Understanding and Exploring Behavioural Change: Readiness to Change and Response to Cognitive Behaviour Therapy; Recording of Clients' Child Dependants by Mental Health Service Staff and Improving Fluid Restriction and Quality of Life in People Receiving Haemodialysis

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Table of Contents

Title Page 1

Abstracts

Critical Review of the Literature …… 6

Service Improvement Project …… 7

Main Research Project …… 9

Critical Review of the Literature 11

Abstract ……. 12

Highlights …….. 13

Introduction …….. 14

Method …….. 18

Results …….. 24

Discussion …… 60

References …….. 67

Service Improvement Project 76

Abstract ……. 77

Introduction …….. 78

Methods …… 81

Results…….. 83

Recommendations …….. 96

Conclusions …… 101

References …….. 102

Main Research Project 105

Abstract ……. 106

Highlights……... 107

Introduction …….. 108

Method …….. 111

Results …….. 127

Discussion …… 154

References …….. 159

Executive / Dissemination Summary 165

Connecting Reflective Narrative 169

Acknowledgements 173

Appendices 174

Critical Review

A. Full Psychinfo Search …… 175

B. Detailed title/abstract Screening Criteria …… 176

C. Quality Appraisal Tool: Selection and implementation …. 178

Service Improvement Project

D. Audit Approvals …….. 182

E. Information Sheet for Service Improvement Project ……. 186

F. Questions for Care Coordinators ……. 188

G. Nvivo Coding Frame and Themes ……... 190

H. Members of Trust Families Working Group ……... 191

I. Table Notes and Supplementary Information …… 192

Main Research Project

J. Description of the ACT Matrix …….. 193

K. Questionnaire Administration and Details of Measures ... 197

L. EQ5D-5L Supplementary Data …… 202

M. Explanation of Randomisation Protocol …… 204

N. Tau-U Statistic – Additional Information ……. 205

O. Study Documents and Approvals …… 206

O1. Patient Information Sheet …….. 206

O2. Consent Form …….. 213

O3. NRES Approval ……. 215

O4. HRA Approval ……. 220

O5. Sponsorship Approval …… 222

O6. OUH Management Approval/ Letter of Access …….. 223

P. Tau U Analysis of Outcome Measures ……..…….. 227

Q. Clinical Psychology Review – Author Guidelines …….. 231

R. Family, Systems and Health – Author Guidelines ……. 244

S. Contextual Behavioural Science – Author Guidelines ….. 256

The association between individual differences in motivational readiness at entry to treatment and treatment attendance and outcome in cognitive behaviour therapy: a systematic review

Abstract

There is considerable interest in identifying factors that predict outcome from psychological treatment. This review examines the relationship between readiness / stage of change at entry to CBT treatment and treatment attendance or outcome in people with mental health problems other than addiction. A systematic literature search identified 20 eligible studies of which 19 were included in the narrative synthesis. Seventeen explored the relationship between readiness and symptom outcome, with a majority (*n*=12) identifying at least one statistically significant relationship between variables, either directly or in interaction with another measure. A number of these also tested other associations which were non-significant. In contrast, five studies explored the association between readiness and treatment attendance, and findings were inconclusive. The review identified little evidence that the association between readiness and outcome varied according to clinical problem being treated or measure of readiness used. The five studies adopting an RCT design identified no evidence of differences in the relationship between readiness and outcome when comparing CBT to other psychotherapeutic interventions. Study quality was variable, and a range of methodological limitations and potential avenues for future work are discussed.

Recording of Child Dependants in Electronic Health Records: A Service Improvement Project

Abstract

Introduction: Recording information about the child dependants of adults accessing mental health services has an important safeguarding function and can support preventative parenting initiatives. However, services frequently do not record this information in line with good practice. This study explored facilitators and barriers to compliant recording in two mental health teams.

Methods: Twenty-six staff members across two teams provided information on 300 clients (of which 61% female, mean age 41 years). Information from staff was cross-referenced with information held in electronic health records and staff shared their perspectives on potential improvements to recording practices.

Results: Sixteen percent of the clients had known child dependants. Information about these children was present in almost all clients' records but was recorded in line with expected practice in less than 50% of cases. Staff identified barriers to obtaining and recording information about child dependants, including uncertainty about which children to record, concerns about the impact of asking about children on fragile therapeutic relationships and challenges related to time, workload pressures, and difficulties navigating IT systems.

Discussion: Findings were discussed with participants and stakeholders to incorporate their perspectives. A range of potential improvements targeting different levels of the system (e.g., both people-focussed and system focused changes) are proposed.

Public Significance Statement: Safeguarding children is everybody's responsibility. This paper considers ways to improve one aspect of safeguarding, recording information about service-users' children within adult mental health services.

Use of the ACT Matrix to Support Fluid Restriction and Quality of Life in People Receiving Haemodialysis for End-Stage Renal Disease

Abstract

Many people receiving haemodialysis for end-stage renal disease struggle with adherence to fluid intake restrictions. This study explored the feasibility, acceptability and outcomes of a four-session intervention using the ACT Matrix targeting fluid restriction and valued living in people experiencing difficulties managing fluid intake on dialysis. Eight participants were randomised in two blocks in a concurrent multiple baseline single case experimental design. Participants were allocated to baselines of 6-8- or 10-weeks, followed by a four-week intervention and four-week follow-up. Participants provided self-report data on fluid adherence and valued living throughout the study period. Data on interdialytic weight gain data was obtained from medical records for the 12 weeks prior to the start of the self-report baseline and for the duration of the study thereafter. Participants rated the intervention as moderately credible and had modest expectations for change. Six of the eight participants were admitted to hospital as inpatients during the intervention phase and only three completed both the intervention and self-report follow-up, complicating interpretation of data on fluid restriction. Two participants showed reliable improvements in psychological distress (assessed at baseline, intervention sessions 1 and 4, and at follow-up) and three showed significant shifts in aspects of valued living, although these were modest in size. There was no evidence of change on the measure assessing ACT processes (compACT). This study suggests that further work is required to tailor the format of the intervention to meet the needs of patients on renal dialysis, for example triaging patients to different intervention durations based on degree of complexity and orientation to

active behavioural change. Timing of the intervention and delivery during periods of relatively physical stability is also likely to be key to intervention success.

The association between individual differences in motivational readiness at entry to treatment and treatment attendance and outcome in cognitive behaviour therapy: a systematic review

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Abstract

There is considerable interest in identifying factors that predict outcome from psychological treatment. This review examines the relationship between readiness / stage of change at entry to CBT treatment and treatment attendance or outcome in people with mental health problems other than addiction. A systematic literature search identified 19 eligible studies of which 18 were included in the narrative synthesis. Sixteen explored the relationship between readiness and symptom outcome, with a majority (*n*=11) identifying at least one statistically significant relationship between variables, either directly or in interaction with another measure. A number of these also tested other associations which were non-significant. In contrast, five studies explored the association between readiness and treatment attendance, and findings were inconclusive. The review identified little evidence that the association between readiness and outcome varied according to clinical problem being treated or measure of readiness used. The five studies adopting an RCT design identified no evidence of differences in the relationship between readiness and outcome when comparing CBT to other psychotherapeutic interventions. Study quality was variable, and a range of methodological limitations and potential avenues for future work are discussed.

Highlights

- Historically, most research on readiness to change and treatment outcome has focused on addictions

- We present a narrative synthesis of 18 studies examining the association between readiness to change at entry to CBT treatment and treatment attendance and outcome for mental health problems other than addiction.

- There was some evidence of an association between readiness and outcome but research design and study populations were highly variable.

- The relationship between readiness to change and spontaneous improvement is under-researched despite its obvious implications for interpretation of observed associations between readiness to change and treatment outcome.

- Limitations and areas for future research are discussed.

Introduction

People entering psychological treatment vary in their motivations for change (Holtforth & Mikalak., 2012). Concepts of readiness to change (RTC) and treatment motivation have received most research attention within the field of addiction (DiClemente, Schlundt & Gemmell, 2004), where it is widely considered that an individual needs to be 'ready to change' for treatment to succeed. However, clinical experience suggests that RTC may play a role in treatment outcome across a range of conditions. Although various concepts have been considered relevant to understanding motivation within therapy (Holtforth & Mikalak), the Trans-Theoretical Model of Stages of Change, (TMSC; Prochaska & DiClemente, 1984; Prochaska, DiClemente & Norcross, 1993) is one of the most influential.

The TMSC describes the process and tasks of behaviour change, within or outside therapy contexts. It outlines five consecutive stages: *precontemplation*, in which the individual does not regard themselves as having a problem, or has no intention of changing; *contemplation*, the process of weighing up pros and cons of change; *preparation*, anticipation of imminent action and initiation of small steps; *action*, active engagement in effortful behaviours in the service of change; and *maintenance*, engagement in relapse prevention or maintenance behaviours.

Since the early 1980s, the TMSC has generated a huge volume of research. It has also been subject to critique (for reviews see Littell and Girvin, 2002; Drieschner, Lanners & van der Staak, 2004). Key challenges include recognition that the process of behaviour change is non-linear, with relapse as a normal part of any recovery journey, the fact that people completing measures of RTC often endorse items reflecting multiple stages of change simultaneously and evidence that people rarely make sequential transitions from one adjacent stage to another, as predicted by the model. Despite this,

the TMSC is still regarded as a useful heuristic for conceptualising variations in client motivational readiness. Littell and Girvin, (2002, pp.255) in their critical review state that "*The stage model's contributions—emphasis on cognitive precursors and correlates of behavioral change, the concept of readiness, and nonlinear movement—can be retained without a stage theory*". Reflecting this, measures derived from the model, including those which explicitly operationalise RTC as a continuum, continue to be used to explore the relationship between RTC and therapy outcomes.

Other attempts to define and measure treatment motivation have also been criticised for conceptual confusion. For example, Dreischner, et al., (2004) highlight the fact that the Neijmegen Motivation List – 2 (Keisjers et al., 1999), developed specifically to assess motivation for treatment in Cognitive Behaviour Therapy (CBT), includes items which conflate treatment motivation with factors that are likely precursors or associates of motivation (e.g., treatment expectancy), or arise as its consequence (e.g., session attendance). This results in a degree of circularity when the measure is used to explore the relationship between treatment motivation and CBT outcome and limits use in other treatment contexts.

RTC and CBT

CBT is time-limited and requires active collaboration from the start. As such it might be expected that client pre-treatment RTC would be predictive of outcome. Research has demonstrated that client active engagement *during* therapy influences therapeutic response. For example, individuals with high levels of attendance, adherence to homework and compliance with key behavioural techniques in CBT for anxiety disorders, achieve better outcomes than those with lower levels of treatment engagement (e.g., Glenn et al., 2014). There is also evidence to suggest that RTC at entry to therapy is associated with better outcome. For example, a systematic review and meta-analysis of

the relationship between stage of change and clinical outcome across 76 studies of different forms of face-to-face psychotherapy (Krebs, Norcross, Nicholson & Prochaska, 2018) identified a moderate effect (*d*=0.41) of RTC on treatment outcome, with those clients who had greater RTC showing better outcomes. However, although around half the studies in this review involved CBT-based treatments, a majority addressed substance misuse and 95% were published before 2016.

