of the intervention on outcomes at different time points may help an in-depth understanding about how shared patient experience could support the process of decision-making about starting insulin.

In addition, several factors that contribute to patients' reluctance to use shared patient experience at the decision-making process were reported by a few patients, which included a preference for information from healthcare providers, disbelief in personal relevance in terms of others' disease experiences (the view that no two disease experiences can be the same), perceptions about diabetes as a non-serious disease compared to the other diseases they have, a desire to avoid hearing/observing others with a worse condition, perceptions about diabetes as an inappropriate subject to share with others, and being *'fed up'* with hearing '*people's sob stories'*. These findings suggest that a shared patient experience intervention may produce fruitful results if designed to recruit only those who genuinely showed interest in shared patient experience by screening their preferences for such information at the recruitment process.

Format of peers' experiences

The analysis found that each format contained both negative and positive comments and that a clear preference was not always expressed by participants. The importance of providing the option of different formats was also raised by some patients. Nevertheless, face-to-face one-to-one discussion was identified to be the least criticised format among seven formats of shared patient experience, while online forums and face-to-face support groups attracted more criticism than positive comments.

In the course of the analysis, certain features of information presentation commonly valued across the formats were identified, including authenticity/credibility, convenience (whether the materials allowed people to have convenient access to information), and impact (whether the materials have an impact as a way of absorbing information). Among seven formats of shared patient experience, face-to-face one-to-one discussion along with an online curated collection of the filmed narrative interview material were found to satisfy most of these features while the rest of the formats including the online forum, face-to-face support group, an offline curated collection of the filmed narrative interview material, and an online and offline individual's written story were found to represent the opposite.

Moreover, the data described in the 'roles of peers' experiences' section informs certain formats that potentially have a positive impact on insulin decision-making. For instance, an online curated collection of the filmed narrative interview material commonly prompted patients especially those who were in the middle of decision-making, to re-consider their previous decisions about insulin by making them think that they should have started insulin earlier. The same material also prompted patients who are in the early stage of the disease management to talk with their healthcare providers about future use of insulin. There were also several examples during the interviews where patients took the initiative to suggest face-to-face one-to-one discussion as a way of supporting insulin decision-making even before the sample materials were presented.

These results suggest that shared patient experience interventions using formats of face-to-face one-to-one discussion and an online curated collection of the filmed narrative interview material may have the highest potential to be accepted by patients and to positively impact on insulin decision-making.

Access to peers' experiences

This analysis found that patients felt it was important that healthcare providers should take the initiative in providing sources of shared patient experience information to patients. This finding suggests that an intervention based on shared patient experience may be more accepted among potential participants if designed with input from healthcare providers and if this point was emphasised in any information accompanying the intervention. It also suggests that recruitment and delivery of the intervention would be more successful if healthcare providers are responsible for them.

6.5.2 Strengths and limitations

The data from this primary qualitative work have built on the findings from the secondary analysis and the narrative review, by providing evidence to fill gaps identified in the previous work streams. In particular, the interviews provided rich evidence regarding the use of shared patient experience in insulin decision-making. The interviews also added several new perspectives about patients' attitudes and experiences toward insulin while confirming many of the findings identified from the previous work streams. Second, the application of various psychological theories to research findings not only helped to understand how shared patient experience supports decision-making about insulin but can also inform design of an intervention by identifying several key ingredients that could be incorporated based on shared patient experience. Third, the interviews were conducted initially by asking participants broad questions, which explored their general experiences of living with type 2 diabetes from the time when they were first diagnosed. This provided participants with time to make themselves comfortable and think

about or recall their experiences and views toward insulin and their information/support needs before answering the more focused questions that specifically explored their views and preferences toward the use of shared patient experiences. As noted above, there were several examples during the interviews where some patients actually took the initiative to suggest the use of information based on shared patient experience, even before the sample materials were presented. Fourth, the interview was conducted solely by a DPhil student who has a background in health psychology without any personnel with clinical backgrounds such as nurses or general practitioners. This might have helped participants to disclose their honest opinions about their views and experiences in relation to diabetes care including insulin treatment that they receive(d) at clinics (see e.g. the main theme 'communicating about insulin with healthcare providers').

On the other hand, there are several limitations to this primary interview study. The use of purposive sampling enabled the inclusion of people from a wide range of ethnic, social, and educational backgrounds to provide a wide breadth of views and perceptions. Still, the numbers in each category were small (particularly ethnic minority groups as well as female participants). Further investigation with particular groups may provide more depth to various perspectives discussed in this study. Second, in the early interviews, the researcher who did not have much experience of conducting individual interviews was quite nervous about conducting interviews with a stranger, and sometimes failed to focus on what interviewees said despite comments being central to the study, and changed the direction of the topic without probing interviewees' comments. This might have affected potential chances to gain valuable comments that might have enriched this study. However, this study benefited from having supervision from a senior qualitative researcher and a general practitioner, who reviewed early interview transcripts in order to suggest improvements in the researcher's interviewing technique, such as further probing of what the interviewee said. Third, when participants did not have much to say about their views toward insulin, the researcher raised other participants' views (which were obtained from the previous interviews) as examples in order to prompt their response. These examples were often

negative rather than positive views about insulin such as *fear of needles*. This might have influenced their response by guiding their views of insulin toward a negative stance. Fourth, participants were presented with a total of seven formats of information based on peers' experiences during the interviews (three formats were presented using the sample materials, four other formats were verbally explained to the participants). Participants were then asked whether, why, and how such information might be useful for them at the time of insulin decision-making. However, presenting too many formats might have confused participants who were not familiar with this type of information before the interviews, and might have influenced their responses (response bias). This might have been especially true for non-insulin treated patients, since some of them already had difficulty in putting themselves in the hypothetical scenario of making the decision to start insulin, but still had to imagine how such information might be useful for them in such a scenario. One of the sample materials presented during the interview – an online curated collection of the filmed narrative interview material was partly developed by a research team at the University of Oxford. While the participants commonly regarded the developer as a credible source, this might have been influenced by the fact that the researcher herself was from the development team (response bias).

6.6 Reflexivity

Conducting qualitative research is an inherently subjective process in which the researcher is integral. 'Reflexivity' concerns recognition of the influence a researcher brings to the actual conduct of the research[21,22]. Reflexivity enables a researcher to extend his/her understanding of how his/her own actions, values, preconceptions, and perceptions can affect data collection, analysis, interpretation[23], and intervention design. Acknowledging reflexivity thus lets a researcher reflect upon ways in which it might impact upon a qualitative research practice. Also, providing information in terms of both technical details of conduct and potential impacts allows

others to 'scrutinize the objectivity of the investigation'[21], and 'imaginatively replicate studies'[24]. The process of reflexivity could thus identify limitations of the study.

While some questions still remain in terms of how best to practise reflexivity[25-27], Clancy (2013) for instance, suggests that 'to be fully reflexive, researchers need to stand back from their understandings and views of the world to see how and why interpretations have been made, before documenting full conclusions. This is not easy but by researchers writing things down and reviewing them later, this process can begin'[27]. Obtaining the support of a supervisor or colleague who has the courage to question any assumptions made[23] and looking back at field notes[28] are some of the strategies commonly used to practise reflexivity. The discussion below highlights factors such as a researcher's characteristics (e.g. the multiple identities that the interviewer brings to the interview) as well as the role of a researcher at interview (e.g. level of disclosure about the interviewer herself), and how these factors might have influenced the process of data collection/generation (e.g. the design of the data collection, participants' responses), analysis, and/or interpretation.

1) Reflective listening is one of the techniques in motivational interviewing, where a counsellor repeats what patients have said by expressing empathy. This technique is used in counselling to develop a rapport between counsellors and patients and let patients know their counsellor understands them. Because I had a background in psychology, I tried to use this technique during the interviews. Yet in some cases, I felt this technique perhaps reduced the opportunities for the interviewees to construct their thoughts and as a result I could have missed an opportunity to understand what they really wanted to say.

2) I felt a deep appreciation of the contribution and efforts in recounting all the experiences encountered when managing insulin by one particular rich informant. Such feelings created a kind of connection with this participant and perhaps made me more likely to include quotations from

her interview. Due to this, the analysis took considerable thought to ensure it gave interpretation of what was most important to her rather than myself, and ensure her interview was not given undue weight.

3) In the early interviews, I did not feel comfortable sharing personal matters (e.g. age, relationships) with the participants or was not sure of the degree to which I should disclose information about myself. This may have limited the amount of potential information that could have been gained from the participants. Realising that reciprocity could enhance the rapport between myself and the interviewees, I eventually grew in confidence in sharing personal matters. But this is a controversial topic in qualitative interviewing.

4) I had explored patients' attitudes and beliefs toward insulin in the previous two work streams before conducting the present interviews. Such pre-conceived ideas might have made me focus on an interpretation of what had already been identified, therefore inhibiting the identification of new ideas and phenomena that could have been buried in the data of the present work stream.

6.7 Conclusion

The analysis of primary qualitative interviews makes three new contributions to the research on the use of shared patient experience in insulin decision-making among patients with type 2 diabetes. First, it provides primary interview data collected to explore both patients' attitudes and beliefs toward insulin as well as the use of shared patient experience in the process of decision-making about starting insulin therapy in type 2 diabetes. To date, there have been many studies that have investigated patients' attitudes and beliefs toward insulin, whereas the current interviews provide new evidence about the use of shared patient experience in insulin decision-making along with patients' attitudes and beliefs toward insulin. Second, the present analysis

provided empirical evidence built on the findings from the earlier qualitative work streams (the narrative literature review and the secondary analysis). All the data identified in this study amount to promising evidence to inform the development of an intervention that aims to support effective insulin decision-making. Third, this primary qualitative work drew on several theoretical perspectives from various disciplines to make sense of what people said about the use of shared patient experience in insulin decision-making and how an intervention might work.

In the next chapter (chapter 7), the applicability of theories underpinning the causal model of shared patient experience intervention that aims to support the decision-making process in starting insulin therapy will be considered based on the evidence available from this and the previous work streams. Through this process, intervention points that facilitate behaviour change at a theoretical level will be identified (e.g. barriers/enablers that are likely to explain the pathway between shared patient experience and the target behaviour) and the mechanism that is most likely to inform the way in which shared patient experience supports the process of insulin decision-making will be suggested. Also, in light of the evidence obtained from the current work as well as practicality (e.g. feasibility according to available resources), all the formats of shared patient experience will be further assessed to develop an intervention that achieves the greatest good for the greatest number. This will then be used to inform the discussion of the shared patient experience intervention design in terms of what might be the most appropriate, efficient, and acceptable way to deliver a shared patient experience intervention that aims to support insulin decision-making.

6.8 References

1. Ritchie J, Lewis J, Elam G. Designing and selecting samples. In: Ritchie J, Lewis J, eds. *Qualitative Research Practice: A Guide for Social Science Students and Researchers*. London: SAGE; 2003:77-108.
2. Lewis J. Design issues. In: Ritchie J, Lewis J, eds. *Qualitative Research Practice: A Guide for Social Science Students and Researchers*. London: SAGE; 2003:47-76.
3. Arthur S, Nazroo J. Designing fieldwork strategies and arterials. In: Ritchie J, Lewis J, eds. *Qualitative Research Practice: A Guide for Social Science Students and Researchers*. London: SAGE; 2003:109-137.
4. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Methodol.* 2013;13:117.
5. Vaismoradi M, Turunen H, Bondas T. Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. *Nurs Health Sci.* 2013;15(3):398-405.
6. Pope C, Ziebland S, Mays N. Qualitative research in health care. Analysing qualitative data. *BMJ.* 2000;320(7227):114-116.
7. Parkinson S, Eatough V, Holmes J, Stapley E, Midgley N. Framework analysis: a worked example of a study exploring young people's experiences of depression. *Qualitative Research in Psychology.* 2016;13(2):109-129.
8. Wyke S, Entwistle V, France EF, et al. *Information for choice: what people need, prefer and use. Report for the National Institute of Health Research Service Delivery and Organisation Programme.* London: Queen's Printer and Controller of HMSO; 2010.
9. Goffman E. *Stigma: Notes on the management of spoiled identity.* London: Penguin; 1963.

10. Sillence E, Hardy C, Harris P, Briggs P. Modeling patient engagement in peer-to-peer healthcare. Proceedings of the 23rd International Conference on World Wide Web; 2014; Seoul, Korea.

11. Leventhal H. Toward a comprehensive theory of emotion. *Adv Exp Soc Psychol.* 1980;13:139-207.

12. Green MC. Transportation Into Narrative Worlds: The Role of Prior Knowledge and Perceived Realism. *Discourse Processes.* 2004;38(2):247-266.

13. Bandura A. *Social Foundations of Thought and Action: A Social Cognitive Theory.* Englewood Cliffs, NJ: Prentice-Hall; 1986.

14. Wills TA. Downward comparison principles in social psychology. *Psychol Bull.* 1981;90(2):245-271.

15. Locock L, Ziebland S. Mike Bury: Biographical Disruption and Long-Term and Other Health Conditions. In: Collyer F, ed. *The Palgrave Handbook of Social Theory in Health, Illness and Medicine.* Vol 1. UK: Palgrave Macmillan 2015:582-598.

16. Wood JV. What is social comparison and how should we study it? *Pers Soc Psychol Bull.* 1996;22(5):520-537.

17. Locock L, Brown JB. 'All in the same boat'? Patient and carer attitudes to peer support and social comparison in Motor Neurone Disease (MND). *Soc Sci Med.* 2010;71(8):1498-1505.

18. Hinyard LJ, Kreuter MW. Using narrative communication as a tool for health behavior change: a conceptual, theoretical, and empirical overview. *Health Educ Behav.* 2007;34(5):777-792.

19. Dimond R, Bartlett A, Lewis J. What binds biosociality? The collective effervescence of the parent-led conference. *Soc Sci Med.* 2015;126:1-8.

20. Friedner M. Biopower, Biosociality, and Community Formation: How Biopower Is Constitutive of the Deaf Community. *Sign Language Studies.* 2010;10(3):336-347.

21. Snape D, Spencer L. The foundations of qualitative research. In: Ritchie J, Lewis J, eds. *Qualitative Research Practice: A Guide for Social Science Students and Researchers*. London: SAGE; 2003:1-23.