It has been argued that the concepts of RTC apply more to problems which have a clear behavioural manifestation (e.g., substance misuse, binging) than to those where it is unclear what behavioural changes might be required to bring about improvement (e.g., depression, chronic pain, e.g., Dreischner et al., 2004), and the bulk of research into RTC and therapy outcomes reflects this. However, it seems plausible to consider that a client may approach therapy with varying degrees of readiness to 'do what it takes' to make progress with their problems even if they are not sure what this might entail. Likewise, it also seems plausible that even where required behavioural changes are apparently clear (e.g., to stop drinking) the process of achieving these changes may require unanticipated effortful commitments. As such it seems useful to consider the potential contribution of RTC to treatment outcome across a broader range of common mental health problems, with RTC encompassing a willingness to come into contact with distressing emotions, be open to considering different ways of responding to difficult situations, or to confront distressing past experiences in the service of change.

The aim of the current review is to examine the association between pre-treatment RTC and treatment outcome in studies examining the efficacy/effectiveness of CBT for mental health problems, excluding addictive behaviours. The review focuses on studies which have used measures conceptually linked to the TMSC, as one of the most prominent theories of motivational processes in psychological and behavioural change,

whilst holding in mind some of the recognised limitations of this theory. Importantly the TMSC is concerned with the person's RTC (hereafter termed 'readiness' for continuous measures and 'stage of change' for categorical measures) in relation to a problem, rather than their desire to engage with a particular change method (Carey et al., 1999) and thus measures linked to this model are applicable when considering the potential role of RTC across different treatment (or no-treatment) conditions. This is important because there is one conceptual issue which is central to interpretation of the relationship between RTC and treatment outcomes, but which is rarely discussed. Specifically, many studies appear to operate under the assumption that where an association between RTC and treatment outcome is observed, it results from some influence of RTC on the way a person engages with treatment. However, a first step in establishing whether RTC exerts an influence on *treatment response* rather than, for example, simply being associated with positive change over time, would be to demonstrate a differential impact of RTC on symptom change in those receiving psychological treatment as compared to those in those in waitlist / non-treatment control conditions. This question has important theoretical implications and requires a measure which is relevant across contexts. Second, various authors have hypothesised that an individual's RTC may be more relevant to some treatment interventions than others depending on their proposed mechanism of change (e.g., Wolk & Devlin, 2000; Lewis et al., 2009, Gorrell et al., 2019). This review will therefore consider the following questions:

1. Is there a relationship between an individual's readiness/stage of change at the start of CBT and (a) treatment attendance and/or (b) symptom change, over the treatment period?
2. For controlled studies only: Is the association between readiness/stage of change and symptom change greater in those receiving CBT than those in waitlist or no-

treatment control groups? (e.g., is any effect observed more substantial than might be expected from a relationship between readiness/stage of change and spontaneous symptom change?)

3. For controlled studies only: Is the association between readiness/stage of change and symptom change greater for those receiving CBT than those receiving other therapeutic interventions?

Method

Protocol and Registration The protocol for the review was registered with Prospero (most recent update 29th September 2021, REF: CRD42020209173).

Search Strategy Four databases: PsycINFO; MEDLINE; Embase and CINAHL were searched to identify relevant studies using the search terms shown in Table 1. Terms were searched in the following domains: title, abstract, heading word, table of contents, key concepts, original title, tests and measures, Medical Subject Headings (MESH; OVID). Terms addressing each criterion were combined with OR and returns across criteria were combined with AND. Returns were limited to English language publications from 1st January 1980 to current. Initial searches were conducted on November 16th and 17th 2020. Following identification of eligible full texts, reference screening and forward citation searching were conducted to determine the final review sample. The full search run in PsycInfo, is shown in Appendix A.

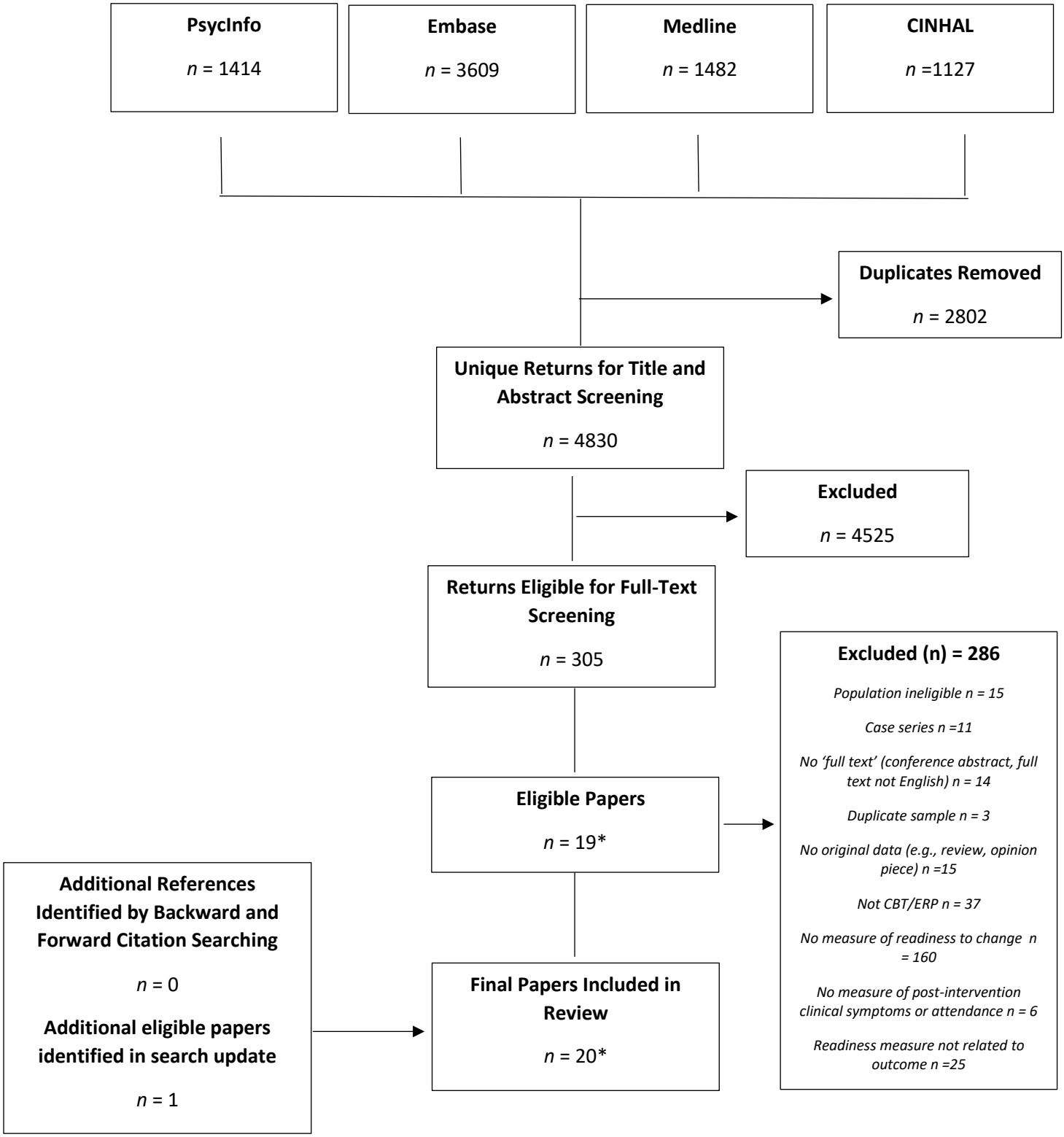
Table 1. Search terms used to identify potentially eligible articles

Criterion for Initial Literature Search	Search Terms
Study includes a measure of motivational readiness conceptually linked to the transtheoretical model of stages of change.	Readiness to Change OR Stages of Change OR Transtheoretical Model OR Motivation OR readiness ruler OR URICA OR SOCRATES OR Contemplation ladder
The study includes the delivery of a cognitive behavioural psychological intervention	Cognitive behavio$ OR Cognitive Therap$ OR CBT
The study reports engagement or outcomes of the intervention	outcom$ OR effect$ OR prognos$ OR impact$ OR treatment$ OR benefi$ OR engag$ OR attend$ or dropout$.

Study Selection A Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA: Moher et al., 2009) flow chart is shown in Figure 1. Searches were conducted in each database and returns were combined and deduplicated. The exclusion criteria applied at the title/abstract screening phase and the full text screening phase are shown in Table 2 (see also Appendix B)**.** Separate criteria were applied at the title/abstract and full text stage because certain qualifying features of studies could rarely be determined by inspection of the abstract alone.

After removal of duplicates *n*=4830 unique returns were identified. Following title/abstract screening *n*=304 were moved to full text screening and *n*=19 were identified as eligible for inclusion in the review. No further eligible papers were identified through backward and forward citation searching.

Figure 1: PRISMA flow-chart illustrating the study selection process



* One study was excluded from narrative synthesis after discussion with the corresponding author due to an inconsistency in reporting the results which rendered them uninterpretable.

Table 2. Title and abstract and full text exclusion criteria

Title/Abstract Exclusion Criteria	Full Text Exclusion Criteria
The study did not include a CBT arm	On inspection of full text, the study met one of the title/abstract exclusion criteria
The population under investigation was not defined by the presence of a mental health problem (studies where the population of interest was defined only by the presence of an addictive behaviour were excluded)	Study did not include a measure of motivational readiness linked to transtheoretical model of stages of change
The clinical target of the intervention was not a mental health problem (studies where the clinical target was related to an addictive behaviour, e.g., craving, abstinence, were excluded)	The measure of motivational readiness was not taken prior to intervention or in session 1
The report did not include original data (e.g., a commentary, opinion piece or protocol);	No measure of clinical symptoms post-intervention or no measure of engagement with intervention
The study was a qualitative study, a case study or case series, was a cross-sectional study or a review.	Study did not include a CBT intervention (note: ERP included for OCD spectrum disorders)
	Study did not report analysis which directly examined link between motivational readiness and outcome/engagement in those receiving CBT

Titles and abstracts were screened by CC, with the first 20% (n = 968) also screened by an independent reviewer. This yielded an initial concordance of 91% and an inter-rater reliability of k = .45 (SE = .05; t=14.00, p <.001, agreement moderate). Review of discrepancies indicated an equal proportion in which CC made an inclusion

decision, and the independent reviewer made an exclusion decision and vice versa. In both cases most disagreements reflected missed exclusions: that is, when abstracts were reinspected, they had a clearly stated reason for exclusion which had been overlooked. Recoding these missed exclusions as agreements in discussion with a third reviewer (based on re-review of content in relation to exclusion criteria) yielded a revised concordance rate of 97%, k =.75 (SE = .04, t=23.21, p <.001, agreement substantial). In remaining, ambiguous, cases the third reviewer's judgement was used to determine whether a paper moved to full text screening. Given that most disagreements between CC and independent rater were conservative (e.g., comprised inclusion of ineligible abstracts), CC's decisions were retained for the remainder of the titles/abstracts screened.

At the full text screening stage, a sample of n=60 (20%) texts were screened for eligibility by CC and the independent reviewer. There was 100% concordance between raters and CC's decisions were accepted for the remainder of the full texts. Reasons for exclusion of full texts are shown in Figure 1.

Data Extraction. A data extraction tool was developed incorporating: authors, study design, study location, publication year, journal, hypotheses/research question, population, participant eligibility criteria, number of participants, age (range, mean), participant gender, participant ethnicity, CBT intervention description, control intervention description, measure of motivational readiness (including reliability/validity of measure), symptom outcome measures, attendance and engagement outcome measures, statistical analysis used to examine relationship between RTC and treatment outcome, findings, conclusions, limitations. A second reviewer conducted independent data extraction for 20% of full text articles (n=4, 68 data items extracted), yielding a very high degree of consistency (96%). Disagreements were resolved through discussion.

Quality Assessment Quality assessment was conducted using the Downs and Black (1998) Quality Index, which is designed to assess quality across both randomised and non-randomised studies of healthcare interventions. It yields an overall quality rating, alongside subscales addressing quality of reporting, external validity, internal validity (bias), internal validity (confounding, selection bias), and power. Following Morton, Barton, Rice and Morrisey (2014) the item addressing power was simplified to record only whether a power calculation was reported. Coding of items that related to non-relevant aspects of study design (e.g., items assessing the equivalence of recruitment procedures between study arms in single group designs) was standardised to ensure consistency across studies (see Appendix C). The independent reviewer assessed 20% of included studies (n=4) yielding an agreement rate of 89%, k = .77 (SE = 0.06, t=8.07, p<.001, agreement substantial) across the 108 items rated. Discrepancies were resolved through discussion. Information was also gathered from each study concerning any details of: the training/qualifications of those delivering CBT interventions; intervention fidelity, and reliability and validity of measures of readiness.

Search Update Searches were re-run in September 2022. A further 834 titles/abstracts, and four full texts were reviewed, yielding one additional paper eligible for inclusion.

Data Synthesis Findings were synthesised according to: outcome examined; clinical problem addressed; measure of readiness; study design – whether the study allowed for a comparison between the relationship between readiness and outcome in CBT and another psychotherapeutic intervention or non-intervention control condition. The heterogeneity of study designs and analytic approaches precluded extraction and comparison of effect sizes. However, strengths and limitations of analytic approaches, and their comparability, are discussed.

Results

Study Characteristics

Overview Table 3 provides an overview of the studies included in the review. Each study was assigned an ID number, used for identification in the remainder of the results section.

Table 3. Studies Included in the Review

ID	Author, Year and Country of Origin	Population/ Setting and Study Design	Sample characteristics (total N, mean age (SD), % female, ethnicity	Treatment Intervention	Measure of Readiness	Outcome(s)	Relevant Findings
1	Berry (2010) USA	Adult women admitted to a psychiatric inpatient unit Naturalistic pre-post study.	N=160 Mean Age=34.3 (11.0) Gender: 100% female	Group CBT on inpatient unit (5 x groups per day) with adjunctive medical/psychosocial interventions	URICA	Length of inpatient stay (days to discharge) Number of CBT group sessions attended.	Higher URICA score at admission associated with a longer length of stay after controlling for baseline symptom measures which were positively associated with baseline URICA score. URICA score at admission not associated with number of CBT group sessions attended.
2	Boswell et al (2012) USA	Adults seeking treatment for an anxiety disorder at University Anxiety Disorder Clinic Quasi-experimental	N=29 Mean Age=29.76 (9.54) Gender: 56% Female	Individual Transdiagnostic CBT for Anxiety Disorder (unified protocol) 8 – 18 x 60 minute sessions covering 8 modules.	URICA	HAM-A HAM-D WSAS None defined as primary outcome, but treatment protocol is for anxiety disorders.	URICA score was significantly positively associated with HAM-A change; HAM-D change and WSAS change: i.e., greater readiness significantly associated with greater symptom reductions across treatment.

		pre-post study (data collapsed across immediate and waitlist arms of RCT)				Outcomes assessed at end of treatment.	URICA score moderated the effect of initial symptom severity on symptom change for both HAM-A and HAM-D - High baseline severity was associated with greater change when URICA score was high.
3	Castro-Fornieles et al. (2011) Spain	Consecutive referrals to child and adolescent Eating Disorders unit. Naturalistic pre-post study	N=31 Mean Age=16.2 (1.10) Gender: 98% female	Individual and Group CBT following Fairburn and Wilson, (2003). Sessions 2 x weekly for outpatients and daily for inpatients. All patients receive adjunctive medical management	BNSCQ Total Score	EDI -2 – 11 subscales derived). Number of binges per week Number of vomits per week [assessed at end of treatment]	Higher BNSCQ scores at baseline significantly associated with greater reductions in binges per week at end of therapy BNSCQ significantly associated with changes on EDI-2 bulimia subscale and EDI-2 interoceptive awareness subscale No significant association between BNSCQ and any of the other EDI-2 subscale scores examined. BNSCQ score was the only variable significantly associated with clinical change in binges and decrease in EDI bulimia subscale after controlling for significant univariate correlates and known potential confounders.

4	Clarke et al., (2013) USA	Women with (PwSA) and without (PwoSA) a substance use problem admitted to acute psychiatric inpatient unit. Naturalistic pre-post study	N=117 (*n*=50 PwSA, *n*=67 PwoSA) Mean Age - PwSA = 32.5 (11.3) PwoSA =35.6 (10) Gender: 100% female	4 x CBT groups per day plus individual sessions with adjunctive substance use group and medical management (variable duration of admission)	URICA	OQ [Assessed 24 hours prior to discharge]	URICA score at treatment entry was associated with better psychological functioning at discharge, after controlling for potential confounders (marital status, length of stay, baseline symptoms), and accounted for 24% variance in discharge symptoms. No significant interaction was observed between URICA score and substance abuse status in predicting psychological outcome.
5	Goodwin (2019) Canada / USA	Community volunteers seeking treatment for anxiety Secondary analysis of RCT	N= 85 (MI+CBT = 42; CBT = 43) Mean Age: MI+CBT = 32.45 (10.54) CBT = 34.19 (11.92) Gender: MI-CBT 81% Female; CBT 95% Female	15 sessions CBT (following Borkovec & Costello, 1993; Borkovec & Matthews, 1988; Borkovec et al., 2002) 15 sessions MI +CBT – 4 initial sessions of Motivational Interviewing (following Westra, 2012's guidelines) and 11 sessions of CBT.	MISC 1.1 Adapted for CBT.	PSWQ [Assessed weekly during treatment]	Increased Session 1 Change Talk associated with significantly increased hazard of clinical response by end of treatment (controlling for treatment site, baseline motivation – Change Questionnaire - and medication). Session 1 Counter Change Talk associated with significantly reduced hazard of clinical response by end of treatment (controlling for treatment site, baseline motivation – Change Questionnaire - and medication). No significant *Change Talk x treatment (CBT or MI-CBT)* or

							Counter Change Talk x treatment (CBT or MI-CBT) interaction.
6	Gorrell et al., (2019) USA	Adolescent outpatients with Bulimia Nervosa. Secondary analysis of RCT	N = 110 (CBT n = 58; FBT N = 52 Mean Age = Not reported, Range 12-18 years Gender: 93.6% Female.	CBT for Adolescents adapted from adult CBT for Bulimia (Lock et al., 2005) Family-Based Treatment for Adolescent Bulimia Nervosa adapted from a family-based treatment for Anorexia Nervosa (Lock, Le Grange, Agras, Dare, 2002) 18 sessions over 6 months	YBC-EDS-MC	EDE Derived: EDE Global Score (attitudes: restraint, eating concern, weight concern, shape concern) Abstinence from ED behaviours: 0 = not abstinent/ 1 = abstinent (binging, vomiting, laxatives, diuretics, other medications, excessive exercise, fasting) [Assessed at end of treatment]	Higher motivation to change associated with lower EDE Global score at end of treatment (controlling for age and BMI) No treatment x motivation interaction. No significant association between motivation to change and abstinence at end of treatment (controlling for age and BMI) No motivation to change x treatment interaction for abstinence at end of treatment
7	Greenberg et al., (2019) USA	Individuals with a diagnosis of Body Dysmorphic Disorder	N=44 Mean Age: 34.8 (10.1)	Individual modular CBT treatment designed to treat core features of BDD.	URICA	BDD-YBOCS Responders defined as those showing a reduction of >=	Among the 14 independent variables examined, three, including URICA score, were significantly associated with treatment response.

		(BDD) or its delusional variant. Quasi-experimental pre-post study-data combined from uncontrolled pilot trial and treatment arm of waitlist-controlled RCT.	Gender: 61% Female	Sessions for 18-22 weeks, with last two sessions spaced at 2-weekly intervals (Wilhelm, Philips & Steketee, 2013)		30% at post-treatment. [Assessed at end of treatment]	For every unit increase in the URICA score the odds of being a post-treatment responder increased by 145%
8	Heider et al., (2018) Germany	Patients with a diagnosis of somatization disorder, an undifferentiated somatoform disorder, a pain disorder or a conversion disorder Pre-post study - per-protocol analysis of data from two samples. Participants adhering to the	Sample 1: N=109 Sample 2: N=35 Mean Age: Sample 1: M=48 (12.38) Sample 2: M=46 (12.29) Gender: Sample 1: 76% Female Sample 2: 71% Female.	Sample 1: 8 x weekly sessions of manualised group CBT (see Schroder et al., 2013). Sample 2: 8 x weekly sessions of CBT with some individual and some group sessions Samples combined for secondary analysis	FF-STABS	SOMS-7 [Assessed at end of treatment]	<u>Main effects</u>: No association between precontemplation, preparation, action or maintenance and symptom reduction. Interaction Effects: Significant interactions between symptom levels and both precontemplation and action scores (see conditional effects below): <u>Conditional effects</u> *Pre-Contemplation*: People with high levels of precontemplation showed no significant symptom reduction. People with moderate

treatment protocol (attending 5/8 sessions) included.

or low levels of pre-contemplation showed significant symptom reduction.

Preparation: People with high preparation scores showed no significant symptom reduction. People with moderate or low preparation scores showed significant symptom reduction.

Action. People with high action scores showed no significant symptom reduction. People with moderate or low action scores showed significant symptom reduction.