22. Kuper A, Lingard L, Levinson W. Critically appraising qualitative research. *BMJ.* 2008;337:a1035.

23. Jootun D, McGhee G, Marland GR. Reflexivity: promoting rigour in qualitative research. *Nurs Stand.* 2009;23(23):42-46.

24. Lewis J, Ritchie J. Generalising from qualitative research. In: Ritchie J, Lewis J, eds. *Qualitative Research Practice: A Guide for Social Science Students and Researchers*. London: SAGE; 2003:263-286.

25. Riach K. Exploring Participant-centred Reflexivity in the Research Interview. *Sociology.* 2009;43(2):356-370.

26. Engward H, Davis G. Being reflexive in qualitative grounded theory: discussion and application of a model of reflexivity. *J Adv Nurs.* 2015;71(7):1530-1538.

27. Clancy M. Is reflexivity the key to minimising problems of interpretation in phenomenological research? *Nurse Res.* 2013;20(6):12-16.

28. Grant J. Reflexivity: interviewing women and men formerly addicted to drugs and/or alcohol. *Qualitative report* 2014;19(38):1.

6.9 Appendices

Appendix 6.1a: Advertisement material (for community notice board)



Nuffield Department of Primary Care Health Sciences

Paid Research Volunteers Needed

DO YOU HAVE TYPE 2 DIABETES?

&

Are you between 18 and 65 living in the area of London or Oxford?

Those who *have* and *have not* started insulin are both welcome!

What will you be asked to do?

Spend about 1 hour answering questions in an individual interview

Compensation: The cost of any travel expenses incurred & **£20** for your participation in the study

Please contact: Nami Minorikawa

📞 01865 289359

@ nami.minorikawa@phc.ox.ac.uk

Appendix 6.1b: Advertisement material (for newspaper)

Advert title: Paid Volunteers

Advertisement text: DO YOU HAVE TYPE 2 DIABETES? & ARE YOU OVER 18? If so, you are being invited to take part in our research study conducted at Nuffield department of primary care health sciences, University of Oxford! *What will you be asked to do?* Spend about 1 hour answering questions in an individual interview. *Compensation:* The cost of any travel expenses incurred & 20 pounds for your participation in the study. For more information or to find out if you are eligible, contact Nami Minorikawa on 01865 289359, email nami.minorikawa@phc.ox.ac.uk, or NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES, University of Oxford, New Radcliffe House, 2nd Floor, Walton Street, Jericho, OX2 6NW.

Appendix 6-2: Individual participant demographics

ID	Sex	AGE at interview	AGE at diagnosis	INSULIN	MARITAL STATUS	LEVEL OF EDUCATION	WORKING STATUS	ETHNICITY	LOCATION OF INTERVIEW
DIA 1	m	62	60	N/A	separated	Third level	In work	White/Native American	Oxford
DIA 2	m	71	65	N/A	single	Secondary school	Rt'd.	White/British	London
DIA 3	m	54	44	54	married	Secondary school	Not working owing to ill health	White/Other	London
DIA 4	m	72	57	N/A	single	Third level	Rt'd.	White/British	London
DIA 5	m	64	40	60	married	Third level	Rt'd.	White/British	London
DIA 6	m	49	48	N/A	single	Secondary school	Not working owing to ill health	Black/Caribbean	London
DIA 7	m	76	70	N/A	single	Third level	Rt'd.	White/British	London
DIA 8	m	69	47	N/A	married	Third level	Rt'd.	White/British	London
DIA 9	m	63	45	N/A	married	Third level	Rt'd.	White/British	Buckinghamshire
DIA 10	m	39	31	N/A	long term partner	Third level	in work	White/British/Maori	Oxford
DIA 11	f	59	51	N/A	single	Third level	Suspended from working owing to injury	White/Other	London
DIA12	m	65	45	N/A	widowed	Third level	Rt'd.	White/British	Oxford
DIA13	f	51	50	N/A	single	Third level	In work	White/British	Oxford
DIA14	m	66	64	N/A	single	Secondary school	Rt'd.	White/British	Oxford
DIA15	f	52	51	N/A	Divorced	Third level	In work	White/British	Oxford
DIA16	m	74	28	70	married	Other (technical)	Rt'd.	White/British	Oxfordshire
DIA17	f	45	40	N/A (G)	separated	Other (college)	Not working owing to other reasons	Asian/of other origin	London
DIA18	m	65	51	51	single	Third level	Rt'd.	White/British	London
DIA19	f	43	33	33 (G)	married	Third level	in work	White/British	Essex
DIA20	m	57	52/3	N/A	single	Secondary school	Not working owing to ill health	White/British	London
DIA21	m	64	52/3	57	married	Secondary school	Rt'd.	White/Other	London
DIA22	m	56	45	N/A	married	Third level	in work	Asian/Indian	Warwickshire
DIA23	m	61	34	56	single	Third level	Not working owing to ill health	White/British	Kent
DIA24	f	70	66	68	married	Third level	Rt'd.	White/British	Kent
DIA25	m	61	41	N/A	married	Third level	Rt'd.	White/British	Warwickshire
DIA26	m	63	56	N/A	married	Third level	Rt'd.	Asian/Indian	Middlesex
DIA27	f	57	46	N/A	married	Secondary school	Rt'd.	White/British	Essex
DIA28	f	44	39	N/A	single	Other (diploma)	Not working owing to ill health	Black/Caribbean	London
DIA29	m	66	54	58	married	Third level	Rt'd.	White/Jewish	Oxford
DIA30	f	76	56	71	married	Other (diploma)	Rt'd.	White/British	London
DIA31	m	61	57	N/A	married	Secondary school	in work	White/British	Kent
DIA32	m	64	39	39	married	Secondary school	in work	Asian/Indian	London
DIA33	f	50	37	39 (G)	married	Third level	in work	White/British	Oxfordshire
N/A = Not Applicable; G = expereinced gestational diabetes; Rt'd. = retired									

Appendix 6.3: Participant information sheet

Participant Information Sheet

"What would help people in changing to treatment with insulin in type 2 diabetes?"

You are being invited to take part in a research study to find possible answers to the question: "What would help people in changing to treatment with insulin in type 2 diabetes?" This information sheet explains why the study is being conducted and what it means for you if you take part. Please read this leaflet carefully, and talk to other people about it if you would like to do so.

Please telephone or email us if you would like to ask any questions (our contact information is provided at the end of this leaflet).

Please take your time to decide whether you would like to take part. If you decide you want to take part please contact us within two weeks of receiving this information pack.

Information about the research team

This is a research study being undertaken as part of a doctoral degree at the Nuffield Department of Primary Care Health Sciences, University of Oxford. The researchers who are involved in this study are Ms. Nami Minorikawa (doctoral student), Professor Andrew Farmer (professor of general practice), and Professor Louise Locock (associate professor and director of applied research, health experiences research group).

Why is the study being conducted?

People newly diagnosed with type 2 diabetes may successfully manage their condition through meal planning and physical activity. However, sometimes people need to consider taking oral medication (tablets) or moving onto injected insulin if their diabetes is not well enough controlled by diet and exercise alone.

Changing to insulin therapy can feel like a big step and one which people can be reluctant to take. As a result, many people who might benefit from insulin currently do not receive it or do not change to insulin early enough. This study is being conducted to find out what people think would help them in changing to treatment with insulin in type 2 diabetes.

Why have I been invited to take part in the study?

You have been invited to take part because you have type 2 diabetes. We want to talk to people who **are** and **are not** currently using insulin. As a person who is currently using insulin, you have already gone through a process of moving onto insulin and so will be able to tell us about your experience of deciding to start insulin. As a person who is not currently using insulin, you can tell us what you think about insulin treatment in general and what information you would find helpful. Your opinion is important for us even if you are not currently using insulin. This study is being conducted by the University of Oxford and we would like 30 - 40 people to take part.

Do I have to take part?

No. It is your choice whether or not to take part. You can decide not to take part at any point during the study without giving a reason and you can choose not to discuss your responses to the questions if you think that it may make you feel uncomfortable. If you choose to stop taking part, we will delete or destroy any information you have already given us. There is no penalty for withdrawal. If you think you would like to be involved in the study, but would like to talk to us before deciding whether to participate, we are happy to answer all your questions. Please contact us using the email address and telephone number provided on the back of this leaflet.

What will happen if I take part?

If after reading this information leaflet you decide to take part, please contact us within two weeks of receiving this information pack (our contact information is provided at the end of this leaflet), and we will arrange a time to interview you.

What will taking part in the interview involve?

The researcher will ask for some background information about you including what your experience of having diabetes has been to date, and then show you some sample materials

containing different types of health information to give you an idea of how they may be used. You will also be asked how you think this information could be used in the process of deciding whether to start insulin treatment.

You can choose where to be interviewed in a place and at a time that suits you (for example, this may be in your own home or in the Nuffield Department of Primary Care Health Sciences, University of Oxford). The time it takes for an interview varies and depends on how much you have to say, but most interviews last for up to an hour. The interview will be audio recorded but any information you give will remain strictly confidential and you will not be identified in any way in any reports.

Why should I take part?

If you decide to take part you will be helping us to learn about what kind of support people with type 2 diabetes need in starting treatment with insulin, which may help people manage their condition better in the future. We offer **£20** to those taking part in this research and in addition will cover any travel expenses you may incur.

What are the possible disadvantages or risks of taking part?

There are not likely to be any harms or risks to you by taking part in this study. Some people may find talking about their health difficult and the interview can be stopped at any time.

If I take part, will people be able to find out who I am from what I say?

All information you give will remain strictly confidential and you will not be identified in any way in any reports. Your interview will be given a number instead of your name so nobody else will be able to find out who you are. Things that you may say could be quoted directly in our reports, but you will not be named or identified if this is done. The only people who have access to the provided personal data are our research team as indicated above, including Ms. Nami Minorikawa, Professor Andrew Farmer, and Professor Louise Locock. We will keep the recordings of each interview in a safe and secure place for 5 years after the study has been published. All the information we collect will be kept securely according to the Data Protection Act 1998, which is a guide for protecting personal information that people might give to businesses.

What will happen to the results of the study?

The results of this study will be used to guide future work to develop new ways of supporting people with type 2 diabetes in the process of deciding whether to begin insulin treatment. Findings from the study will be published in a peer-reviewed journal and online in University archives, and presented at conferences.

The University of Oxford believes that it is important to share research findings for the benefit of society and the wider economy and, in support of this commitment, has established an online archive of research materials. This archive includes digital copies of student theses successfully submitted as part of a University of Oxford postgraduate degree programme. Holding the archive online gives easy access for researchers to the full text of freely available theses, thereby increasing the likely impact and use of that research. If you agree to participate in this study, the research will be written up as a thesis. On successful submission of the thesis, it will be deposited both in print and online in the University archives, to facilitate its use in future research. The thesis will be published with open access.

If you would like to know what we found out we will give you a separate form to fill in your name and address, and we will send you a copy within two weeks of the study being finalised.

Who is running and funding the research?

This project will be undertaken by the Nuffield Department of Primary Care Health Sciences, University of Oxford.

Has anyone checked the study?

This project has been reviewed by, and received ethics clearance from, the University of Oxford Central University Research Ethics Committee. Two members of the research team (Professor Andrew Farmer and Professor Louise Locock) have also checked the project and have agreed that it can be carried out.

Who do I contact if I have a concern about the study or I wish to complain?

If you have a concern about any aspect of this project, please speak to the relevant researcher, Ms. Nami Minorikawa (Tel: 01865 289359) or Professor Andrew Farmer (Tel: 01865 617942) who will do his/her best to answer your query. The researcher should acknowledge your concern within 10 working days and give you an indication of how

he/she intends to deal with it. If you remain unhappy or wish to make a formal complaint, please contact the chair of the Research Ethics Committee at the University of Oxford who will seek to resolve the matter in a reasonably expeditious manner: Chair, Medical Sciences Inter-Divisional Research Ethics Committee; [Email: ethics@medsci.ox.ac.uk; Address: Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD].

More information and contact details

Contact person: Nami Minorikawa

Telephone: 01865 289359

Email: nami.minorikawa@phc.ox.ac.uk

Postal address: Nuffield Department of Primary Care Health Sciences, University of Oxford, New Radcliffe House, 2nd floor, Walton Street, Jericho, OX2 6NW

Appendix 6.4: Consent form

Consent Form

Title: What would help people in changing to treatment with insulin in type 2 diabetes?

Investigators: Ms. Nami Minorikawa, Professor Andrew Farmer, & Professor Louise Locock

Contact: *Telephone*: 01865 289359, *Email*: nami.minorikawa@phc.ox.ac.uk, *Postal address*: Nuffield Department of Primary Care Health Sciences, University of Oxford, New Radcliffe House, 2nd Floor, Walton Street, Jericho, OX2 6NW

Study purpose: This study is being conducted to find out what people think would help them in changing to treatment with insulin in type 2 diabetes

Please indicate that you understand the following by placing your initials in each box:

1. I have read the study information sheet and had the opportunity to ask questions, and received satisfactory answers	
2. I understand that this project has been reviewed by, and received ethics clearance from, the University of Oxford Central University Research Ethics Committee	
3. I understand that my participation is voluntary and that I am free to withdraw myself or my data at any time, without giving any reason, and without any penalty, by advising the researchers of my decision	
4. I understand who will have access to any personal data provided	
5. I understand how personal data will be stored according to the Data Protection Act 1998, and what will happen to the data at the end of the project	

6. I understand how the research will be written up and published (in journal articles, online University archives, presented at conferences), and how the data will be included in a doctoral thesis	
7. I understand how to raise concerns or make a complaint	
8. I understand the interview will be audio recorded	
9. I understand that audio recordings will be used in research outputs (e.g. academic conferences, journal publications, research archives)	
10. I agree to take part in the study	

Name of participant: _____

Signature:_____ Date:_____

Name of researcher: _____

Signature:_____ Date:_____

Appendix 6.5: Demographic information form

Background information form

The following questions are about *you* and *your diabetes*

1. How old are you in years?

_____

2. How old were you when you were diagnosed with diabetes?
(or approximately how long have you been suffering from diabetes?)