Maintenance: Significant conditional effects at high, moderate and low values of maintenance (in absence of main effects or interaction effects). At all levels of maintenance, participants with higher baseline symptoms showed greater symptom reduction.

Robust Regression was consistent with OLS for precontemplation, contemplation and action. Robust Regression for maintenance showed a significant main effect of

							maintenance on symptoms reduction but no interaction.
9	Hudson & Neil (2020) Canada	Female adults treated at an ED outpatient unit over a 2.5 year period. Naturalistic pre-post study	N=108 Mean Age: 27.24 (10.59) Gender: 100% Female	16-week CBT group programme for eating disorders (see Mac Neil, Leung, Nadkarni, Stubbs and Singh, 2016). Some patients had adjunctive ACT or cognitive remediation therapy to address problems *other than* ED psychopathology (25% of total).	Readiness Ruler	Number of CBT sessions attended. Engagement – person did or did not attend first session of CBT Dropout – person did or did not attend any of the last 6 sessions of CBT	*Readiness Ruler* rating not significantly associated with number of CBT sessions attended, initial engagement in CBT or dropout from CBT.
10	Lewis et al., (2009) USA	Adolescents aged 12-17 with major depression. Secondary analysis of RCT	N=332 Mean Age: 14.6 (1.5) Gender: 59.3% Female	CBT – 15 sessions over 12 weeks, 2 parent sessions and 2-3 joint adolescent & parent sessions. Fluoxetine – dose monitored in 6 medication	SCQ - 18-item version with wording modified for an adolescent sample.	CDRS-R [Assessed at 12 weeks]	Baseline action score significantly associated with treatment outcome: adolescents with higher action scores at baseline showed a greater symptom reduction across treatment. Interaction between treatment arm and *action* score did not reach significance but analysis

				review over 12 weeks. Placebo -. monitored in 6 medication visits over 12 weeks. CBT + Fluoxetine – CBT delivery independent of medication protocol but increases in medication informed by response to CBT in cases of partial response. Fluoxetine and Placebo administered double-blind.			underpowered to examine the interaction effect.
11	Lombardi et al., (2014) Canada	Community volunteers with an anxiety disorder. Quasi-experimental pre-post study	N=37 Mean age: 41.05 (11.85) Gender: 73% Female	CBT following Borkovek & Costello, 1993; Borkovek & Matthews, 1988; Borkovek, Newman, Pincus & Lytle, 2002)	CQ MISC 1.1 (78% session 1 22% session 2)	PSWQ Recovery status: Responder - participant shows reliable change and a post-treatment score below the clinical	Change Questionnaire scores significantly associated with post-treatment worry, controlling for baseline worry. Counter Change Talk (session 1 or 2) additionally associated with higher post-treatment worry.

				6 x 2-hour sessions (weekly) + 2 x 1 hour sessions.		cut-off on the measure *versus* non-responder. [Assessed at post-treatment]	Change Talk not associated with post-treatment worry. Participants showing reliable symptom change at post-treatment had significantly lower levels of session 1 or 2 Counter Change Talk than those who did not show reliable symptom change. Change Talk was not associated with reliable symptom change.
12	Monaghan et al., (2015) USA	Patients admitted to a residential intensive inpatient programme for OCD. Naturalistic pre-post study	N=424 Mean Age=33.89 (14.16) Gender: 50% female	2-3 individual CBT sessions / week. 2 hours/ day therapist-guided ERP + 2 hours/day self-guided ERP. Adjunctive groups and milieu experiences to reinforce ERP. Medical management.	URICA	YBOCS [Assessed at discharge]	URICA subscale scores were not significantly associated with change in YBOCS score.
13	Pellizzer et al (2017)	Consecutive referrals to Flinders University	N=78 Mean Age: 27.19 (9.60)	10 weekly session CBT-T intervention for eating disorders	Single item assessment:	EDE - Global Score (restraint, eating concern,	Readiness to change was not significantly associated with attrition from treatment.

	UK	Eating Disorders Outpatient Clinic Naturalistic pre-post study.	Gender: 92.3% Female	(see Waller et al., 2017)	*How ready are you to change*? 0 to 100	weight concern, shape concern) [Assessed mid treatment, post-treatment, follow-up 1; follow-up 2] <u>Attrition</u> – defined as termination of therapy before completion of 10th session.	Readiness to change did not interact with time to predict change in EDE Global score across treatment.
14	Solem et al., (2016) Norway	Outpatients with a diagnosis of OCD Naturalistic pre-post study	N=121 (n=65 group treatment; n=56 individual treatment) Mean Age = 33.8 (12) Gender: Not Reported	Group ERP – 12 x 2.5 group sessions /week adapted from manual by Krone, Himle and Nesse (1991). Individual ERP – 15 x 90-minute sessions based on manual by Kozak and Foa (1997).	URICA	YBOCS Dropout from treatment (definition not provided) [Assessed at end of treatment]	The 8 treatment dropouts scored significantly lower than 113 treatment completers on the URICA contemplation subscale. No differences between treatment dropouts and treatment completers on other URICA subscales. URICA subscales were not significantly associated with end of treatment YBOCS score (controlling for baseline symptoms).
15	Treasure et al., (1999) UK	Women with Bulimia Nervosa	N=125 (MET n=87; CBT n=38) of which n=91 completed the URICA	CBT: Bulimia Nervosa: A guide to recovery (Cooper 1993).	URICA	Binge frequency, vomit frequency and frequency of use of laxatives at end of treatment phase 1	Individuals classified as in the contemplation stage on the URICA showed less improvement in binge eating frequency than those in the action stage. Improvement in

		Secondary analysis of RCT	Mean Age: MET=28.8 (7.8) CBT=28.5 (7.2) Gender: 100% Female	MET: first four chapters of clinician handbook of Getting Better bit(e) by bit(e) Individuals randomised to 4wks MET+ 8 weeks Individual CBT; 4wks MET followed by 8 weeks group CBT; 4 weeks individual CBT followed by 8 weeks group CBT. Groups allocated to MET combined for current study to give n=87 to MET and n=38 to CBT.		[Assessed 4 weeks into treatment – end of treatment phase 1]	binge eating was moderated by stage of change on the URICA. No *time x stage of change* interaction for vomiting or laxative abuse. No *treatment* x *stage of change* interaction for any outcome.
16	Vogel et al., (2006) Norway	Consecutive referrals with OCD to city psychiatric outpatient clinic in Norway from 1993-1998	N=39 with N=37 providing study data. Mean Age: 35.1 (12.1) Gender: 73% Female	Random assignment to one of two individual ERP treatments based on Foa (1991). Structurally identical for 75%	URICA	YBOCS [Assessed at end of treatment and 12 months follow-up]	URICA score not significantly associated with treatment response at end of treatment or 12 month follow-up.

		Naturalistic pre-post study.		of session time. Differed in including either additional CBT strategies or relaxation techniques. 120 minutes twice a week for 6 x 120-minute sessions. 60-minute follow-up at 3, 6, 9, 12 months.			
17	Wagner et al., (2014) Austria	Participants aged 18-35 with Bulimia Nervosa or EDNOS Secondary analysis of RCT	N=126 (70 INT-GSH; 56 BIB-GSH) Mean Age: 24.17 (4.46) INT-GSH 25.02 (3.84) BIB-GSH Gender: 100% Female	CBT internet-based guided self-help with weekly email therapist support (SALUT-BN, 7 modules) CBT Bibliotherapy with weekly email therapist support (15 chapters-Getting Better Bit(e) by Bit(e), by Treasure & Schmidt 1993).	BNSCQ	Diagnostic Status at end of treatment (participant did or did not fulfil DSM-IV criteria based on previous month's binging / purging behaviour). Drop-out during treatment (participating for less than 2 months or completing less than 3 modules of INT-GSH or 6	BNSOC score significantly associated with remission at end of treatment in model exploring role of personality factors BNSOC not significantly associated with dropout from treatment.

						chapters of BIB-GSH).	
18	Wolk & Devlin (2000) USA	Women with Bulimia Nervosa Secondary analysis of data from a single site of RCT	N=110 randomised and n=66 completing 19 sessions of treatment. Mean Age: for 110 randomised CBT: M=28.2 (6.6) IPT: 25.1 (5.4) Gender: 100% Female	CBT (n=32) 19 sessions - Fairburn Marcus and Wilson, 1993) IPT (n=34) 19 sessions (Fairburn. 1997)	SCS	EDE used to categorise participants into: full remission, partial remission/sub-threshold or still meeting diagnostic criteria [Assessed at end of treatment]	Overall stage of change associated with outcome (full remission/partial remission/still meeting criteria). None of the participants in the pre-contemplation stage at treatment entry achieved remission. Association between stage of change and outcome was not significant for CBT but was significant for IPT.
19	*Lewis et al., (2012)* *USA*	*Participants presenting to a university training clinic for treatment of psychological problems.* *Naturalistic pre-post study*	*N=173* *Age: 27.94 (11.42)* *Gender: 66.5% Female*	*Case formulation driven CBT as in routine clinical practice.*	*SOCS*	*BDI* *BAI* *Assessed weekly until end of treatment.*	*Description of analysis and results inconsistent and impossible to interpret. Communication with author did not lead to resolution. Included as eligible but results not reported.*
20	Wade, Ghan &	Consecutive referrals to a University	N = 98	CBT-T – manualised transdiagnostic	100 point likert scale assessing	EDE– Global Score	Main effect of readiness to change on symptom levels – Lower readiness to change at

Waller, (2021) Australia /UK	Eating Disorder Service RCT comparing two active CBT interventions	Age: CBT-T = 26.91 (SD = 10.88) CBT-M = 25.77 (SD = 7.45) Gender: CBT-T – 91% Female CBT-M – 94% Female	CBT for eating disorders (Waller et al., 2001) CBT-M – Individually delivered CBT supported by two self-help books (Cooper, 1993; Cooper et al., 2001)	readiness to change	Assessed at 4 weeks, 10 weeks, 14 weeks, 22 weeks	baseline was associated with a greater symptom burden over treatment. Significant readiness x time x group interaction: participants with low motivation to change in CBT-T showed lower rates of improvement at one-month and three-month follow-up than those with high motivation randomised to CBT-T and those with both low and high motivation randomised to CBT-M.

BAI = Beck Anxiety Inventory Beck & Steer, 1993; BDI = Beck Depression Inventory (Beck, Ward, Mendelsohn, Mock & Erlbaugh, 1961); BDD-YBOCS = Body Dysmorphic Disorder Yale-Brown Obsessive-Compulsive Scale (Phillips et al., 1997); BNSOCQ =Bulimia Nervosa Stages of Change Questionnaire (Rieger et al., 2000); CDRS-R = Children's Depression Rating Scale – Revised Children's Depression Rating Scale-Revised (Poznanski & Mokros, 1995); CQ = Change Questionnaire (Miller & Johnson, 2008); EDE = Eating Disorder Examination (Fairburn & Beglin, 2008); EDI-2 = Eating Disorder Inventory -2 (Garner, 1991); FSTABS = German translation of Pain Stages of Change Questionnaire (adapted for somatoform disorders, Maurischat et al., 2002); HAM-A = Hamilton Anxiety Rating Scale (Hamilton, 1959); HAM-D = Hamilton Rating Scale for Depression (Hamilton, 1960); MISC 1.1 = Motivational Interviewing Skills Code 1.1 (Glynn & Moyers, 2009); OQ = Outcome Questionnaire (Lambert et al., 1996); PSWQ = Penn State Worry Questionnaire (Meyer et al., 1990); Readiness Ruler (Miller & Rollnick, 2002); SCQ = Stages of Change Questionnaire (Bellis, 1994); SCS = Stage of Change Scale (DiClemente et al., 1991); SOCS = Stages of Change Schedule (McConnaughy, Prochaska & Velicer, 1983); SOMS-7 = Screening for Somatoform Disorders (Rief & Hiller, 2003); URICA = University of Rhode Island Change Assessment (URICA: McConnaughy et al., 1983); WSAS= Work and Social Adjustment Scale (Mundt et al., 2002); YBOCS= Yale Brown Obsessive Compulsive Scale (Goodman et al., 1989); YBC-EDS-MC = Yale Brown Cornell Eating Disorders Scale Motivation for Change Subscale (Mazure et al., 1994).

Location and Design Studies were conducted in North America (*n*=12), Western Europe (*n*=7) or Australia (*n* =1) and comprised primary (*n* = 1, 20) or secondary analyses of data from randomised trials (*n*=6: 5, 6, 10, 15, 17, 18), secondary analyses collapsing data across studies or trial arms (*n*=2: 2, 8), naturalistic pre-post studies in clinical settings with routine referrals (*n*=9: 1, 3, 4, 9, 12, 13, 14, 16, 19), and quasi-experimental studies utilising a pre-post design (*n*=2: 7, 11. Seventeen studies were published after 2009, with the earliest published in 1999.

Population Characteristics Most studies included adults (*n*=17) whilst three used adolescent samples (3, 6, 10). The proportion of Caucasian participants ranged from 58.9% to 92.5% for the n=11 studies reporting ethnicity. Females were in a majority in all 19 studies reporting gender and in 11 more than 90% of the sample were female. Three studies included participants with varied diagnoses (1, 4, *19*), but the majority focused on single conditions: anxiety disorders (2, 5, 11), OCD or BDD (12, 7, 14, 16), eating disorders (3, 6, 9, 13, 17, 18, 20), depression (10) or somatoform disorders (8). Likewise, three studies had inpatient samples (1, 4, 12) or mixed inpatient/outpatient samples (3), whilst the majority included outpatients (*n*=15), and those receiving therapist-supported guided self-help (17). Most studies reported that participants met DSM-III/IV/V diagnostic criteria for their stated condition (American Psychiatric Association, 1980, 2000, 2013), whereas three focused on inpatient samples (1, 4, 12) and reported diagnoses but not the diagnostic criteria employed (see Table 4).

Table 4. Clinical Problems, Sample Description and Outcome Measures

Disorder/Problem/ Population	Study ID	First Author and Year	Description of Sample	Ethnicity	Outcome Measure
Mixed Disorders	1	Berry 2010	Women admitted to inpatient unit. Diagnoses: 50.3% Major Depression; 23.3% Bipolar Disorder; 9.8% Psychotic Disorder or Schizophrenia; 10.4% Eating Disorder; 6.1% Other mental disorder.	58.9% Caucasian; 19% Hispanic; 6.7% African American; 6.1% Mixed Ethnicity; 3.1% Asian; 5.5.% other	Length of inpatient stay (days)
	4	Clarke 2013	Women with and without a substance use disorder admitted in a psychiatric inpatient unit. Depression 50%; Bipolar Disorder 24%; Schizophrenia 10%; Anxiety 2%; Eating Disorder 12%.	PwSA (n=50) 68% Caucasian; 18% Hispanic, 8% Mixed ethnicity, 2% Asian, race; 2% African American. PwoSA - 70% Caucasian, 17.9% Hispanic, 3% African/American, 1.5% Asian, 1.5% Mixed ethnicity.	Outcome Questionnaire (OQ)
	19	*Lewis, 2012**	*Adults seeking treatment from a university outpatient clinic.*	*92.49% Caucasian*	*Beck Depression Inventory*

		**This study was not included in the narrative synthesis due to inconsistencies in reporting of results.*	*Participants assessed using structured clinical interview for DSM-IV (SCID-I First, Spitzer, Gibbon & Wiliams, 1997)* *Reported Diagnoses:* *Depressive disorders – 56.1%* *Anxiety Disorders – 32%* *Other Disorders (e.g. dissociative disorder, bipolar disorder) – 12%* *Participants excluded if BDI score indicated less than mild symptoms.*		*Beck Anxiety Inventory*
Anxiety Disorder	2	Boswell, 2012	Adults meeting diagnostic criteria for one or more anxiety disorders according to Anxiety Disorders Interview Schedule for DSM-IV-Lifetime version (ADIS-IV-L)	94.5% Caucasian	Hamilton Anxiety Rating Scale (HARS)
	5	Goodwin, 2019	Adults meeting DSM-IV-Tr and DSM-V diagnostic criteria for Generalised Anxiety Disorder according to SCID-I (First, Spitzer, Gibbon & Williams, 1996) with a Penn state worry questionnaire score >=68.	MI: 74% Caucasian; 14% Asian; 5% African-Canadian; 2% Hispanic; 5% Multiracial. CBT: 74% Caucasian; 12% Asian; 0% African-Canadian; 5%	Penn State Worry Questionnaire (PSWQ)

				Hispanic; 7% Multiracial.	
	11	Lombardi, 2014	Community adults with a principal diagnosis of Generalised Anxiety Disorder based on Anxiety Disorders Interview Schedule for DSM-IV (ADIS-IV; Brown, DiNardo & Barlow, 1994).	59% Caucasian 22% Asian 11% Hispanic 8% African Canadian	Penn State Worry Questionnaire (PSWQ)
OCD/BDD	12	Monaghan, 2015	Adults admitted to a residential intensive inpatient programme for OCD with a primary diagnosis of OCD determined by clinical interview. Participants' mean YBOCS score in severe range.	84.2% White; 4.5% Asian 0.9% Black or African American 0.5% American Indian or Native Alaskan 0.5% Native Hawaiian or Pacific Islander and 0.7% Other ethnicity.	Yale Brown Obsessive Compulsive Scale (YBOCS)
	7	Greenberg, 2019	Adults with a DSM-IV primary diagnosis of Body Dysmorphic Disorder (BDD) or its delusional variant based on Structured Clinical Interview for DSM-IV patient version (SCID I/P First, Spitzer, Gibbon & Williams, 1995) and BDD-YBOCS score 24 or greater.	White 88% Black 7%, Other ethnicity 5%	Body Dysmorphic Disorder- Yale Brown Obsessive Compulsive Scale (BDD-YBOCS)

	14	Solem, 2016	Adult outpatients with a DSM-IV diagnosis of OCD	Not Reported	Yale Brown Obsessive Compulsive Scale (YBOCS)
	16	Vogel, 2006	Adults meeting DSM-II-R criteria for primary OCD with overt compulsions assessed via Anxiety Disorders Interview Schedule Revised (ADIS-R).	Not Reported	Yale Brown Obsessive Compulsive Scale (YBOCS)
Eating Disorder	3	Castro Fornieles, 2011	Children and adolescents meeting DSM-IV diagnostic criteria for Bulimia Nervosa assessed by clinical interview.	Not Reported	Eating Disorder Inventory-2 Number of binges/vomits per week
	6	Gorrell, 2019	Adolescents meeting DSM-IV criteria for Bulimia Nervosa as assessed by Eating Disorder Examination.	Not Reported	Eating Disorder Examination Global Score
	9	Hudson, 2020	Adults Meeting DSM-5 criteria for AN, BN or OSFED based on structured clinical interview with psychiatrist	Not Reported	Number of CBT sessions attended. Engagement, Drop out.
	13	Pellizer, 2017	Adults meeting DSM-V diagnostic criteria for an eating disorder.	88.5% Caucasian	Eating Disorder Examination Global Score

17	Wagner, 2014	Adults aged 18-35 meeting DSM-IV-TR criteria for BN (90%) or EDNOS (10%) with BMI >18.	Not Reported	Diagnostic Status at End Treatment
18	Wolk, 2000	Adult women meeting DSM-III criteria for bulimia nervosa	For *n*=110 Randomised: CBT: White 78% Hispanic 9% African American 7% Asian 6% American Indian 0% IPT: White 66% Hispanic 18% African American 9% Asian 7% American Indian 0%	Eating Disorder Examination – women categorised as: full remission, partial remission/ sub threshold, still meeting criteria
15	Treasure, 1999	Adult women meeting DSM-IV criteria for bulimia nervosa.	Not Reported	Binge Frequency, Vomit Frequency, Laxative Frequency
20	Wade, Ghan & Waller, 2021	Adults meeting DSM-V criteria for an eating disorder: : Anorexia, *n*=5, 5%; Bulimia, *n*=68, 69%; Binge Eating Disorder, *n*=5, 5%; Other Specified Feeding or Eating Disorder, *n*=20, 21%	Not Reported	Eating Disorder Examination – Global Eating Disorder Psychopathology Score.

Depression	10	Lewis, 2009	Adolescents with a DSM-IV primary diagnosis of major depressive disorder	75.9% White; 10.2% African American; 9.3% Hispanic; 0.3% Pacific Islander	Children's Depression Rating Scale-Revised (CDRS-R)
Somatoform Disorders	8	Heider, 2018	Adults with various somatoform disorders according to DSM-IV-TR criteria assessed using the International diagnostic checklist for DSM-IV (IDCL: Hiller, Zaudog & Mombour, 1997)	Not Reported	Screening for Somatoform Disorders (SOMS-7)

Intervention Characteristics Studies explored various CBT formats: group (*n*=2), individual (*n*=13) combined individual and group (*n*=4) and guided self-help (*n*=1). In some naturalistic settings CBT was augmented with medical management and/or adjunctive therapies addressing comorbidities (e.g., substance use education) or general psychosocial support (e.g., milieu experiences in inpatient facilities). One study reported on the first four sessions of CBT, compared to a four-session motivational interviewing module (15). The remainder examined outcomes of courses of CBT treatment, with length depending on treatment protocol and setting (see Table 3).

Reports varied in the detail provided about CBT treatment. For six (6, 7, 9, 10, 11, 18) further information was obtained from primary outcome studies. Four provided no information about therapist training (3, 8, 10, 14). Seven reported that interventions were delivered in whole or part by trainee psychologists (2, 4, 5, 11, 13, 19, 20), whilst the remainder (*n*=9) reported delivery by a range of professionals with varying degrees of post-qualification experience. Ten either referenced adherence checks, weekly supervision and/or measures to establish competency prior to delivery of therapy (2, 4, 5, 6, 7, 11, 16, 18, 19, 20).