_____

3. If you are currently taking insulin, when did you start to take insulin in terms of age?

_____

4. Are you male or female?

[ ] Male [ ] Female

5. To which of these groups do you consider you belong?

[ ] ASIAN: of Indian origin
[ ] ASIAN: of Bangladeshi origin
[ ] ASIAN: of Bangladeshi origin

[ ] ASIAN: of Chinese origin origin

[ ] ASIAN: of Pakistani origin

[ ] ASIAN: of other origin

[ ] BLACK: of African origin

[ ] Don't know
[ ] Other _____

[ ] BLACK: of Caribbean origin

[ ] BLACK: of other origin

[ ] WHITE: of British origin

[ ] WHITE: of other origin

6. What is your marital status?

[ ] Single
[ ] Married
[ ] Separated
[ ] Divorced
[ ] Long term partner

7. Select the highest level of education you have completed?

[ ] No formal education
[ ] Primary school
[ ] Secondary school
[ ] Third level (degree or higher)
[ ] Don't know
[ ] Other _____

8. What is your working status?

[ ] In work
[ ] Unemployed
[ ] Student
[ ] Retired
[ ] Not working owing to ill health
[ ] Not working owing to other reasons
(e.g. housework, looking after children or other persons)

Name of Participant:_____ **Date:**_____

Appendix 6.6: Topic guide

Introduction

- Introduces myself
- Explains purpose of interview (what you think would help you in changing to treatment with insulin in type 2 diabetes?)
- Explains that I am not a clinician so cannot comment on anything to do with clinical side of diabetes
- Allows me to have some memo while interview

Prior to insulin

I would like to hear about your experiences of having Type 2. You could start from the point when you were first diagnosed with it. I would like you to tell me *in as much detail as possible* what the symptoms were like, what help you were given, what treatment and information you were given, and how you feel about it now looking back.

- I think the first thing to ask you is how you knew you were ill? What happened to make you go to the GPs and seek help?
- What did you know about Type 2 before you got the diagnosis?
- How are you managing your condition at the moment?
- Do you have any thoughts about how your diabetes might be in the future?
  What do you think will happen to you, say… 10 years from now?

View toward insulin

I would now like to move on and talk about your view toward insulin therapy.

- Could you please tell me about your current views on insulin therapy? Is it something you have thought about? What do you think about it?
- Is it something GPs have mentioned?
- Is it something you have discussed with other patients or friends or family?
- Some people I interviewed say that they are worried about (e.g. needle/injection; inconvenience in carrying injection while travelling/eating out; increase of insurance cost). Do you also worry about these things? How do you think of these opinions?

I understand that you have NOT started insulin, but hypothetically speaking, if you were in a position where you had to make a decision whether or not to move onto insulin,

- What support/information do you think could help you when deciding whether to begin insulin?
- How would you prefer to receive information in order to help you make the decision about insulin?
- When people start insulin treatment, there are lots of sources of information available to them, and obviously people will want factual information from their healthcare professionals (HCPs). But, are there other sources of information that you would also find useful?

SPE

One thing you have talked about in the beginning is .... I would like to ask you bit more about using 'experiences of other patients' to help people think about insulin and make decision to move onto insulin… I know that it would be difficult for you to imagine what it means 'using experiences of other patients', So I am now going to show you 3 types of information where patients talk about their own experience of how they manage Type 2 or insulin therapy OR patients share their own experiences of how they manage Type 2 or insulin therapy with other patients.

1) The first type of information is.. This is a single story of one patient talking about how she manages Type 2 Diabetes. This story was available from Diabetes UK website. You can read her experience from here.
2) The second type of information is… Online Forum. Have you ever heard of that?
This is just one example of Online Forum, and this one is called 'www.diabetessupport.uk', and supported by Diabetes UK. You can share and exchange your views and experiences of the disease with many other patients…
3) The third type of information is… This is developed by university of Oxford and it's called, 'healthtalk.org' and it's available online. This is just a screen shot from the computer… If you click here, you can see some video clips where multiple patients talk about their experiences of having Type 2 or managing insulin therapy. Here you can't interact with other patients as in 'online forum', but you can see actual patients and hear them talking. I will now show you some video clips. Some of them are available from this website while some are not.

Thank you very much… so please let me summarise what we have seen. I now showed you several types of information which contain experiences of other patients:
1) The first type of information was a single story of one patient talking about her illness experience. This one needs to have an online access, but you can also read information based on experiences of other patients such as from diabetes magazines. The point of the first type of information is that <u>you can read</u> experiences of other patients either from online or through magazine.
2) The second type of information was Online Forum where you can share/exchange your views/experiences of the disease with other patients. Again this one uses computer and you need to have an online access, but you can also share and exchange your views and experiences of the disease with other patients if you join a face-to-face support group or individual-based face-to-face support (E.g. scenario where your HCP introduces you one of his patients who has already started insulin treatment and you have a chance to discuss about insulin with that patient). The point of the second type of information is that <u>you can share/</u>exchange your views and experiences of the disease with other patients either online or through face-to-face interaction.
3) The third type of information was video clips of several patients talking about their disease experiences. Here, you can't interact with other patients as in Online Forum or face-to-face support group, but <u>you can see</u> <u>and hear</u> actual patients talking about their disease experiences.

- People will want information from their HCPs when starting insulin, but do you think that you would consider these kinds of information based on 'sharing experiences' as a supplement to advice/information from HCPs, <u>when making the decision over whether to</u>

begin insulin? *this is just an example so the contents of these information do not necessarily be the ones.

- Would these types of information be something you might think useful when making the decision over whether to begin insulin?

  If NOT useful, What are your issues with using these types of information?

  If YES useful, Why? & What benefits/risks do you think there might be to sharing experiences?
- Some people I interviewed say that they hope that this kind of information might provide them with the opportunity to gain more insight & knowledge about insulin/the impact of insulin on their health and well-being. Others also say they predict that this kind of information might offer them some emotional support. What do you think of these opinions?
- Some people I interviewed say that they want to avoid seeing depressed people/they feel that this kind of information (based on 'sharing experiences') might not provide them enough useful info / they have sufficient support from your family members or cultural considerations. What do you think of these opinions?
- Why/How different the info from GPs and peers

(Format)

- How would you prefer to receive information based on 'sharing experiences' to help you make the decision about insulin initiation?
- Do you suggest any other forms of presenting 'patients' own experiences' to help you make the decision about insulin initiation?
- If you use information based on 'sharing experiences' either online, through magazines, or in a support group, what type of online website, magazine, or support group do you trust as a source?

FINAL Qs

- We have reached the end of our interview.
- We have discussed the use of information based on 'sharing experiences', and how these types of information could help you make the decision over insulin?
- Is there anything else you would like to add about this topic that we might have missed out?
- Thanking them for their participation.

Appendix 6.7a: Sample material 1 – a laminated print-out of a particular individual's written story surrounding disease/insulin management

DIABETES UK
CARE. CONNECT. CAMPAIGN.

'It was such a relief to be able to share experiences of my condition with others'

John Roberts, who was a patient representative on the NICE guideline development group talks about his experience of diabetes and the importance of receiving ongoing structured education around the time of diagnosis.



"When I was diagnosed with diabetes at the age of 47 I had already been experiencing many of the classic symptoms of the condition, such as regularly getting up during the night to use the toilet, excessive thirst and tiredness. Up until this point, the only other person I had known with diabetes was my grandmother.

"I remember going to visit her as a child and seeing her steel insulin needles being sterilised in a pan on the stove. When my diagnosis was confirmed, I resigned myself to the fact that this was the type of everyday regime I would now have to follow in order to manage my condition.

"Looking back, what I really needed was a book that gave me straightforward facts about Type 2 diabetes based on up-to-date medical knowledge rather than the distorted memory of my youth.

"I needed answers to important questions such as how changing my diet could help my condition, long terms effects, what insulin is and information about medications that could help me. Unfortunately the little information I did manage to obtain was written in medical jargon and I found myself getting extremely frustrated.

"A friend told me about a local support group for people with diabetes, which I reluctantly agreed to attend. It was such a relief to be able to share experiences of my condition with others and receive clear information for the first time.

"Not only did the classes cover information such as what foods to eat, how to understand food labels and possible complications of the condition – the group gave me reassurance that I was not the only person out there who wanted to get answers to separate the fact from the fiction about diabetes.

"I now help in running patient education programmes at the Merseyside Diabetes Support Group. The sessions we run, in line with the X-pert programme, help address issues that often get overlooked in the management and care of diabetes.

"As part of the sessions I run, we take members out on a tour around a local supermarket to address some
common confusion surrounding dietary fat, starchy and sugary foods, salt, fibre and food labels.

"This encourages a diet that is enjoyable and balanced whilst dispelling the concept of 'good' and 'bad' foods. It also allows participants to become familiar with food labels and confident in making

sensible food choices. The programme also includes a close look at carbohydrate digestion and the resulting rise in blood glucose levels, and explanation of health results such blood cholesterol levels, body mass index (BMI) and waist circumference.

“I’m really glad that the new NICE guideline calls for structured education to be offered to every person and/or their carer at and around the time of diagnosis. Being diagnosed with diabetes can throw up questions about how it fits into your lifestyle - from how it makes you feel, to the best ways of managing diabetes when you are exercising.



"Although there’s no known drug to cure the condition, clinicians and other healthcare professionals can provide important practical help to individuals - for example, advice on how to ensure they are getting accurate and helpful blood glucose results.

"By putting a structured education programme in place, people with the condition and their carers will have access to good information when they need it most – this will mean they feel more confident in managing their condition and that they have good information at the right time to help them make decisions about their care that are right for them. ”

Appendix 6.7b: Sample material 2 – a laminated print-out of an online forum where patients exchanged their opinions and experiences about the initiation of insulin

www.diabetessupport.co.uk
talking blood sugars

(UK online community supported by Diabetes UK)

Title of forum: 'Starting on insulin this week! Nervous!'

24-11-2014, 17:19 PM	
eggyg Member Type of Diabetes: **Type 2** Join Date: Nov 2010 Location: Cumbria Posts: 43	Hi all, I haven't been on for quite a while, well actually it's three years. Been burying my head in the sand. Well I can't any longer. A very quick background.... I am not normal! It's ok, I know I'm not. I had most of my pancreas removed because of, luckily, a pre cancerous tumour, in 2007. I was told I could wake up from the op **type** 1 diabetic. I didn't and I lasted until 2010 before being diagnosed diabetic and proceeded to take metformin. The last year or so has been hard, nobody knows how much **insulin** my little bit of pancreas is producing and my BGs are all over the place. **Insulin** was mentioned in the summer but I managed to get my long range bloods down to 59. But the last month I have felt so run down and tired, depressed even, I am generally a very positive person, I've lost a few pounds without trying, I'm only a few pound overweight anyways, thirsty, dry mouth, the usual. My DN asked me to test before meals and bed and through the night, which is fine because I am up at least twice in the night. Running high all the time, I'm not talking 20/30s but 11/12/13/14. So **insulin** it is to be, going to sort it out tomorrow, my DN is going to "throw" out the rule book because I'm not "normal" (in the nicest possible way). I am so worried about hypos, they tried me on Glicazide last year, I lasted 2 days, I was down to 1.5! I need some practical advice from someone who has experienced something similar. I did partake in some correspondence from a couple of people in a very similar situation a few years ago but can't remember their names, I am hoping they are still on here. Any help would be gratefully received. Sorry for the VERY long post. Elaine.
24-11-2014, 21:27 PM	
stephknits Senior Member	Hey there. Not the same, but am not normal too! Started out diagnosed **type** 2, then diagnosed **type** 1 in May. My



Type of Diabetes: **Type 1**
Join Date: Nov 2013
Location: Bury St Edmunds, Suffolk
Posts: 471

pancreas is, I'm sure, still producing a bit of **insulin**, albeit sporadically, which can be a bit hairy.

I felt very nervous and still worry about hypos, but you can start on very small amounts of **insulin** and build up gradually to find the right levels / ratios. What insulins are you starting on?

Let us know about your regime and I'm sure there will be lots of people doing the same thing here.
Best of luck

Yesterday, 06:24 AM

KookyCat
Senior Member



Type of Diabetes: **Type 1**
Join Date: Mar 2014
Location: Lancashire
Posts: 1,652

Hiya Eggyg

It's normal to be a bit scared of **insulin**, but it's actually lovely stuff, you'll feel much better when you have more control and it's much more precise than oral blood sugar medication so hopefully the hypos won't be quite so full on. I'm not in exactly the same situation as you, but Patty Pancreas is definitely still having a crack at **insulin** production, she currently has a sign outside her picket fence (she likes the finer things in life, thatch cottage and Cath Kidston curtains) that reads "happy to help at night, daytime extreme emergencies only". It took a while to work out what that sign said but now we're largely in agreement about her management time and when me and the novorapid take over.

A half unit pen was a life changer for me, who knew half a unit could make so much difference? So definitely ask for one, if they give you novorapid then the echo does half units, not so sure about the others but the nurse should know.

Hypo wise if you test lots you'll learn quickly how you feel when something isn't quite right, you already know what too high feels like, but I worked out fairly quickly what 4.5 and staying there felt like and how it differed from 4.5 and falling lower (wobbly legs and no balance for me!). You can start out cautiously and aim for the upper end of the range until you feel more confident about hypos.