Outcome Measures Most studies described the relationship between readiness and change on a validated symptom measure corresponding to the primary treatment target (see Table 4), usually assessed on a continuous measure of symptom severity. Single studies examined abstinence from ED behaviours (6), diagnostic status at end of treatment (17), meeting recovery criteria (11) or demonstrating clinically significant response (7). Five examined the relationship between readiness and treatment engagement: length of inpatient stay & number of CBT sessions attended (1); number of CBT sessions attended, engagement with treatment, dropout (9); attrition from treatment (13), dropout (14); drop-out (17).

Measurement of Readiness. Eight studies used the URICA (McConnaughy, Prochaska & Velicer, 1983), either the 32-item version (1, 2, 4, 7, 12, 16), the 24-item version (15) or an unspecified version (14). Five derived a total score conceptualising readiness as a continuum (1, 2, 4, 7, 16), corresponding to the sum of the raw/mean contemplation, action and maintenance item scores, with the sum of the precontemplation score subtracted ('Readiness Index', Carbonari, DiClemente & Zweben, 1994). Two studies used subscale scores (12, 14), one categorised participants to a stage of change based on the subscale on which they scored highest (15) and two (3, 17) used the BNSCS total score (Martinez et al., 2007). Two used the Motivational Interviewing Skills Code 1.1 (Glynn & Moyes, 2009) to derive measures of change talk and counter change talk (5, 11). One of these derived all ratings in session 1 (5). A second derived ratings from session 1 (78%) or 2 (22%) but was included as it also employed another measure of motivational readiness, obtained prior to the start of treatment (11). One study used a Readiness Ruler (10-point rating of readiness to change; 9) and two used a single item rating on a scale from 0-100 (13, 20). A range of other measures were used by single studies (FF-STABS: 8; Stages of Change Schedule: [19]; Stages of Change Questionnaire: 10; Change Questionnaire: 11; Stage of Change Scale: 18). See Table 5 for full details.

Nine studies reported data on the internal consistency of the measure used (1, 2, 4, 5, 7, 8, 10, 17, 19) and in most cases, reliability was adequate to good. More than half the studies provided no information on the internal consistency of the measure within the sample.

Table 5. Measure of Readiness

Measure	First Author, year	Further Details	Information on Reliability
URICA	Berry, 2010	"Total Score"	alpha = .76
	Boswell, 2012	Total readiness score calculated by summing mean contemplation, action, and maintenance item scores and subtracting mean pre-contemplation item score.	alpha = .82
	Clarke, 2013	Total readiness score calculated by summing raw subscale scores for contemplation, action and maintenance and subtracting raw pre-contemplation score from this total.	alpha = .68
	Monaghan, 2015	URICA subscale scores used for analysis: precontemplation, contemplation, action and maintenance.	Not reported
	Greenberg, 2019	Total Readiness score calculated by summing mean contemplation, action, and maintenance item scores and subtracting mean pre-contemplation item score.	Internal consistency of subscales at baseline ranged from alpha =.70 (precontemplation) to alpha =.87 (maintenance).
	Solem, 2016	Version not reported. Subscale scores used for analysis: precontemplation, contemplation, action, maintenance.	Not reported
	Vogel, 2006	Readiness to change index (McDonald & Warren, 2001): mean precontemplation score subtracted from the sum of the means of the three other	Not reported

		subscales, contemplation, action, maintenance.	
	Treasure, 1999 (URICA – 24)	Derives scores for three subscales: precontemplation, contemplation and action. Participants assigned to a stage based on the subscale on which they scored highest.	Not reported
Bulimia Nervosa Stages of Change Scale (Martinez et al., 2007).	Castro-Fornieles, 2011	20 item measure yielding a total score.	Not reported
	Wagner, 2014	20 item measure yielding a total score.	Internal consistency alpha = .94 1 week test-retest *r* = .93
Change Talk and Counter Change Talk via Motivational Interviewing Skills Code 1.1	Goodwin, 2019	Measurement of Change Talk and Counter Change Talk during session 1 assessed via Motivational Interviewing Skills Code 1.1. (MISC 1.1 Glynn & Moyes, 2009) adapted for CBT.	25% double rated k = .86
	Lombardi, 2014 (also below)	Assessed during Session 1 - 78% or Session 2 - 22% so study included on basis of Change Questionnaire but data on MISC 1.1 reported.	Not reported
Readiness Ruler	Hudson, 2020	Measure asked participants to: "*Rate where you are now on this line that measures your change in eating behaviour. Are you not prepared to change, already changing, or somewhere in the middle*?" Line ranged from: 0=not prepared to change to 10=already changing	Not reported

Single item 100-point rating	Pellizzer, 2017	Single item assessment. Participants asked: "*How ready are you to change*?" Report response on scale ranging from 0 to 100. Anchors not provided.	Not reported
	Wade, Ghan & Waller, 2021	Single item measure of readiness to change. Anchors not provided.	Not reported
FF-STABS (Pain Stages of Change Questionnaire)	Heider, 2018	17 item German modification of the Pain Stages of Change Questionnaire adapted for somatoform symptoms. Includes 4 subscales: precontemplation, preparation, action, maintenance.	Internal Consistency: Precontemplation (alpha =.68) Preparation (alpha = .57) Action (alpha = .82) Maintenance (alpha = .73).
Stages of Change Questionnaire	Lewis, 2009	Four subscales: precontemplation, contemplation, action, maintenance.	EFA in sample yielding four subscales with coefficient alpha for each factor 'satisfactory or greater'.
Change Questionnaire	Lombardi, 2014	Target change: "to worry less" Assesses desire, ability, reasons, need, commitment and taking steps towards change and yields total score.	
Stage of Change Scale	Wolk, 2000	3 items used to assign to pre-contemplation, contemplation or preparation phases: Q1. Do I intend to stop binge eating and purging in the next six months? Q2. Do I intend to stop binge eating and purging in the next 30 days?	No internal consistency data reported.

		Q3. In the past year before coming to this clinic, have I had definite plans to stop binge eating and purging (either on my own or with outside help) and have I actually attempted to carry out those plans?	
Yale Brown Cornell Eating Disorder Scale – MCS	Gorrell, 2019	Interviewer based measure which assesses: Resistance, insight, and desire for change for ED-related preoccupation and rituals. Lower MC score equates to greater motivation to change.	
The Stages of Change Schedule	*Lewis, 2012*	*Measure yielded four subscales: precontemplation, contemplation, action, maintenance derived through summing the eight items corresponding to each of the four subscales.*	*Internal Consistency* alpha *= .82.*

Association Between Readiness and Symptom Change

Seventeen studies (2, 3, 4, 12, 5, 6, 8, 10, 11, 13, 7, 14, 15, 16, 17, 18, 20) examined the relationship between readiness and outcome following CBT/ERP[1], with a majority (*n*=12) identifying at least one significant association.

A study of the relationship between readiness and outcome following two formats of guided self-help CBT for bulimia (17), found that those with higher pre-treatment readiness were more likely to achieve remission irrespective of treatment format. A study of CBT for eating disorders (20) reported an interaction between readiness, treatment condition (CBT-T or CBT-M) and outcome, such that participants with low readiness randomised to CBT-T, which did not address motivation for change, showed higher symptom burden at 1 and 3 month follow-up than either those with high readiness allocated to CBT-T, or those with low or high readiness allocated to CBT-M (which addressed motivation in early sessions). In a study of transdiagnostic CBT for anxiety disorders, those with higher readiness showed greater improvements on measures of anxiety when baseline symptom severity was also high (2). Finally, an interactive effect was also observed in CBT for somatoform disorders (8): both precontemplation and action subscale scores interacted with symptom levels at baseline to predict post-treatment symptoms, with a range of other conditional effects observed (see Table 3).

Some studies adopted an exploratory approach. For example, a study of people receiving CBT for BDD (7) reported that baseline readiness was one of three variables (of 14 examined) associated with treatment response. A second (3) found that higher baseline readiness was associated with a greater reduction in binges, and greater change

[1] Lewis et al (2012) also examined this relationship. However, the analyses reported were uninterpretable due to an inconsistency in study reporting, which could not be resolved though direct contact with the author and is not discussed further.

on two of the 11 subscales of the EDI, with readiness being the only variable associated with clinical change in binges and decreases in the EDI bulimia subscale, after controlling for known confounders. Two other studies reported mixed findings. The first (6) identified an association between higher baseline readiness and a lower score on the EDE at end of treatment in adolescents with bulimia, but no association between readiness and abstinence from ED behaviours. The second (15) found that stage of change was associated with change in binge frequency at end of treatment, but not frequency of vomiting or laxative use.

The above studies employed self-report measures. However, others captured participant in-session behaviour. One study (11) focused on anxiety disorders demonstrated that participants with higher readiness at pre-treatment had lower levels of post-treatment worry. Additionally, after accounting for self-reported readiness, increased *counter*-change talk in early treatment was associated with higher post treatment worry and a reduced chance of reliable symptom change. Extending these findings, a second (5) showed that after controlling for self-reported readiness, session one change talk was associated with an increased chance of clinically significant response, and counter-change talk a decreased chance.

Five studies did not report any significant associations between readiness and clinical outcome. A study of people receiving ERP for OCD (14), identified no association between readiness and post-treatment symptoms, whilst another exploring inpatient CBT for OCD (12) identified no association between readiness and symptom change. A third (16) found no association between readiness and outcome in people with OCD receiving ERP augmented with CBT strategies and a fourth (18) found that stage of change was not associated with remission in people receiving CBT for bulimia nervosa (although it was associated with remission for the overall sample combining CBT and IPT, and for

those receiving IPT only). Finally, a study of people receiving CBT for EDs found that readiness did not predict change in EDE-Global Score (13).

Association Between Readiness and Treatment Attendance

Five studies (1, 9, 13, 14, 17) explored treatment attendance and found only limited evidence of an association with readiness. One (1) identified a significant association between greater readiness at admission and longer inpatient stay, but no significant association with number of CBT sessions attended. A second (14) compared those who completed ERP for OCD with those who dropped out on the four URICA subscales (precontemplation, contemplation, action, maintenance) and found those who dropped out scored significantly lower on the contemplation subscale than those who remained in treatment but did not differ on the other subscales. Of the remaining studies, one (9) identified no significant association between readiness and number of sessions of CBT attended, initial engagement with CBT or dropout from treatment, whilst two (13, 17) found no association between baseline readiness and dropout.