Good luck with it all, shout if you have questions people here are great and a mine of fabulous info and advice

Yesterday, 13:39 PM

eggyg
Member

Type of Diabetes: **Type 2**
Join Date: Nov 2010
Location: Cumbria
Posts: 43

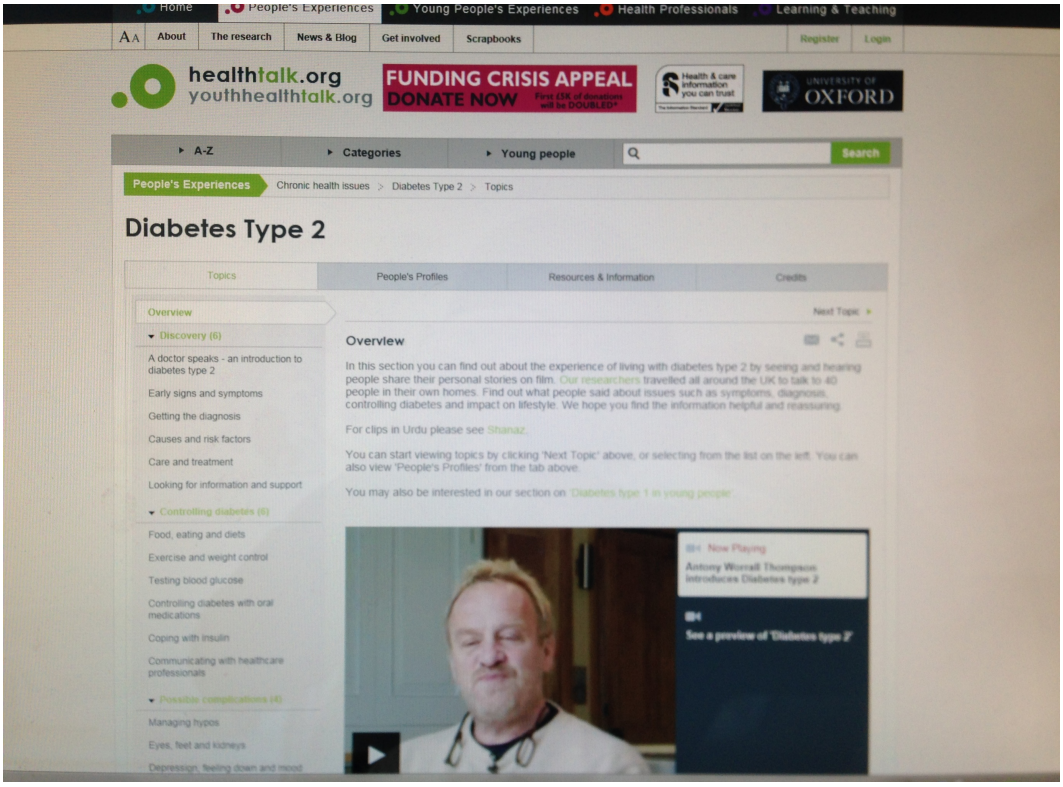
Well, been to appointment, starting on Humulin I, just on 4 units to start, before bed. Have to test 4 times a day and record it. Had the lecture about hypos etc.
Came home with sharps bin, new testing meter, as apparently not allowed to prescribe Freestyle strips anymore because of cost, and loads of pamphlets! It was like Christmas had come early! Back to see DN on Monday. Got a short week at work, thank goodness. But have got a busy weekend lined up, hopefully everything will go according to plan.

	Well, going to stock up on the jelly babies and fruit pastels, yuk! Never liked them even before I became a diabetic. Any other suggestions? Elaine
Yesterday, 14:18 PM	
Shirl1946 Junior Member Type of Diabetes: **Type 2** Join Date: Nov 2014 Posts: 17	Hi Eggy I have just started on Humulin1 and have had no bad affects from it so far I started on 8 units before bed and increase 2 units every 4th day I take my 1st 12 units tonight, at the moment I cannot see any changed my BS are still 9-10 fasting and 15-20 before and after meals. Like you, I am a bit worried about hypos if I get a sudden drop. I am trying to sort my carbs out but being 68 yrs old and the old grey cells slowing down doesn't help...lol I am finding it difficult.. especially what my intake should be. So any help from anyone would be appreciated. I hope you get on with the Humulin ok one thing I will say I feel I have a little more energy and not so lethargic.. hope you feel the benefit soon
Yesterday, 17:20 PM	
KookyCat Senior Member  Type of Diabetes: **Type 1** Join Date: Mar 2014 Location: Lancashire Posts: 1,652	Good luck with the first jab eggy, it doesn't hurt, but takes a while to get used to, there are a variety of needle lengths available though if you do find it uncomfortable. Shirl, it takes a while to get the **insulin** right because everyone needs different amounts. What was your blood sugar when you woke up in the morning?

Appendix 6.7c: Sample material 3 – a laminated print-out of a screen shot of an online curated collection of the filmed narrative interview material containing a large sample of patients speaking about their opinions and experiences surrounding insulin initiation/management

Healthtalk.org

(Collection of patient experience interviews led by the Health Experiences Research Group at The University of Oxford and disseminated through a charity website)



*To illustrate how the above website would work in practice, participants were shown a DVD containing recordings of several patients speaking about their opinions and experiences surrounding insulin initiation/management (participants were told that these recordings are available from the website mentioned above). The followings are actual transcripts from the recordings:

Patient 04 – age 52, Duration since diagnosed 1 year, Non-insulin treated

Interviewer: No. I interrupted you when you were talking to me about the insulin so can we just finish that conversation off? You were talking about you set it up and you said the GP had said at some point it's quite likely that.

Interviewee: Quite likely that I'd have to go onto to to to to insulin. [um]

Interviewee: He said, "You've gone from nowhere to being this very,very diabetic very quickly. The first few months we were fighting this". He said, "It was progressing and we were we were battling as we were, you know, it was changing all the time." He expects that it will progress further in the future, and he expects looking at the drugs he's had to give me the medicines he's had to give me, that I will end up being an injector. [pause 6 seconds] So he's prepared me for that, well he hasn't prepared me for that at all because I'm needlephobic so nothing's going to prepare me for that. [pause 3 seconds] Only one of those Star Trek things, you know [*kerchoo]*.

Patient 14 - age 54, Duration since diagnosed 15 years, Non-insulin treated

Interviewer: So [um] how do you feel about the possibility of being put on insulin?

Interviewee: Not, not worried about it at all. [um] As I said, it, it might be perhaps [um] the, the best way to go because of the amount of tablets I'm taking. If we can reduce that, [um] it might control my diabetes a bit more. [um] Yes, and I know a lot of people that are on, [um] injecting insulin and they generally feel a lot better. They didn't realise they necessarily felt ill when they were on all the tablets, but those that have gone onto insulin generally say, oh, they feel a lot better, you know, because they don't get the highs and the lows. As long as you control it right, they, they seem to, you know, [um] have a, a better lifestyle once they're on the insulin. [um] But we'll let the doctor decide that.

Also with, with being on insulin,-the problem with the tablets, no matter what I eat or what I drink or what exercise I do, I still have to take the same number of tablets day in, day out, day in, day out, whereas the insulin, you can [um] increase it or decrease it depending. If I was going to go out and do 15 miles on the pushbike tonight I would obviously take less insulin, but with the tablets, I have to take the same ones. [um] So you've got better control I think. But it wouldn't worry me at all.

Interviewer: **The injections wouldn't?**

Interviewee: No, not at all, no.

Interviewer: **Because lots of people are quite sort of, it's a big deal for them.**

Interviewee: Oh, yes, I think when I was first diagnosed fifteen-odd years ago, if I'd have gone, you know, they'd have said, "Right, here's a syringe. Here's, you know, you have . . ." I think that could have been a, a, a, a big thing for me. But [um] having been diabetic for fifteen years, taking lots of tablets, [um] yes, it, it wouldn't worry me at all. I think I'd almost welcome it to get away from all the tablets. But, yes.

Patient 17 - age 45, Duration since diagnosed 12 years, Insulin treated

Interviewee: So I was screened and they told me it was 17. And so that was it, I was put on [um] [er] well it was diet based first of all [um] and that did lower my sugar levels. [um] But over a sort of course of time I was then on to tablets which were met- metformin and [um] I [er] then went on [um] to try various different [um] diabetic tablets over the course of the next few years but I didn't, it wasn't very controlled very well [um] and they didn't want to put me on insulin [um] at the hospital because they said it was a fat-producing product [um] so they said that would be a last resort [um] so.. yeah.

Interviewer: **Now looking back on it all, what do you think you could have done differently?**

Interviewee: I think I should have gone on insulin earlier because as soon as I went on insulin, that my sugar levels sort of came down. [um] And it's still, I mean even on insulin, you can still can have high sugar levels, because it does you know, depends on what you eat [um] and it depends on, you know, how regularly you are at you know, making sure you do your injections and all the rest of it. So you still can have high sugar levels but not as high as they used to be on just tablets. [um] So I think I should have gone on insulin, really. But I didn't push it and [pause 3 seconds] you know, that was it. [laughs]

Patient 15 - age 81, Duration since diagnosed 9 years, Insulin treated

Interviewer: Have you ever had a, have you ever had hypo that you have collapsed or something?

Interviewee: No, no, never. I know, I get very, very good warnings. I know when I'm coming down round between the 4 and 3 mark, I know I am coming down and I've got extremely good warnings right from the word go. So I know that I've got to do something and of course I always carry my glucose tablets with me. And I a couple of Mars Bars in my pocket. So, I can always adjust.

Interviewer: How do you know then? How do you know when you're about to …?

Interviewee: I get a light feeling, a funny feeling. I can't really explain the feeling. It's [um] you know when I say a distant feeling. You, you… lightness. I always think if you've had a, a number of drinks and you are starting to go light, you're not drunk, but you're starting to, things aren't quite as sharp as they should be, and it comes on quite, you know, quite, I know when I am coming in to that point between 4 and 3, or 3 and 4 whichever way. [um] I know then that I am going low. I have been low. I have been down to 2.8 but that has been for other reasons, you know when I have [um] gone down, it' s a, not getting my meal on time and that type of thing but you can't always cater for. You try to, you try to sort of, [um] look at all emergencies that could possibly have and try to cater for them. But you can't always, there have got to be times when you can't. And in 10 years, 9 years, I think, I have down pretty well.

DIA24 - age 61, Duration since diagnosed 11 years, Insulin treated

Interviewee: Yeah. I did yes. So you know. You know, you pick up things, but there we are, because you always remember you go to casualty especially with somebody with diabetes who is in a hypo and one of the sisters here used to say, "Go and get a Mars Bar for them." And you know it is only simple things like that but [er] you remember, or a sugary drink. You know, to try to get them to drink it, milk is another thing, which you try and do. Marie biscuits. So, you know you tend to [er] prepare yourself. Afterwards I was prepared for it, you know, I always had something like that. And make sure that you, I make sure that I eat fairly regularly at times, you know within a certain times. Not exactly heavy meals. But may, I have a little something to eat before I got to bed in the night because when you are at rest sometimes you don't want to go want to go hypo in the middle of the night, and you have got to experience being hypo as

well. Because it's really, ah it is something different. It is like walking on eggshells. Its [er] you are sort of like getting a little bit risen, it is just surprising and [um].

There is no pain with it, it is just that you feel that you're in a different part, you are just rising, in my experience that is, you know, [um] but the eggshells, and you know, you start to know how, what you're having and how it was coming about, so you know, even in the, you wake up in the night sometimes, you know, very rarely happens to me, but I have woke up in the night and I've had to get up. I know I am sweating, and [er] so I come down and make myself a piece of toast or some bread or have a drink, biscuit etc. anything, just so that it is quite then. And you, but it's like walking as I say it is walking on eggshells, you know, you know your know your feet are going there, but you know you can't really feel it, as if you are walking.

Appendix 6.8: Thank you note

Thank you note

Following the interview, each participant was sent a personalised thank you note, as well as a reminder that if they have any worries they should not hesitate to ask their GP and/or nurses. The note included the following points:

Dear Sir/Madam

Thank you very much for your participation in this study. Your contribution is extremely valued. If you have any queries about your diabetes management as a result of this study we recommend that you contact your own GP and nurses to talk about it. Again, thank you for taking the time to complete this.

Kind regards,
Research team

Appendix 6.9: Request for the results of the study

Request for the results of the study

I, *(participant's name)*_____ would like to obtain the results of the study.

Address to be sent:

House number or name _____

Street _____

Town or city _____

County _____

Postcode _____

Participant's signature:_____ ***Date:***_____

Chapter 7. Discussion, Proposed intervention design, and Conclusion

7.1 Overview of the thesis

This thesis aimed to answer the following five research questions:

- How had shared patient experience (or had not) been incorporated/defined in previous interventions?

- Could shared patient experience interventions improve health in the context of type 2 diabetes care in general? And what methods have been used to evaluate such interventions (e.g. components of shared patient experience)?

- What does a non-systematic narrative review of the existing literature say and what is known about patients' attitudes and beliefs toward the initiation of insulin therapy as well as their attitudes and experiences in relation to information/support needs (in particular, support through shared patient experience) in the context of the decision-making process to commence insulin therapy?

- How do patients feel about the use of shared patient experience to support the process of decision-making in starting insulin therapy?

- What do these findings suggest would be a possible shared patient experience intervention design to support patients in the process of decision-making in starting insulin therapy?

To address these questions, five work streams were carried out: a review of existing systematic reviews - a definition and systematic approach to components of shared patient experience in adults with type 2 diabetes (chapter 3); a systematic review of randomised controlled trials (RCTs) on effects of shared patient experience on health in adults with type 2 diabetes (chapter 4); analysis of existing sources of qualitative evidence exploring patients' attitudes, experiences, information/support needs in relation to the initiation of insulin therapy including a narrative literature review of qualitative studies (chapter 5 – part 1) and a secondary analysis of an existing collection of qualitative interviews (chapter 5 – part 2); and a new primary qualitative study exploring patients' views and preferences toward the use of shared patient experience to support the process of decision-making in starting insulin therapy (chapter 6).

This chapter reviews how this project adds to existing evidence including the methods used and the results of the individual work streams, and sets out to propose a design of a shared patient experience intervention aimed at supporting insulin decision-making in type 2 diabetes.

7.2 How this project adds to the evidence base

The literature review in chapter 2 identified the following gaps in the evidence base: 1) the lack of a common understanding of the idea of shared patient experience as a concept; 2) uncertainties about the impact of shared patient experience in the decision-making process in type 2 diabetes; 3) the need for a more in-depth understanding about patients' attitudes and beliefs toward the initiation of insulin therapy as well as their attitudes and experiences in relation to information/support needs (in particular, support through shared patient experience); and 4) uncertainties about patients' views and preferences toward the use of shared patient experience to support the process of decision-making in starting insulin therapy. Each of these was addressed

by this thesis and contributed to the design and delivery of the shared patient experience intervention aimed at supporting the process of insulin decision-making.

7.2.1 The lack of a common understanding of shared patient experience as a concept

The essential first step was to clarify the idea of shared patient experience through the review of existing systematic reviews conducted in a context of type 2 diabetes management in general (chapter 3).