Relationship between Readiness and Outcome by Diagnosis

All three studies exploring the relationship between readiness and outcome in people with anxiety disorders (2, 5, 11) identified significant associations, as did the single study exploring a mixed inpatient sample (4). Studies of OCD spectrum disorders (7, 12, 14, 16) identified only limited evidence of an association between readiness and outcome. One (7) reported that baseline readiness was one of three variables associated with treatment response in people receiving CBT for BDD. However, the remaining three studies (12, 14, 16) found no association between readiness and outcome in patients with OCD.

Across the seven studies focused on eating disorders, five (3, 6, 15, 17, 20) identified a significant direct or moderator effects of readiness on symptom outcome and two did not (13, 18). Finally, two studies explored other disorders (adolescent depression: 10; somatoform disorders: 8) and found direct or moderator effects of readiness on symptom outcome.

Association between Readiness and Outcome in Randomised Controlled Trials

None of the seven studies that employed an RCT design (5, 6, 10, 15, 17, 18, 20) included a waitlist arm or no-treatment control arm. As a result, it was not possible to compare the association between readiness and outcome in those receiving CBT and those experiencing spontaneous symptom change (research question 2). Five of the seven RCTs compared CBT to another therapeutic intervention: Interpersonal Psychotherapy (18), Family-Based Therapy (6), Motivational Interviewing combined with CBT (5), Fluoxetine or Placebo (10), Motivational Enhancement Therapy (15), whilst one (17) compared two forms of guided self-help CBT, and one two forms of CBT (20). All five comparing CBT to another intervention identified at least one significant association between readiness and outcome across the whole study population. However, exploring research question 3, none of the four which tested for a significant *readiness by treatment group* interaction (5, 6, 10, 15) identified one, providing little evidence that readiness influences outcome differently in CBT and other forms of therapeutic intervention when examined in the same clinical population. The fifth study, (18) examined the association between stage of change and outcome separately for participants receiving IPT and CBT and identified a significant association only in the IPT group. The authors suggested that CBT may be better suited to addressing ambivalence to change than IPT and hence the association between readiness and outcome (which was observed for the sample overall) may have been attenuated in the CBT group. However, in the absence of a test of

interaction it is not possible to conclude that the association was *significantly stronger* in the group receiving IPT than CBT, simply that it was observed to reach a conventional level of significance only for those receiving IPT.

Evidence for Differential Effects of Readiness on Symptom Change by Measure Used

Six of the eight studies that utilised the URICA (1, 2, 4, 7, 14, 15) identified a significant association between readiness/stage of change and at least one outcome, although in some cases these studies also had null fundings in relation to other outcomes, and two (12, 16) identified no significant effects. There was no obvious relationship between the way the URICA was used to derive a measure of readiness/stage of change and the presence of significant findings. Two exploratory studies (3, 17) used the BNSOCQ, and both identified readiness as a factor associated with either one of several clinical outcomes (3) or as one factor amongst many explored that predicted clinical response (17). Other multi-item self-report measures (FFSTABS; Stages of Change Questionnaire; Change Questionnaire; Stage of Change Scale) all showed significant associations with participants' clinical response, overall, or for specific subscales.

Two studies (5, 11) used the Motivational Interviewing Skills Code 1.1. (Glyn and Moyes, 2009) to explore evidence of change talk and counter change talk in client natural language and both found that variables derived from this measure were associated with clinical response. Finally, whilst the study (6) that utilised the motivation subscale of the interview-based Yale-Brown-Cornell Eating Disorder Scale (Mazure, Halmi, Sunday, Romano, Einhorn, 1994) also identified a positive association with aspects of treatment response, three studies explored single item ratings of readiness to change (9, 13, 20) with only one identifying a significant association with outcomes of interest.

Quality Appraisal

Using the Down and Black Quality Appraisal tool, a majority of studies were rated as of fair quality (1, 2, 3, 4, 5, 6, 7, 8, 11, 12, 16, 17, 18) with three rated poor (9, 13, 14) and three rated good (10, 15, 20). Raw quality scores appeared to be approximately normally distributed, with studies generally performing relatively well on items assessing quality of reporting, but more poorly on items assessing risk of bias. Very few of the studies reported a power calculation for the relevant analyses, or the study overall, which likely relates the fact that many were secondary analyses. Two of the five studies reporting no significant effects were rated poor and three were rated fair. Table 6 reports quality ratings for each study and some of the major issues identified are described in the discussion.

Table 6. Down and Black Quality Rating

ID	First Author and Year	Reporting (/11)	External Validity (/3)	Internal Validity (bias) (/7)	Internal Validity (confounding, selection bias) (/6)	Power (/1)	Total (/28)	Rating
1	Berry (2010)	10	1	3	3	0	17	Fair
2	Boswell (2012)	7	0	4	3	1	15	Fair
3	Castro-Fornieles (2011)	9	2	4	3	0	19	Fair
4	Clarke (2013)	6	1	5	3	0	15	Fair
5	Goodwin (2019)	8	0	5	5	0	18	Fair
6	Gorrell (2019)	7	0	3	5	0	15	Fair
7	Greenberg (2019)	8	0	5	3	0	16	Fair
8	Heider (2018)	7	0	5	3	0	15	Fair
9	Hudson (2020)	6	2	3	3	0	14	Poor
10	Lewis (2009)	8	0	7	6	0	21	Good

11	Lombardi (2014)	6	0	5	4	0	15	Fair
12	Monaghan (2015)	8	0	4	3	0	15	Fair
13	Pellizzer (2017)	6	1	3	3	0	13	Poor
14	Solem (2016)	5	1	4	2	0	12	Poor
15	Treasure (1999)	8	3	5	4	0	20	Good
16	Vogel (2006)	7	2	5	4	0	18	Fair
17	Wagner (2014)	8	0	4	3	0	15	Fair
18	Wolk (2000)	8	0	5	4	0	17	Fair
20	Wade (2021)	9	0	4	6	1	20	Good

*Items of questionable relevance to pre-post single group designs – see Appendix C for discussion of how these items were rated and discussion of selection of quality appraisal tool**.**

Discussion

This review considered studies examining the relationship between pre-treatment RTC and subsequent attendance or outcome of CBT for mental health problems other than addiction. A systematic search identified 20 eligible studies, with 19 included in the narrative synthesis.

Seventeen studies explored the relationship between RTC and symptom outcome (2, 3, 4, 5, 6, 7, 8, 10, 11, 12, 13, 14, 15, 16, 17, 18, 20), with 12 (2, 3, 4, 5, 6, 8, 10, 11, 15, 17, 18, 20) identifying a statistically significant relationship, either directly or in interaction with another variable. A number also tested other associations between RTC and outcomes, which were non-significant. Few (1, 9, 13, 14, 17) explored the association between RTC and treatment attendance and findings were inconclusive. It has been suggested that RTC may be more relevant when the problem in question has clear behavioural markers (Drieschner, et al., 2004), and the TMSC has historically been applied most to addictions. However, there was no clear evidence to suggest that findings were more consistent for studies involving some clinical populations than others.

RTC is often conflated with treatment motivation (Carey et al., 1999) although they are distinct constructs. Further, it is often assumed that an association between RTC and treatment outcome is the result of some influence of RTC on how the person interacts with a treatment. However, without a comparison between this relationship in people both within and outside a treatment context, it is not possible to establish whether this is in fact the case. None of the studies identified in this review reported data from both a CBT arm and a no-intervention control arm, preventing further exploration of this issue. However, although likely underpowered, those studies which compared the association between RTC and outcome in people randomised to CBT versus to another non-CBT therapeutic intervention (5, 6, 10, 15, 18) found no clear evidence indicating that RTC had a differential impact on treatment response across a

range of interventions, suggesting that any mechanisms are likely to be relatively non-specific. The most recent study included in the review compared the relationship between RTC and outcome in two forms of CBT for eating disorders (20), one of which required behaviour change from session 1, and one of which included two sessions of individual formulation and consideration of pros and cons for change. As predicted, RTC influenced symptom outcome only in the treatment requiring session 1 behavioural change. However, the two forms of CBT differed in other respects (e.g., provision of between session resources) and understanding how RTC influences different aspects of a client's engagement with treatment is clearly an area where further research is required.

Study Limitations

Generalisability Across the studies in the review, female participants were in the majority, with several studies recruiting *only* female patients. Likewise, where ethnicity data were reported, most participants were Caucasian and for nine studies ethnicity data was not reported at all. The review was restricted to English language studies, with almost all originating in North America or Western Europe. It is established that both gender (e.g., Wendt & Shafer, 2016) and ethnicity (e.g., McGuire & Miranda, 2008) influence patterns of treatment seeking for mental health problems, and it is likely that these factors may also influence the processes through which individuals recognise take steps towards change and interact with treatment, as well as the relative accessibility of services. None of the studies in the review explored the role of gender or ethnicity as they pertained to the relationship between RTC and treatment outcome, and this remains an important avenue for future work, in line with efforts to increase ethnic diversity in research populations (NIHR, 2018).

Randomisation Seven studies employed an RCT design (5, 6, 10, 15, 17, 18, 20), and these tended to achieve higher quality ratings (M = 17.99) than non-randomised

studies (*M* = 14.41). However, whilst randomisation is a gold standard for intervention efficacy research, it is arguably of little relevance as a design factor where the research question focuses on RTC as a correlate or moderator of treatment response. None of the studies reported stratification by baseline RTC, and it is questionable whether randomisation exerted much methodological benefit in relation to research question 1. Indeed, randomisation may have introduced factors such as resentful demoralisation (a deterioration in symptoms associated with participant randomisation to non-preferred treatment options, e.g., Onghena, 2005) which would not occur in more naturalistic studies or single arm quasi-experimental designs, and which may attenuate the relationship between pre-randomisation RTC and eventual outcome. The inclusion of randomisation was however a prerequisite for examination of the relationship between RTC and outcome across treatment conditions.

Analytic Approach Studies used a variety of analytical approaches. Some examined the relationship between RTC and outcome after controlling judiciously for possible confounders, for example through theory-driven hierarchical regression analyses (e.g., 6, 7, 8, 11) in which the unique effects of RTC could be determined, whereas others took a more exploratory approach and were concerned with identifying the best fitting, most parsimonious models to predict clinical outcome (e.g., 3), or used techniques such as survival analysis or multilevel modelling (e.g., 5, 10) to consider change across therapy. Every approach has potential strengths and weaknesses: exploratory analyses without appropriate control for multiple tests of association may identify spurious effects or may include or exclude variables from explanatory models as a function of the combination of other independent variables included. Highly focused theoretically driven studies may fail to identify and control for important confounders. Indeed, the evaluation of treatment of covariates or confounders was a challenging issue in quality assessment. The range of

clinical populations and study designs meant that unless specific confounding factors were identified by the authors, it was unclear which should reasonably be controlled for. The studies reviewed here did not pre-publish protocols for the analyses conducted and it is reasonable to assume that the presence and strength of any statistical associations observed between RTC and a clinical outcome has the potential to have been substantially influenced by the authors' selection of covariates and the broader analytic approach adopted.