The review explored the 26 systematic reviews and identified 31 RCTs containing the idea of shared patient experience. However, no particular concept that describes the idea of shared patient experience was observed in such RCTs. These RCTs were, therefore, further analysed, and a working definition for the idea of shared patient experience was proposed, which was defined by the author for the purpose of this study as the "*Provision of and/or learning from patients' personal accounts about health, health care, and health decision- making"*. The review suggested that research on shared patient experience in type 2 diabetes care is still in its infancy but that the utilization of a consistent definition of shared patient experience would provide greater standardisation of the concept among researchers, and advance the existing research on shared patient experience in this research field.

In addition, the review found that currently the likelihood of finding systematic reviews on shared patient experience in adults with type 2 diabetes is quite low (hence this is a good gap to fill), and that none of the RCTs included in the systematic reviews that contain the idea of shared patient experience was conducted in the context of insulin decision-making in type 2 diabetes.

7.2.2 Uncertainties about the impact of shared patient experience in the decision-making process in type 2 diabetes

The results of the review of existing systematic reviews (chapter 3) demonstrated a need for a new systematic review on the effect of shared patient experience in adults with type 2 diabetes, and informed the development of such a review by providing a working definition of shared patient experience. Chapter 4 detailed the systematic review of RCTs on effects of shared patient experience on health in adults with type 2 diabetes.

The results of the review provided promising evidence to inform the potential use of shared patient experience to improve health in the context of type 2 diabetes care in general. Nevertheless, the review could only provide limited evidence on the type of shared patient experience that appears most important to achieving specific outcomes. This reflects the complex and heterogeneous multi-component nature of the interventions, which has been further complicated by poor study design, and incomplete reporting of methodological details. Also, the evidence from this review was not specific to the context of decision-making in starting insulin in type 2 diabetes, since there are currently no trials on the impact of shared patient experience in such a context. There were still many uncertainties about the evidence to support the design and development of an intervention based on shared patient experience in the process of decision-making in starting insulin therapy.

7.2.3 The need for a more in-depth understanding about patients' attitudes and beliefs toward the initiation of insulin therapy and their attitudes and experiences in relation to information/support, particularly through shared patient experience

To provide evidence to inform the design of a shared patient experience intervention, two qualitative work streams that reported complementary perspectives were conducted, namely a narrative literature review of qualitative studies (chapter 5 - part 1) and a secondary analysis of an existing collection of qualitative interviews (chapter 5 - part 2).

The findings from the two qualitative work streams were fairly consistent and mutually reinforcing. Some of the main findings included: 1) patients were, in general, reluctant to move onto insulin and expressed various concerns that contributed to such reluctance; 2) patients' anticipated concerns over insulin evolved in several ways once insulin had been started; 3) patients expressed concerns over a lack of communication about insulin, and hoped healthcare professionals would bring up the subject of insulin from the early stages of the disease; and 4) patients commonly used peers' experiences (often encountered informally) when forming initial responses to insulin, making decisions to accept/refuse insulin, and managing insulin.

All these findings from the two qualitative work streams amounted to promising evidence to inform the potential use of shared patient experience in the context of insulin decision-making. Nonetheless, the data regarding patients' views and preferences toward the use of shared patient experience specifically in such a context were limited. As such, the evidence was still not sufficient from either of the work streams to inform the development of a shared patient experience intervention that supports insulin decision-making.

7.2.4 Uncertainties about patients' views and preferences toward the use of shared patient experience to support the process of decision-making in starting insulin therapy

New primary qualitative interviews (chapter 6) were conducted to supplement the evidence found from the previous qualitative work streams (chapter 5 - part 1 and part 2), and in particular, to facilitate a more in-depth understanding of patients' views and preferences toward the use of shared patient experience in the context of insulin decision-making.

Crucial new empirical evidence found in this work stream regards the *roles of peers' experiences*: it was found that the use of shared patient experience may be a useful strategy for some patients in insulin decision-making, particularly by helping patients gain informational advice on insulin; recognise a diversity of views and experiences of insulin; appraise their own approach to insulin;

feel camaraderie and reassurance; and gain self-empowerment. The application of various theoretical perspectives to these findings also shed light on some key 'peers' experiences' stories that are likely to prompt such roles.

Other new empirical evidence regards the *formats of peers' experiences*: while face-to-face one-to-one discussion was identified to be the least criticised format among seven formats of shared patient experience, each format elicited both negative and positive responses and a clear preference was not always expressed by participants. The importance of providing the option of different formats was also raised by some patients. Overall face-to-face one-to-one discussion and an online curated collection of the filmed narrative interview material were the formats that were often favoured by patients, satisfied many features of information presentation commonly valued across the formats (authenticity/credibility, convenience, and impact), and/or that patients thought might have a positive impact on insulin decision-making. These results suggested that shared patient experience interventions using these formats and including some key 'peers' experiences' stories (as noted above) may have the highest potential to be accepted by patients and to impact positively on insulin decision-making.

7.3 Proposed intervention design

In this final section, all the evidence identified from the five work streams (as discussed above) is drawn together to inform the design of a shared patient experience intervention to support decision-making about starting insulin in type 2 diabetes. As well as acceptability, the question of what can be delivered practically and efficiently is also considered.

A wide range of approaches to intervention development and evaluation has been proposed, often employing various mapping techniques to guide intervention development[1,2] [i], including RE-AIM (reach, efficacy, adoption, implementation and maintenance)[3], intervention mapping[4,5], and logic models[6]. More recently, the use of the Medical Research Council (MRC) framework for developing and evaluating complex interventions[7,8] has been recommended. The MRC framework provides guidance to assist researchers in designing complex interventions informed by theory and evidence, with attention to the early phases of developing the intervention and trial design. Their model includes the following points: *identifying the evidence base, identifying or developing theory*, and *the modelling process and outcomes*[7,8]. The MRC framework stresses the importance of theory to optimise design and implementation of complex interventions. Theories or models provide an overarching framework (causal pathways) for the behavioural determinants (e.g. psychological and environmental factors) that explain behaviours to be targeted by an intervention[2], and inform components of interventions (e.g. contents) and appropriate outcomes to measure and when to measure them. A theoretical basis also permits predictions to be made for outcomes that are/are not expected to change, which provides a powerful test of the intervention's effects (as discussed in chapters 2 and 4). The MRC framework has, however, also been criticized for not providing clear and detailed instruction on how to develop theory-based interventions[1,9], and some approaches have been suggested to complement it, one of which is a causal modelling approach[1]. A causal modelling approach emphasises the development of a causal pathway (mediating mechanisms of behaviour change) to guide the design of a programme to support behaviour change, in which theory and evidence are used to guide the selection of *theory-based behavioural determinants, intervention points*, *techniques to support behaviour change,* and *measures of change in behavioural determinants*[1].

[i] Each approach varies in the amount of emphasis placed on the implementation process or intervention theory.

Drawing on the MRC framework[7,8] and a causal modelling approach[1], this section describes the development of a shared patient experience intervention aimed at supporting insulin decision-making in type 2 diabetes, with the following steps: identifying/developing appropriate theory (section 7.3.1), defining key behavioural determinants (section 7.3.2), defining intervention components to address key behavioural determinants (section 7.3.3), and choosing outcome measures (section 7.3.4).

7.3.1 Identifying/developing appropriate theory

A selection of relevant theory underpinning causal pathways of shared patient experience intervention that aims to support insulin decision-making was mainly informed by the criteria proposed in the causal modelling approach[1]: 1) clear definition of causal pathways between shared patient experiences, behavioural determinants, and behaviour; 2) use in interventions aimed at similar target behaviours; and 3) applicability to understand patients' accounts of the use of shared patient experience to support decision-making about starting insulin.

For instance, criterion 1 (theories with clear definition of causal pathways between shared patient experiences, behavioural determinants, and behaviour) was explored through the literature review (chapter 2). The review found four theories that meet such a criterion, namely the theory of reasoned action[10], the precaution adoption process model[11], the self-efficacy theory[12], and the self-regulation model[13] (see chapter 2 for detailed description of each theory/model).

Criterion 2 (theories that were used in interventions aimed at similar target behaviours) was explored through the systematic review (chapter 4). The review, however, identified no shared patient experience interventions conducted specifically in the context of insulin decision-making. The review did not, therefore, point to any theories that meet such a criterion.

Criterion 3 (theories that are applicable for understanding patients' accounts of the use of shared patient experience to support decision-making about starting insulin) was explored thorough the narrative review (chapter 5 – part 1), the secondary analysis (chapter 5 – part 2), and the primary qualitative work stream (chapter 6). The qualitative findings point to several theoretical perspectives which may illuminate how the causal mechanisms may work. These theories included the self-regulation model[13], the self-efficacy theory[12], the concept of downward comparison[14,15], the transportation theory[16,17], a model of patients' peer-to-peer engagement[18], Goffman's work on stigma and spoiled identity[19], and the concept of biographical flow[20] (see chapter 6 for detailed discussion of each theory/concept).

After reviewing the utility of a range of theoretical perspectives, two complementary theoretical perspectives, namely the self-regulation model and the self-efficacy theory were considered useful theories to understand causal pathways of shared patient experience intervention that aims to support insulin decision-making.

As discussed in chapters 2 and 6, the self-efficacy theory suggests that seeing a model (e.g. another person with type 2 diabetes) reinforcing the behaviour in ways that appeal to the audience (e.g. peers successfully manage insulin such as coping with a hypoglycaemic episode) could enhance self-efficacy (i.e. patients develop self-confidence in potentially managing insulin by having their *fear of insulin technology* allayed). This in turn influences health behaviours (e.g. patients make the decision to accept insulin). On the other hand, the self-regulation model assumes that social messages (such as stories of peers talking about the positive impact of insulin on health) develop perceptions about treatment (for example that insulin improves patients' physical condition and reduces their *fear of risk to health*). This in turn influences individuals to perform health behaviours (e.g. patients make the decision to accept or refuse insulin). Appendix 7.1 outlines the figures describing the self-efficacy theory and the self-regulation model (the

theoretical components described in each theory are only those applicable for understanding key behavioural determinants selected in the next section 7.3.2).

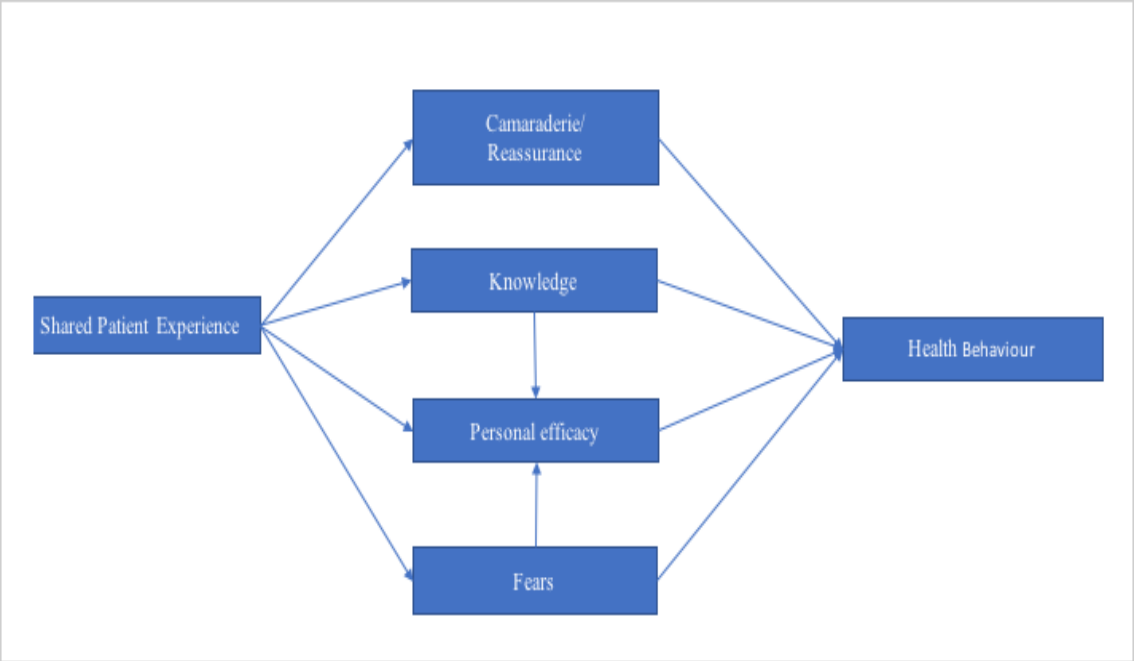
7.3.2 Defining key behavioural determinants

In selecting key behavioural determinants that mediate the link between shared patient experience and the target behaviour (e.g. decision-making to accept insulin), all evidence obtained from the three qualitative work streams was first seen through the lens of two theories (the self-regulation model and the self-efficacy theory selected in the previous section 7.3.1). Then, the final selection of key behavioural determinants was made if they were commonly explained by either/both of the chosen theories and/or if they were commonly observed in the qualitative work streams as the enablers or barriers to the pathways that are likely to link shared patient experience and the target behaviour.

As a result, four key behavioural determinants were selected, namely ***fears*** (including fear of leading a restricted life, fear of discrimination, fear of disease severity, fear of risk to health, fear of insulin injection/technology), ***personal efficacy***, ***camaraderie/reassurance*** and ***knowledge***: fears refer to patients' concerns about several aspects attached to insulin; personal efficacy refers to patients' self-confidence to handle the issues they may have when managing insulin; camaraderie/reassurance refers to patients' sense of camaraderie and emotional comfort in thinking that 'I am not alone' in going through the process of insulin decision-making; and knowledge regards patients' understanding about insulin.

Through the identification of these key behavioural determinants, the causal pathways that are considered most likely to inform the way in which shared patient experience supports the process of insulin decision-making are suggested (see figure 7.1).

Figure 7.1 Causal pathways



Appendix 7.2 describes how the author identified the key behavioural determinants based on the theories and/or the evidence from the qualitative work streams (discussed below in this section - 7.3.2), and then identified key shared patient experience components that address each of the key behavioural determinants (discussed in the next section – 7.3.3). Some examples of how the author selected the key behavioural determinants based on the theories and/or the findings from the qualitative work streams are described below.

For example, one identified key behavioural determinant was ***personal efficacy***. *Personal efficacy* was commonly observed in the qualitative findings as one of the enablers to the pathways between shared patient experience and the target behaviour by building the self-confidence to handle the issues they may face when managing insulin, which in turn, could be/was beneficial in their decision-making (see 'Evidence found in the qualitative work streams' column). Such causal pathways including *personal efficacy* (as an enabler) were also explained by the self-efficacy

theory, in which *personal efficacy* was mapped onto one of the theoretical domains - 'self-efficacy' (see 'Theoretical domains' column).

The key behavioural determinant ***fear of disease severity*** was commonly observed in the qualitative works as one of the barriers to the pathways between shared patient experience and the target behaviour: the qualitative work streams reported that the use of shared patient experience could help patients to overcome such a barrier, which in turn, could be/was beneficial in their decision-making (see 'Evidence found in the qualitative work streams' column). Such causal pathways including *fear of disease severity* (as a barrier) were also explained by the self-regulation model, in which *fear of disease severity* was mapped onto two of the theoretical domains - 'consequence' and 'concerns about medication' (see 'Theoretical domains' column).

While *personal efficacy* and *fear of disease severity* were selected based on the theories and the evidence from the qualitative work streams, ***knowledge*** was selected solely based on the latter: *Knowledge* was commonly observed in the qualitative findings as one of the enablers to the pathways between shared patient experience and the target behaviour by offering advice, exposing people to a diversity of other patients' opinions and advice about insulin regardless of whether or not they supported their own existing perspectives, and providing new aspects of insulin or other patients' views toward insulin which they had not previously known or considered (see 'Evidence found in the qualitative work streams' column). Such causal pathways including *knowledge* (as an enabler), however, were not explained by either of the chosen theories (see 'Theoretical domains' column).

7.3.3 Defining intervention components to address key behavioural determinants

Key elements and contents of shared patient experience that address each key behavioural determinant

The four key behavioural determinants along causal pathways of intervention effects including *fears, personal efficacy, camaraderie/reassurance* and *knowledge* (as identified in the previous section 7.3.2) informed the following eight key elements of peers' stories that are most likely to overcome/enhance such key behavioural determinants. These are described in the 'Key elements of SPE that address each key behavioural determinant' column in Appendix 7.2 (the last column in Appendix 7.2 also describes some examples of shared patient experience contents that reflect such key elements):

1) stories that mitigate fears of leading a restricted life

Stories that are designed to convey information, in particular regarding what to prepare when travelling; how to refrigerate insulin when travelling; where to administer injections in a public place; and how to carry insulin when travelling

2) stories that mitigate fears of discrimination

Stories that are designed to include patients talking about how they see such fear in a more positive light

3) stories that mitigate fear of disease severity

Stories that are designed to increase patients' awareness about the option to initiate insulin in the early stages of the disease and where patients report living well and feeling better

4) stories that mitigate fear of risk to health

Stories that are designed to represent insulin as a protection against progression of the disease (e.g. patients talking about superior effects of insulin in terms of current improved health such as improved blood sugar levels compared with their health condition before the initiation)

5) stories that mitigate fear of insulin injection/technology

Stories that are designed to convey information, in particular regarding how to administer injections; how to mitigate needle phobia; how to cope with a hypoglycaemic episode; and how to adjust insulin dose

6) stories that motivate a sense of personal efficacy

Stories that are designed to include not only stories of peers successfully managing insulin (e.g. by mitigating fears), but also stories of peers perceived to be in a worse situation (e.g. patients who have various fears attached to insulin) successfully managing insulin. Topics of such stories would be similar to those designed to mitigate fears (e.g. fears of leading a restricted life), but emphasise the key element described here

7) stories that motivate a sense of camaraderie/reassurance

Stories from a range of different patients, so that people can find something that resonates with them (e.g. common disease experiences, stage of disease management, or characteristics such as age, ethnicity, and hometown). Topics of such stories would be similar to those designed to mitigate fears, but emphasise the key element described here

8) stories that increase knowledge about insulin therapy

Stories that offer advice, expose people to a diversity of other patients' opinions and advice about insulin regardless of whether or not they support their own existing perspectives, and provide new aspects of insulin or other patients' views toward insulin which they had not previously known

or considered. Topics of such stories would be similar to those designed to mitigate fears, but emphasise the key element described here

Mode of delivery

Evidence to inform the mode of delivery that supports decision-making in starting insulin was mainly obtained from the primary interviews (chapter 6). As noted above in section 7.2.4, face-to-face one-to-one discussion and an online curated collection of the filmed narrative interview material were considered to have the highest potential to be accepted by patients and to impact positively on insulin decision-making. Among these formats, face-to-face one-to-one discussion may be what patients are most likely to favour since this format was identified to be the least criticised. This format enables the delivery of more personally tailored information that matches an individual's needs, and allows patients to directly 'interact' with the individual, so that they can instantly confirm what had been said, ask questions, and receive feedback. Yet, the format poses practical problems and makes it harder to convey a range of perspectives so patients can find something that resonates with them. Flexibility of access is also an issue since the format may not be able to reach the largest number of patients.

On the other hand, an online curated collection of the filmed narrative interview material has sufficient ability to convey most of the key elements of peers' stories (identified above), and the potential to achieve the largest number of patients. Such a format is also considered feasible in terms of cost. For instance, once developed, such a format could come at little or no financial cost to deliver and receive, and could be a highly cost-effective support tool for providers and patients. While the context was not specific to insulin decision-making, there is also evidence suggesting that a shared patient experience intervention using this mode of delivery – a multimedia education programme shown in a waiting room setting led to improvement in the amount of medication consumed/subscribed among type 2 diabetic patients[21]. Yet, the common criticism raised against this format includes a lack of instant access to information since it does not allow patients to

'interact' directly with the individual in the material. It is also hard to deliver personally tailored information.

Both formats (face-to-face one-to-one discussion and an online curated collection of the filmed narrative interview material) have positives and negatives, but they are both promising formats to be included in an intervention based on shared patient experience.

Mixed intervention could be argued – for example one which combines a single session of face-to-face one-to-one discussion with an online curated collection of the filmed narrative interview material for longer term support. Alternatively, an online curated collection of the filmed narrative interview material (or face-to-face one-to-one discussion) could be tested in a trial as a standalone intervention in one arm and in combination with face-to-face one-to-one discussion (or an online curated collection of the filmed narrative interview material) in a different arm.

Design of further pilot and feasibility work

Evidence from the work carried out in terms of ***key elements and contents of shared patient experience*** and ***mode of delivery*** (as described above) suggests that a shared patient experience programme that is likely to facilitate effective decision-making in starting insulin in type 2 diabetes is one that is delivered through an online curated collection of the filmed narrative interview material and/or face-to-face one-to-one discussion. Such a programme shows (various) insulin treated patients talking about their own perspectives and experiences when considering/initiating/managing insulin treatment by conveying the key elements and contents of shared patient experience as identified above. Such mode of delivery(ies) and contents of a shared patient experience intervention would be assessed and evaluated later in terms of acceptability and feasibility of the intervention delivery using the person-based approach[22], and would be modified accordingly (see section 7.5 below for more details about feasibility work). Simultaneously, the detailed protocol of the pilot randomised controlled trial (RCT) that examines

the impact of shared patient experience intervention on patients' perceptions, knowledge, intentions, and decision about starting insulin in non-insulin treated patients in type 2 diabetes would be developed[2,22]. Following the development of feasible and acceptable shared patient experience intervention, the pilot RCT would then be conducted to investigate its efficacy.

For the pilot RCT, male and female non-insulin treated patients with type 2 diabetes aged over 18 and who have reached maximum oral treatment would be recruited from several primary care centres in the United Kingdom (UK). Healthcare providers such as general practitioners would be responsible for recruitment and delivery of the programme (the findings from the qualitative work streams reported patients' preference for healthcare providers taking the initiative to distribute sources of such information for patients, suggesting that such an intervention would be more acceptable if healthcare providers are responsible for recruitment and delivery of the programme). Those who agreed to participate would be scheduled for a visit to their primary care centres for the intervention and randomly assigned to shared patient experience [intervention group(s)] or routine diabetes care (control group). Relevant data would be collected at baseline, and a month or two after the intervention.

7.3.4 Choosing outcome measures

The identification of the causal pathways that are most likely to inform the way in which shared patient experience supports the process of insulin decision-making (see figure 7.1) suggested that the aim of the shared patient experience intervention is to improve *personal efficacy,* reduce *fears* (including *fear of leading a restricted life, fear of discrimination, fear of disease severity, fear of risk to health* and *fear of insulin injection/technology*), and promote *camaraderie/reassurance, knowledge, intentions to accept insulin*, and *actual insulin uptake*.

All these variables are commonly measured using self-report measures. Considering the nature of shared patient experience interventions, where blinding of participants is often not possible,

the use of validated instruments for self-report measures (see chapter 4, sections 4.5.2 and 4.5.3) was considered as the first priority in selecting the appropriate scales in order to minimise bias in patients' outcomes.

A few validated measures exist to assess *fears*, one of which is the Beliefs about Medicines Questionnaire - Specific (BMQ-Specific), developed based on the self regulation model. This scale is designed mainly to assesses patients' beliefs about the necessity of the medicines (prescribed for personal use) for maintaining health – indicating that this mainly assesses *fear of risk to health*, whereas it is not designed to measure various other aspects of *fears* attached to insulin (e.g. *fear of leading a restricted life, fear of discrimination, fear of disease severity, and fear of insulin injection/technology*). The utilisation of the Insulin Treatment Appraisal Scale (ITAS)[23] that is designed to assess perceptions toward insulin treatment of insulin-naive and insulin-treated type 2 diabetic patients, could complement the BMQ-Specific scale since this scale assesses various aspects of *fears* attached to insulin.

There are no known validated/non-validated instruments for assessing outcomes such as *personal efficacy*, *knowledge, camaraderie/reassurance,* and *intention to accept insulin* in a context of making the decision about insulin in type 2 patients. There may be a need to create questionnaires specifically to measure each of these outcomes, such as by modifying existing, validated questionnaires. For instance, such a questionnaire for *personal efficacy* might be the Insulin Management Diabetes Self-Efficacy Scale (IMDSES)[24], which assesses an individual's belief in his/her self-management ability in relation to insulin administration, blood glucose monitoring and other diabetes-related activities of daily living, and which can be used in insulin treated adults (type 1 and type 2). A questionnaire in terms of *knowledge* might be the 9-item insulin-use subscale of the revised Diabetes Knowledge Test (DKT2)[25], which assesses knowledge in relation to insulin treatment, and which is developed for adults with type 1 diabetes and type 2 patients using insulin. For *camaraderie/reassurance* the Interpersonal Support Evaluation List (ISEL)

could be adopted, which assesses the perceived availability of four separate functions of social support including tangible support (to measure perceived availability of material aid), belonging support (to measure perceived availability of people with whom one can do things), self-esteem support (to measure perceived availability of a positive comparison when comparing oneself to others), and appraisal support (to measure perceived availability of someone to talk to about one's problems)[26].

Actual insulin uptake would be assessed through self-reporting by directly asking participants whether or not they have accepted insulin treatment. In addition, the measurement of decisional conflict could be useful to evaluate a shared patient experience intervention and tailor it to particular consumer needs[27,28], which in turn, contribute to promote insulin acceptance. One of the validated measures to assess this is the decisional conflict scale[28]. The scale assesses the level of decisional conflict that patients experience while making health care decisions, and includes the three subscales: 1) uncertainty in making a health-related decision; 2) the factors contributing to the uncertainty; and 3) perceived effectiveness of the decision[28].

7.4 Implications for clinical practice

1) One of the implications for clinical practice is the need to develop an alternative strategy to support healthcare providers to communicate effectively about insulin with their patients. As noted in chapter 2, presently there are various strategies to support insulin decision-making often by equipping healthcare providers to assess patients' concerns about insulin (individually during a consultation or through structured education programmes). Yet, this thesis suggests that patients were in general reluctant to move onto insulin because of a range of overlapping concerns toward insulin, and hoped healthcare professionals would bring up the subject of insulin from the early stage of diabetes. This may suggest that current strategies may not be efficiently used, or may not

be used at all by healthcare providers. Such strategies may not meet patients' needs. Several barriers could contribute to such issues including cost, time, and/or irrelevant topics on insulin that are covered in the programmes (as discussed in chapter 2). In many cases, however, healthcare providers are the first port of call for patients when they think about insulin treatment. Alternative strategies may be necessary to support healthcare providers to communicate effectively about insulin with their patients.

2) The main implication for clinical practice arising from this thesis is the potential value of using shared patient experience programmes to support the process of decision-making in starting insulin in type 2 diabetes. One way to raise awareness of this is by developing guidelines for shared patient experience as a strategy in the context of decision-making. The findings from this thesis suggest that shared patient experience programmes (in particular, an online curated collection of the filmed narrative interview material and/or face-to-face one-to-one discussion which convey(s) the key elements of peers' stories) could be an appropriate, efficient and acceptable way to deliver a shared patient experience intervention. Such programmes also have the potential to support public health systems that face severe resource constraints (e.g. time, money). Yet, there are currently no accepted guidelines for shared patient experience programmes in the context of insulin decision-making. The Health Innovation Network (HIN), for instance, recommends the use of shared patient experience in the process of insulin decision-making in their guidelines developed to support optimal delivery of insulin therapy[29]. These guidelines, however, do not include any detailed information on shared patient experience such as how and which kind of 'peers' experiences' should be delivered by means of supporting insulin decision-making. The development of such guidelines including specific information about shared patient experience (e.g. contents and format) may contribute to the increase in people's awareness of using such a strategy to support decision-making, which in turn, may also accelerate the provision of a potentially flexible and low-cost support for decision-making in insulin.

3) Another implication for clinical practice is the need for healthcare providers to act as a source of distributing information about ways to access shared patient experience. As has been discussed in this thesis, while many patients valued the use of peers' experiences at the time of decision-making, some people were not familiar with or had never heard of information based on shared patient experience prior to the interviews, and reported their preference for healthcare providers taking the initiative to distribute sources of such information for patients. This may effectively motivate patients to use such a programme, and increase the number of patients who use it.

7.5 Implications for research

1) More research on shared patient experience in insulin decision-making in type 2 diabetes should be conducted by consistently using a common definition for the idea of shared patient experience (such as that developed in this thesis). As discussed in chapters 2 and 3, the idea of shared patient experience has usually been grouped under the term 'peer support', whereas the use of the term peer support does not always reflect the idea of 'peers as patients encountering each other in a mutual and non-hierarchical relationship, sharing experiences of illness'. Simmons et al. 2013, for instance, explored the varied meanings of the term 'peer support', and identified a wide range of roles and interactions in the current conception of peer support. There is still disagreement between researchers about what peer support really means. It was assumed that uncertainties about the relevance of studies based on 'peer support' may suggest that there is currently no common understanding of the idea of shared patient experience as a concept in the field of diabetes research. Such an assumption was in fact supported in this thesis (chapter 3), which reported that the idea of shared patient experience was not described as a particular concept in many of the studies that include the components of shared patient experience.

The lack of an agreed and accepted understanding of the idea of shared patient experience causes difficulties when synthesizing studies on shared patient experience and formulating an adequate conclusion about the impact of shared patient experience. The use of a consistent definition to describe the idea of shared patient experience could provide a common understanding of the idea of shared patient experience among researchers, and help consolidate the research in this field and deepen understanding about how and why shared patient experience contributes to health behaviour changes.

2) A new model describing basic frameworks of shared patient experience components that have the potential to support insulin decision-making could be developed based on theories and evidence. The findings from this thesis as well as recent reviews on peer support interventions that include studies on shared patient experience[30-33] all point to the paucity of shared patient experience interventions in type 2 diabetes developed according to a theory-based model. One of the main reasons for this may be the lack of articulated theories that explain whole pathways of how shared patient experiences influence health behaviour (theories that explain such pathways are often called health behaviour theories). In particular, health behaviour theories rarely contain well-defined theoretical domains that explain shared patient experience variables (in fact, health behaviour theories have been criticised for neglecting sociocultural variables in their constructs of the mechanism[34]). For instance, one of the theoretical domains explaining shared patient experience in self-efficacy theory is 'observational learning/modelling'. While this domain was useful for understanding some of the key elements of peers' stories that are likely to facilitate the target health behaviour (insulin decision-making), it is limited in its ability to explain many other key elements that were identified from the qualitative work streams (e.g. shared patient experience works even when other patients have opinions and advice about insulin that do not support individuals' own existing perspectives). The lack of useful theories for understanding the pathways between shared patient experience and health behaviours, however, creates challenges

for researchers when conducting interventions based on theories. As such, to inform the design of shared patient experience interventions aiming to support insulin decision-making, a new model describing basic frameworks of shared patient experience (e.g. contents and formats) may need to be developed based on theories and existing evidence.

3) Multiple shared patient experience interventions using a different mode of delivery or an intervention using a combination of several modes of deliveries could be tested to explore the impact of their effect on insulin decision-making. The findings from this thesis suggest that while face-to-face one-to-one discussion and an online curated collection of the filmed narrative interview material were highly regarded compared to other formats, a clear preference was not always expressed by the participants and each format contained both negative and positive comments. There was also a great deal of variation in terms of how and the extent to which participants perceived particular formats of information useful. For instance, several participants ordered the formats to show the hierarchy of their preferences, while others preferred to use an online forum just for reading but not for contributing. Although it was not in the context of decision-making, the evidence from the qualitative work also suggested that patients' preferences over the degree of interaction with other peers could vary over time or depending on issues faced. These findings suggest that patients' preferences in the format of shared patient experience could be influenced by many factors (e.g. time, situation, condition) and that there may be no particular type of format that can be universally viable for all patients. Examining the impact of different formats of shared patient experience interventions could deepen understanding about their impact on outcomes and expand the number of patients who could benefit from shared patient experience programmes at appropriate points in their condition.

4) The MRC framework recommends the evaluation of initial intervention design in order to examine any uncertainties that have been identified during the development process and determine whether the intervention is appropriate for further testing[7,8]. As briefly discussed in

section 7.3.3, following the initial development of the shared patient experience intervention that incorporates the ***key elements and contents of shared patient experience*** and the ***mode of delivery(ies)***, the person-based approach[22] would be conducted to assess the acceptability and feasibility of the intervention delivery.

The person-based approach uses in-depth qualitative research to investigate systematically the beliefs, attitudes, needs and situation of the people who will be using the intervention, which in turn, enables intervention developers to design or modify the intervention to make it more relevant, persuasive, accessible and engaging[22]. Since there has been no shared patient experience interventions developed specifically to support insulin decision-making in type 2 diabetes, qualitative methods (such as the person-based approach) is considered useful for assessing the acceptability and feasibility of the intervention delivery[22,35]. Several qualitative methods (e.g. focus group, individual interviews, and/or think aloud method) would be carried out to understand "how different people in different situations may view and engage with the intervention, which elements may seem particularly relevant and useful to them and which may be rejected — and thus how the intervention can be made more attractive, persuasive and feasible to implement"[22]. In particular, qualitative methods would be used to explore the views of relevant stakeholders - non-insulin treated patients with type 2 diabetes (recipients of the intervention) as well as healthcare providers (e.g. general practitioners, diabetes specialist nurses) with regard to: the shared patient experience programme (e.g. contents, mode of deliveries); and the RCT design for the programme (e.g. recruitment, intervention delivery - see section 7.3.3). Since it is anticipated that healthcare providers would be responsible for recruitment and delivery of the programme (as discussed in section 7.3.3), it is considered that their views along with the views of intervention recipients would be useful for improving the programme.

Patient and Public Involvement - PPI

In addition to the person-based approach, it would also be useful to conduct PPI by involving a patient advisory panel (patients as advisors – not as participants) to help advise on the trial and intervention design[36].

Based on the results from the person-based approach, and feedback and comments received from the panel in PPI, the changes in the initial intervention materials would be made, and its efficacy would be investigated in the RCT (see section 7.3.3 - for design of pilot RCT).

7.6 Conclusion

By addressing the gaps in the literature on shared patient experience in diabetes care, this thesis explored how shared patient experience could support the process of decision-making in starting insulin therapy in non-insulin-treated adults with type 2 diabetes in the UK.

New knowledge was contributed to this field by identifying a working definition of shared patient experience, some common components of shared patient experience, and some studies highlighting evidence of the effects of shared patient experience on disease-related health in type 2 diabetes. It also revealed that patients were in general reluctant to move onto insulin because of a range of overlapping psychological concerns toward insulin and held concerns over the lack of communication about insulin with their healthcare providers prior to insulin. Moreover, it was found that the use of shared patient experience has a range of valuable potentials to help patients in the decision-making process. Patients' preferences over different formats of shared patient experience information were also reported. This evidence shows that shared patient experience delivered though face-to-face one-to-one discussion and/or an online curated collection of the filmed narrative interview material that conveys the key elements and contents of peers' stories

as identified from this thesis, could be an appropriate, efficient, and acceptable way to deliver a shared patient experience intervention in the context of decision-making about starting insulin in type 2 diabetes.

As observed throughout this thesis, there are still many patients who are left with psychological concerns over insulin without sufficient support to overcome such concerns. This suggests that there remains a need for additional support which can be delivered as a supplement to formal support provided by healthcare professionals. This thesis has shown that shared patient experience can be one of the potential strategies to help ease the process of insulin decision-making. While there are still many tasks left to the implementation of such a programme in the context of insulin decision-making, all the findings from the thesis contribute to the accumulation of the studies in this field, which in turn, could help advance future research in this field and increase people's awareness in using such a strategy in the context of insulin decision-making.

7.7 References

1. Hardeman W, Sutton S, Griffin S, et al. A causal modelling approach to the development of theory-based behaviour change programmes for trial evaluation. *Health Educ Res.* 2005;20(6):676-687.
2. Lakshman R, Griffin S, Hardeman W, Schiff A, Kinmonth AL, Ong KK. Using the Medical Research Council framework for the development and evaluation of complex interventions in a theory-based infant feeding intervention to prevent childhood obesity: the baby milk intervention and trial. *J Obes.* 2014;2014:646504.
3. Austin G, Bell T, Caperchione C, Mummery WK. Translating research to practice: using the RE-AIM framework to examine an evidence-based physical activity intervention in primary school settings. *Health Promot Pract.* 2011;12(6):932-941.

4. Bartholomew LK, Parcel GS, Kok G. Intervention mapping: a process for developing theory- and evidence-based health education programs. *Health Educ Behav.* 1998;25(5):545-563.

5. Pittson H, Wallace L. Using intervention mapping to develop a family-based childhood weight management programme. *J Health Serv Res Policy.* 2011;16 Suppl 1:2-7.

6. Afifi RA, Makhoul J, El Hajj T, Nakkash RT. Developing a logic model for youth mental health: participatory research with a refugee community in Beirut. *Health Policy Plan.* 2011;26(6):508-517.

7. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ.* 2008;337:a1655.

8. Campbell M, Fitzpatrick R, Haines A, et al. Framework for design and evaluation of complex interventions to improve health. *BMJ.* 2000;321(7262):694-696.

9. French SD, Green SE, O'Connor DA, et al. Developing theory-informed behaviour change interventions to implement evidence into practice: a systematic approach using the Theoretical Domains Framework. *Implement Sci.* 2012;7:38.

10. Ajzen I, Fishbein M. *Understanding Attitudes and Predicting Social Behaviour.* Englewood Cliffs, NJ: Prentice-Hall; 1980.

11. Weinstein ND, Sandman PM. A model of the precaution adoption process: evidence from home radon testing. *Health Psychol.* 1992;11(3):170-180.

12. Bandura A. *Social Foundations of Thought and Action: A Social Cognitive Theory.* Englewood Cliffs, NJ: Prentice-Hall; 1986.

13. Leventhal H. Toward a comprehensive theory of emotion. *Adv Exp Soc Psychol.* 1980;13:139-207.

14. Wood JV. What is social comparison and how should we study it? *Pers Soc Psychol Bull.* 1996;22(5):520-537.

15. Locock L, Brown JB. 'All in the same boat'? Patient and carer attitudes to peer support and social comparison in Motor Neurone Disease (MND). *Soc Sci Med.* 2010;71(8):1498-1505.

16. Green MC. Transportation Into Narrative Worlds: The Role of Prior Knowledge and Perceived Realism. *Discourse Processes.* 2004;38(2):247-266.

17. Hinyard LJ, Kreuter MW. Using narrative communication as a tool for health behavior change: a conceptual, theoretical, and empirical overview. *Health Educ Behav.* 2007;34(5):777-792.

18. Sillence E, Hardy C, Harris P, Briggs P. Modeling patient engagement in peer-to-peer healthcare. Proceedings of the 23rd International Conference on World Wide Web; 2014; Seoul, Korea.

19. Goffman E. *Stigma: Notes on the management of spoiled identity.* London: Penguin; 1963.

20. Locock L, Ziebland S. Mike Bury: Biographical Disruption and Long-Term and Other Health Conditions. In: Collyer F, ed. *The Palgrave Handbook of Social Theory in Health, Illness and Medicine.* Vol 1. UK: Palgrave Macmillan 2015:582-598.

21. Khan MA, Shah S, Grudzien A, et al. A diabetes education multimedia program in the waiting room setting. *Diabetes Ther.* 2011;2(3):178-188.

22. Yardley L, Morrison L, Bradbury K, Muller I. The Person-Based Approach to Intervention Development: Application to Digital Health-Related Behavior Change Interventions. *J Med Internet Res.* 2015;17(1):e30.

23. Snoek FJ, Skovlund SE, Pouwer F. Development and validation of the insulin treatment appraisal scale (ITAS) in patients with type 2 diabetes. *Health and Quality of Life Outcomes.* 2007;5:69-69.

24. Hurley A. Measuring self-care ability in patients with diabetes: The insulin management diabetes self-efficacy scale. In: Waltz C, ed. *Measurement of Nursing Outcomes:*

Measuring Client Self-Care and Coping Skills. New York: Springer Publishing Co; 1990:28–44.

25. Fitzgerald JT, Funnell MM, Anderson RM, Nwankwo R, Stansfield RB, Piatt GA. Validation of the Revised Brief Diabetes Knowledge Test (DKT2). *Diabetes Educ.* 2016;42(2):178-187.

26. Cohen S, Mermelstein R, Kamarck T, Hoberman HM. Measuring the functional components of social support. In: Sarason IG, Sarason BR, eds. *Social support: theory, research, and applications*. The Hague, Holland: Martinus Nijhoff; 1985:73–94.

27. Koedoot N, Molenaar S, Oosterveld P, et al. The decisional conflict scale: further validation in two samples of Dutch oncology patients. *Patient Educ Couns.* 2001;45(3):187-193.

28. O'Connor AM. Validation of a decisional conflict scale. *Med Decis Making.* 1995;15(1):25-30.

29. Health Innovative Network. Right insulin, Right time, Right dose, for type 2 diabetes - A toolkit for optimal delivery. 2014; http://www.hin-southlondon.org/system/resources/resources/000/000/139/original/Right_Insulin_Right_Time_Toolkit_210316.pdf. Accessed 10/02/2016.

30. Ali K, Farrer L, Gulliver A, Griffiths KM. Online Peer-to-Peer Support for Young People With Mental Health Problems: A Systematic Review. *JMIR Ment Health.* 2015;2(2).

31. Dale J, Caramlau Isabela O, Lindenmeyer A, Williams Susan M. Peer support telephone calls for improving health. *Cochrane Database of Systematic Reviews.* 2008(4). http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006903.pub2/abstract.

32. Dale JR, Williams SM, Bowyer V. What is the effect of peer support on diabetes outcomes in adults? A systematic review. *Diabet Med.* 2012;29(11):1361-1377.

33. Lloyd-Evans B, Mayo-Wilson E, Harrison B, et al. A systematic review and meta-analysis of randomised controlled trials of peer support for people with severe mental illness. *BMC Psychiatry.* 2014;14:39.

34. Landrine H, Klonoff EA. Culture and health-related schemas: a review and proposal for interdisciplinary integration. *Health Psychol.* 1992;11(4):267.

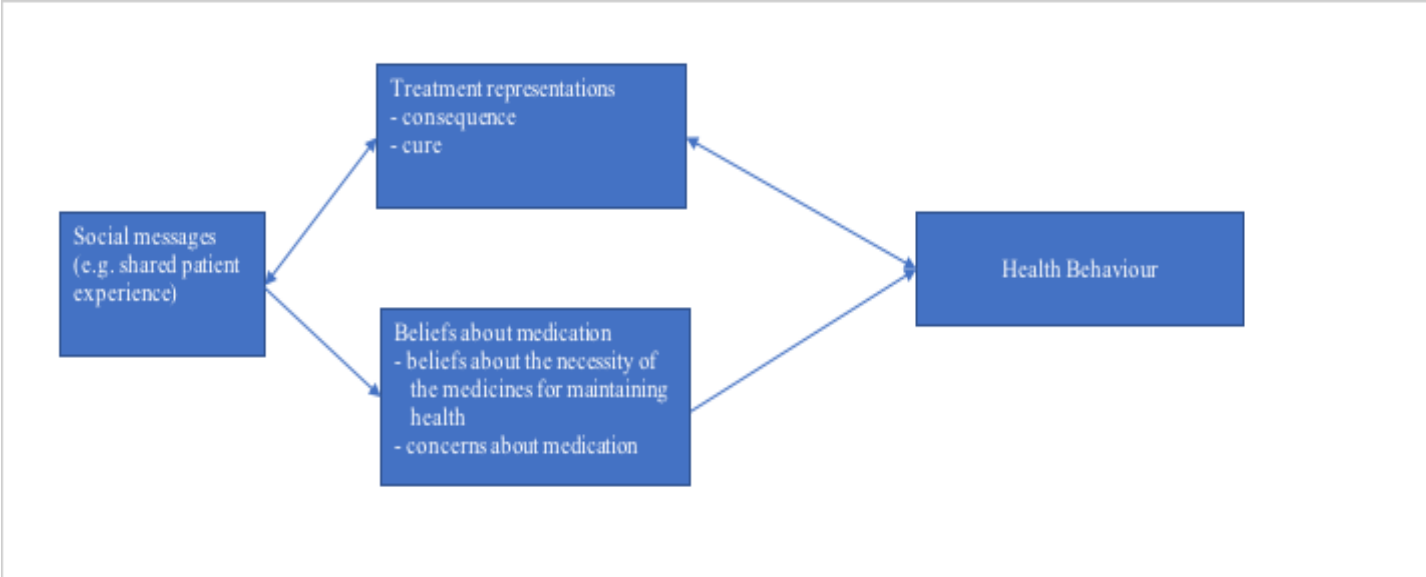
35. Bowen DJ, Kreuter M, Spring B, et al. How We Design Feasibility Studies. *Am J Prev Med.* 2009;36(5):452-457.

36. Joanna C, Jennifer B, Richard B. PPI: calling all surgical researchers…. *The Bulletin of the Royal College of Surgeons of England.* 2016;98(1):30-33.

7.8 Appendices

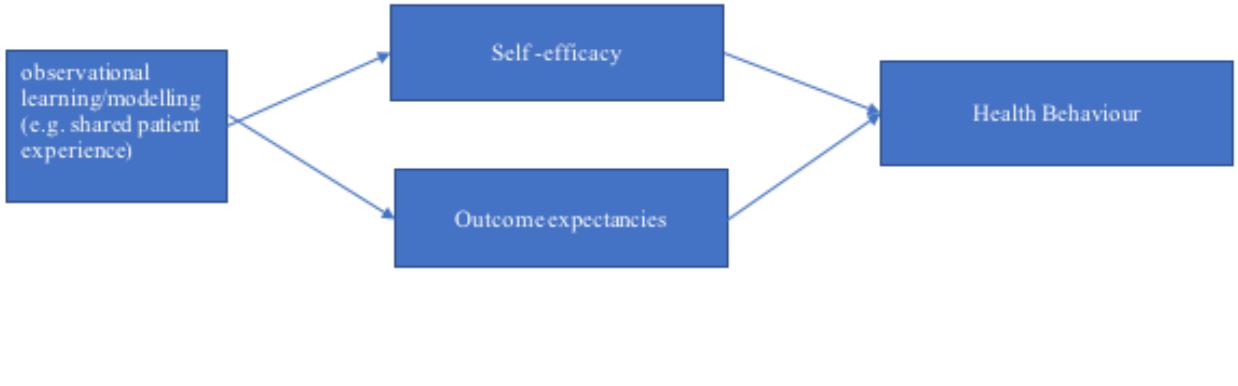
Appendix 7.1: Figures of the self-efficacy theory and the self-regulation model

Self-regulation model



Concerns about medication = general concerns about medication (e.g. 'having to take medicines worries me')
Consequence = beliefs about likely impact of treatment on physical, social and psychological functioning
Cure = the extent to which the patient believes their condition is amenable to cure or control by treatment they receive

Self-efficacy theory



Self-efficacy = beliefs or confidence in one's ability to perform a particular behaviour that leads to the outcome in question

outcome expectancies = beliefs concerning the probability that this specified course of action will lead to certain outcomes or consequences

Appendix 7.2: Defining key behavioural determinants and intervention components to address key behavioural determinants

Key behavioural determinants		Evidence found in the qualitative work streams [name of themes where key behavioural determinants were identified from]	Theoretical domains [name of theory]*	Key elements of SPE that address each key behavioural determinant	Examples of contents of SPE that reflect key elements of SPE
Fears	Fear of leading restricted life	Patients were in general reluctant to move onto insulin because of a range of overlapping (not mutually exclusive) psychological concerns toward insulin [e.g. *Fears; Avoidance or Acceptance; Avoidance or Fatalism; Impact of peers' experiences in forming initial responses to insulin therapy*]. Yet, patients reported that the use of SPE could have/had an impact on their choice to accept insulin by mitigating their fears [e.g. *Impact of peers' experiences in making decisions about starting insulin therapy; To appraise own approaches to insulin*].	Consequence [SRM] Beliefs about the necessity of the medicines for maintaining health [SRM] Outcome expectancies [SET] Concerns about medication [SRM]	Stories that mitigate fears of leading restricted life: stories that are designed to convey information in particular, regarding what to prepare when travelling; how to refrigerate insulin when travelling; where to administer injections in a public place; and how to carry insulin when travelling	What to prepare when travelling: *'Make sure when you get a letter from your doctor if you are travelling by plane that you don't have it time limited. Ask for an open ended one… If possible get it from your DSN [diabetes specialist nurse], because they don't charge you whereas the doctor will. Maybe more now'.* How to refrigerate insulin when travelling: *'We go away for two weeks to Egypt twice a year. It can be very hot there. We always go for one that has got a fridge in the room in any case…I put it in the fridge and it's no problem. Put it at the top. Cold air goes down so it's not going to be in danger of freezing up…you put insulin on the top of the door. That's what I've got in my fridge now…That's the warmest part of the fridge and it's fine for the insulin and you are not going to risk having it getting too cold'* Where to administer injections in a public place: *'Personally, I don't really have any difficulties [doing injection in a public place]. If I'm in a restaurant, depending where I'm sitting, I can do it at the table. Under the waist when sitting at a table, I can quickly inject myself… I have done it so quickly that he's not really noticed it, even though I'm doing it in front of him'* How to carry insulin when travelling: *'I've got the bag and I've got my prescriptions in there. I've got my spare needles in the bottom of the bag… I had all the insulin and in the Free O Bag I had my glucose juice because they are in 50ml bottles. You can carry those with you. [5 sec pause] Nobody has even looked inside it. [Laughs] I could be carrying anything. I am prepared for it'.*
	Fear of discrimination		Consequence [SRM] Outcome expectancies [SET] Concerns about medication [SRM]	Stories that mitigate fears of discrimination: stories that are designed to include patients talking about how they see such fear in a more positive light	'There's nothing to be ashamed about [insulin]. People like us who are already diabetic, we just have to admit we are diabetic. In fact, when you take oral [medication] in front of people, they will ask you what [disease] you have. We have to be very truthful and tell them I'm on medication for diabetes'
	Fear of disease severity		Consequence [SRM] Concerns about medication [SRM]	Stories that mitigate fear of disease severity: stories that are designed to increase patients' awareness about the option to initiate insulin in the early stages of the disease and where patients report living well and feeling better	A story of another person in the media who made his decision to initiate insulin in the early stage of the disease, well in advance of insulin being considered absolutely necessary

	Fear of risk to health		Beliefs about the necessity of the medicines for maintaining health [SRM] Cure [SRM] Outcome expectancies [SET] Concerns about medication [SRM]	Stories that mitigate fear of risk to health: stories that are designed to represent insulin as a protection against the progression of the disease (e.g. patients talking about superior effects of insulin in terms of current improved health such as improved blood sugar levels compared with their health condition before the initiation)	'Interviewer: So you know how initially they changed your medication from tablets to insulin, then how did you feel? *Um. Well… it's been good for me. Because I used to have heat inside my feet, what do you call it?… Itching, and my feet would become really hot. Sometimes when I'd be asleep at night, it would be very warm. It would be very hot… But since using insulin, that is fine, now that doesn't happen'.* *'I think I should have gone on insulin earlier because as soon as I went on insulin, my sugar levels sort of came down… You still can have high sugar levels but not as high as they used to be on just tablets. So I think I should have gone on insulin, really'.* 'I know after a while, oral medication cannot bring down blood sugar. I took insulin because the pills were not working anymore'. *'Gradually they increased the Metformin until I was taking six a day… I carried on with the six Metformin tablets a day and then I had terrible diarrhoea problems… So, eventually, after I was having this, months of diarrhoea…, she [healthcare provider] said, "right, we will put you on insulin"… [at that time] I didn't want to go on insulin… But, I realised that I couldn't go on with this diarrhoea all the time, it was just horrendous… Once I went on the insulin I was a changed person. It really made a difference. It was really fantastic'.*
	Fear of insulin injection/technology		Consequence [SRM] Outcome expectancies [SET] Concerns about medication [SRM]	Stories that mitigate fear of insulin injection/technology: stories that are designed to convey information in particular, regarding how to administer injections; how to mitigate needle phobia; how to cope with a hypoglycaemic episode; and how to adjust insulin dose	How to administer injections: *'I was pregnant and I had a phial of insulin that I used to have to draw up [a syringe] and this was only in 1996, … Now when I was…, second, diagnosed in 2001, I realised that things had moved on the five years it had moved on…I looked at this pen with this tiny little needle and I thought, my goodness me, that's so easy compared to what I had to do… I suppose from a learning point, giving advice point of view for future people, I would say that that needs to be, it needs to be made clear how simple it can be'* How to mitigate needle phobia: *'That one on there [non-insulin treated patient] saying he was a needle phobic, they do have special needles for children who have to inject who are needle phobic. You don't actually see the needle, because it's held up within it. So you've got the barrel and because you don't see the needle, you haven't got that fear sort of hovering over yourself with the needle, no, the thing and you are actually watching the needle go into your arm. So, that makes it better. And that is what they use on children… you can have this'.* How to cope with a hypoglycaemic episode: *'I know when one [episode of hypoglycaemia] is coming on because the symptoms… my own symptoms are I start to get a little bit dizzy, I perspire a lot, my legs go weak. And I think, "Ah, ah" and I run across to the machine, do a quick check and of course, "Oh, blimey, it's you know, 3.7. Where's the Lucozade?" And I just drink it, come back to this chair, sit down ten minutes, then I'm as right as rain'* OR a video clip of an insulin treated man who was perceived to be in a worse situation (e.g. elderly people) talking about how he successfully copes with a hypoglycaemic episode How to adjust insulin dose: *'You wouldn't up your levels [of insulin dose] willy nilly and just 'cause you felt like it, you work on a ratio of what you have got to take, which is consulted with your diabetic nurse, or normally with your GP or your diabetic specialist in the hospital and then work from there then… When I was given 10/10 it didn't suit me and I had to increase it, increase it, increase it. But I done it in stages, with the supervision of people… And I've been on the level that I am taking now for the best part of two, maybe three years and it, suits me'*

Personal efficacy	Some patients reported that the use of SPE could potentially help/helped build self-confidence in themselves to handle the issues they may have when managing insulin, which in turn, could be/was beneficial in their decision-making [e.g. *To gain self-empowerment; Impact of peers' experiences in making decisions about starting insulin therapy*]. In some cases, SPE prompted patients to have personal confidence by mitigating their feelings of fears or by raising their understanding about insulin which in turn, had an impact on their choice to accept insulin.	Self-efficacy [SET]	Stories that motivate a sense of personal efficacy: stories that are designed to include not only stories of peers successfully managing insulin (e.g. by mitigating fears), but also stories of peers perceived to be in a worse situation (e.g. patients who have various fears attached to insulin) successfully managing insulin	Topics of such stories would be similar to those designed to mitigate fears (e.g. fears of leading a restricted life), but emphasise the key element described here
Camaraderie/Reassurance	Some patients reported that the use of SPE could potentially support insulin decision-making, in particular, when patients perceived some similarities with the individual in the sample materials (e.g. common disease experiences, characteristics such as age, ethnicity, and hometown, or stage of disease management) since such perceived personal relevance could allow them to develop a sense of camaraderie and emotional comfort in thinking that 'I am not alone' in going through this process [e.g. *To feel camaraderie and self-reassurance*].	n/a	Stories that motivate a sense of camaraderie/reassurance: stories from a range of different patients, so that people can find something that resonates with them (e.g. common disease experiences, stage of disease management, or characteristics such as age, ethnicity, and hometown)	Topics of such stories would be similar to those designed to mitigate fears (e.g. fears of leading a restricted life), but emphasise the key element described here
Knowledge	Patients raised concerns over a lack of understanding about insulin [fear of unknown]. Patients reported the use of SPE could be advantageous for insulin decision-making by means of gathering informational advice on insulin [e.g. *To gain informational advice on insulin*], and exposing them to new aspects of insulin or other patients' views toward insulin which they had not previously known or considered [e.g. *To recognise diversity of views and experiences of insulin*].	n/a	Stories that increase knowledge about insulin therapy: stories that offer advice and expose people to a diversity of other patients' opinions and advice about insulin regardless of whether or not they support their own existing perspectives as well as new aspects of insulin or other patients' views toward insulin which they had not previously known or considered.	Topics of such stories would be similar to those designed to mitigate fears (e.g. fears of leading a restricted life), but emphasise the key element described here

SPE = Shared patient experience; SRM = Self-regulation model; SET = Self-efficacy theory; HCPs = Health care professionals; n/a - not applicable; * Please see Appendix 7.1 for detailed description of each theoretical concept