Measures of Readiness The 19 studies included in the narrative synthesis employed 9 different measures. Only around half reported information on the internal reliability, and few reported convergent or discriminant validity. Some used methods, for example assigning participants to a stage of change based on an algorithm comprising yes/no questions (18) or according to the URICA subscale on which they scored highest (15), which although widely employed within TMSC research have subsequently had their validity questioned. For example, research suggests that only a minority of people fall into a single stage of change, and so such classifications may be quite arbitrary or reductive (e.g., Littell & Girvin, 2002). Likewise, the typical method for deriving the 'readiness index' involves adding maintenance scores to contemplation and action scores, before subtracting pre-contemplation scores (employed in studies 2, 4, 7, 16). It has been suggested that where individuals are scoring highly on the maintenance facet, the overall measure may not really be capturing 'readiness' to change, but also the process of making changes and protecting those that have been made. Within the context of this review, which focused on people with recognised mental health problems at the start of treatment this is likely to be less of a concern but remains a broader issue for the literature. Additionally, most studies relied on self-report, which is likely to be subject to demand effects. The two studies that employed analysis of client in-session speech (5, 11)

provided evidence to suggest that this had incremental explanatory power. Although labour-intensive to code, it would be useful to conduct further research using these novel methods. Finally, all studies explored RTC in relation to a single problem area, whether specified (‘worrying too much’) or unspecified (e.g., ‘the problem’). It is possible that people may vary in their readiness to make changes in different problem areas, for example being ready to reduce purging, but not to gain weight. Exploring more nuanced aspects of RTC, including potential conflicts between different aspects of change, may be an interesting line of future work.

Nature and Quality of CBT Intervention Studies were included on the basis that they delivered a CBT intervention (or for OCD spectrum disorders ERP/CBT). Many provided references to specific treatment protocols, or described session content, but the dose of CBT delivered varied considerably from study to study depending on the context in which the study was conducted. In most cases CBT was the only treatment offered, but particularly in inpatient settings and in eating disorder samples, it was typical for people to also receive medication management, milieu experiences or adjunctive therapies (studies 1, 3, 4, 9, 12). To support inclusion of more naturalistic samples, where there may be greater variation in RTC, and to broaden generalisability of review findings, such studies were included. However, it is important to bear in mind that in studies including adjunctive interventions, RTC will potentially have influenced engagement with these interventions and these interventions will potentially have influenced outcome. Likewise, where CBT therapists address motivation formally (e.g., as part of the Unified Protocol, or in some forms of CBT for eating disorders) or informally, the relationship between pre-treatment RTC and outcome may be attenuated (e.g., Wade et al., 2021).

Details of therapist training and treatment adherence were not provided for all studies and in a significant proportion CBT was delivered, at least in part, by trainees. Since

trainees may be less skilled in dealing with motivational barriers to engagement, their involvement may accentuate the relationship between RTC and clinical outcome. Finally, whilst many studies referred to clinical supervision, only three described measures to assess treatment fidelity or adherence and so the quality of intervention delivery is largely unknown.

Blindness Relatively few studies described who collected baseline data and it was often unclear whether therapists were blind to participant ratings. Having such knowledge may be advantageous – encouraging the therapist to adapt their approach to the client – or disadvantageous – if it sets up expectations about likely client outcome. Likewise, it was frequently unclear whether those gathering post-treatment data would have been blind to baseline measures of RTC. Whilst most studies employed either self-report questionnaires as outcomes or utilised data on session attendance, it remains possible that in the absence of blinding, bias was introduced.

Review Limitations

Several conceptual and methodological issues should be considered when interpreting review findings. The review included studies which assessed RTC in ways aligned to the TMSC. Whilst it is considered that inclusion of broad search terms such as ‘motivation’ and ‘stage of change’, as well as MESH terms, across a range of databases, will have resulted in a broad initial search, it is nevertheless expected that some potentially eligible studies will have been missed. Likewise, other conceptualisations of readiness and motivation for treatment exist and review findings would have been altered significantly if a different definition had been employed. For pragmatic reasons, the review did not include 100% independent double rating for titles/abstracts, data extraction or study quality, although this would have enhanced methodological rigour. Finally, it was not possible to extract comparable effect sizes or conduct a meta-analysis due to the heterogeneity of data analytic methods. Thus, it was

not possible to create a forest plot and look for evidence of publication bias. However, since many of the published studies comprised secondary analyses, it is highly likely that such a bias exists and that other exploratory analyses with non-significant findings remain in the 'file draw' (Rosenthal, 1979).

Conclusions

The studies included in the review were geographically homogenous with an over-representation of white, female, participants. In contrast they were clinically and methodologically diverse, spanning a range of settings, populations, and designs. Study quality was variable and predominantly fair rather than good, with many studies that were relatively exploratory, or which comprised secondary analyses of existing data. The review identified some evidence of an association between RTC and outcome in CBT, but also highlighted methodological weaknesses and uncertainties affecting the research area.

Despite critique of the TMSC, the concept of RTC is clearly still regarded as a useful heuristic for considering people's orientation to their problems at entry to treatment. Further high-quality research in populations with common mental health problems is required before it can confidently be concluded that the construct of RTC is useful in predicting CBT treatment response within treatment seeking populations. However, in healthcare systems in which demand exceeds supply, identifying those who are most likely to benefit from clinical interventions will remain an important ambition, and readiness is likely to remain a variable of interest. As such, it is encouraging to see continuing innovation in the field and to identify remaining questions which could usefully be addressed in future work

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Recording of Child Dependants in Electronic Health Records: A Service Improvement Project

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Abstract

Introduction: Recording information about the child dependants of adults accessing mental health services has an important safeguarding function and can support preventative parenting initiatives. However, services frequently do not record this information in line with good practice. This study explored facilitators and barriers to compliant recording in two mental health teams.

Methods: Twenty-six staff members across two teams provided information on 300 clients (of which 61% female, mean age 41 years). Information from staff was cross-referenced with information held in electronic health records and staff shared their perspectives on potential improvements to recording practices.

Results: Sixteen percent of the clients had known child dependants. Information about these children was present in almost all clients' records but was recorded in line with expected practice in less than 50% of cases. Staff identified barriers to obtaining and recording information about child dependants, including uncertainty about which children to record, concerns about the impact of asking about children on fragile therapeutic relationships and challenges related to time, workload pressures, and difficulties navigating IT systems.

Discussion: Findings were discussed with participants and stakeholders to incorporate their perspectives. A range of potential improvements targeting different levels of the system (e.g., both people-focussed and system focused changes) are proposed.

Public Significance Statement: Safeguarding children is everybody's responsibility. This paper considers ways to improve one aspect of safeguarding, recording information about service-users' children within adult mental health services.

Introduction

Many men and women with a serious mental illness are parents (Royal College of Psychiatrists, 2016). Their children are vulnerable to poorer outcomes both as a direct result of their parents' conditions (e.g., van Santvoort et al., 2015; Beardslee, Versage & Gladstone., 1998; Lewis, Rice, Harold, Collishaw & Thapar., 2011) and via the wider social and economic disadvantages that commonly co-exist with mental health problems. Parental hospitalization may result in traumatic separation of children from their family member, often following a period in which their care has been compromised (Foster, Hills & Foster, 2018). At its most extreme, parents with serious mental health problems may develop delusional beliefs involving their children, putting them at serious risk of harm (Royal College of Psychiatrists, 2011).

Parenting demands may also affect adult mental health outcomes. Although children are recognized as an important factor in recovery (Thompson, Sheen & Maybery, 2019), little research explores the impacts of parenting on mental health problems. The challenges of pregnancy and parenting may worsen the course of some mental health problems (Pinto et al., 2019) or precipitate relapse (e.g., Rutherford & Mayes, 2019, Lewis et al., 2017). Further, children growing up in families affected by mental health problems are more likely to experience mental or behavioural problems themselves, meaning that the greatest parenting challenges may be placed on those parents who already have fewer resources to cope (Sellers et al., 2016).

Despite the importance of considering parenting responsibilities (Henshaw, 2011), when planning an adult's care, and safeguarding their children, historically adult mental health professionals have not always been oriented to the needs of children (e.g., Howard, 2000). Stallard, Norman, Huline-Dickens, Salter, & Cribb (2004) identified a

range of barriers including limited time and resources which reduced staff capacity to consider children; adoption of a client-focused approach which de-prioritised children's needs; a lack of child/family focused skills, limiting staff confidence, and a desire to protect adult clients from potential guilt and shame related to the impact of their difficulties on their children.

To overcome these challenges, policy documents have stressed the need for mental health teams to develop systems to record the presence of children reliably. Twelve years ago, the *Think Family* strategy document (Social Care Institute for Excellence, 2011) stated that mental health services should systematically identify and record which adult clients are parents. In 2013 a report by OFSTED and the Care Quality Commission noted that mental health services varied in the extent to which they routinely considered the impact of parental mental health problems on children, and that responses of services tended to be reactive rather than proactive.

Within Oxford Health Foundation Trust (OHFT) Adult Mental Health Services, standard operating procedures require the recording of the child dependants of all adult clients within the 'patient info' tab of electronic health records ('Carenotes'), including child name and date of birth. Despite this, current evidence suggests that this information is not systematically recorded. An OHFT Adult Directorate CPA quarterly audit (2016/2017) suggested that parental / childcare responsibilities were 'assessed' in 94% of cases. However, the most recent OHFT Safeguarding Children Audit (Lord, Navrady-Wilson, Marchall-Falland, & Berry, 2018) highlighted that over half the children whose cases were audited, and who had a parent receiving mental health treatment through OHFT, were not recorded on that parent's Carenotes record. These discrepant findings suggest that assessments are not leading to compliant recording of information about dependants in

Carenotes. However, an adult-focused audit of Carenotes records to address this issue has not recently been conducted.

At the individual level, the absence of accurate and accessible information about children may compromise the safety of children when adults are in crisis, and limit opportunities to provide clients with proactive parenting support. At the service level, it makes it harder for services to identify gaps in provision or develop business cases for service developments focused on parenting. It is therefore important to ensure that steps are taken to improve recording practices.

To make such improvements contributory factors which might be potential targets for intervention need to be considered at both the person- and system-level (Cafazzo & St-Cyr, 2012). The findings of Stallard et al., (2004) above suggest that attitudes, skills and competing demands may contribute to sub-optimal practice. However, reasons for failures to record information may also be quite context-specific and any proposed improvements should be informed by evidence from the services in question. The goal of this project was therefore to establish the knowledge required for the preparatory phase of a piece of quality improvement research, with the following aims:

1. To conduct an audit to estimate the current accuracy of recording of child dependants in Carenotes. This will establish whether a 'problem' exists and generate a baseline against which future quality improvements initiatives could be benchmarked.
2. To understand factors influencing current recording practices, as described by care coordinators,
3. To explore care coordinators' perspectives on potential improvements.

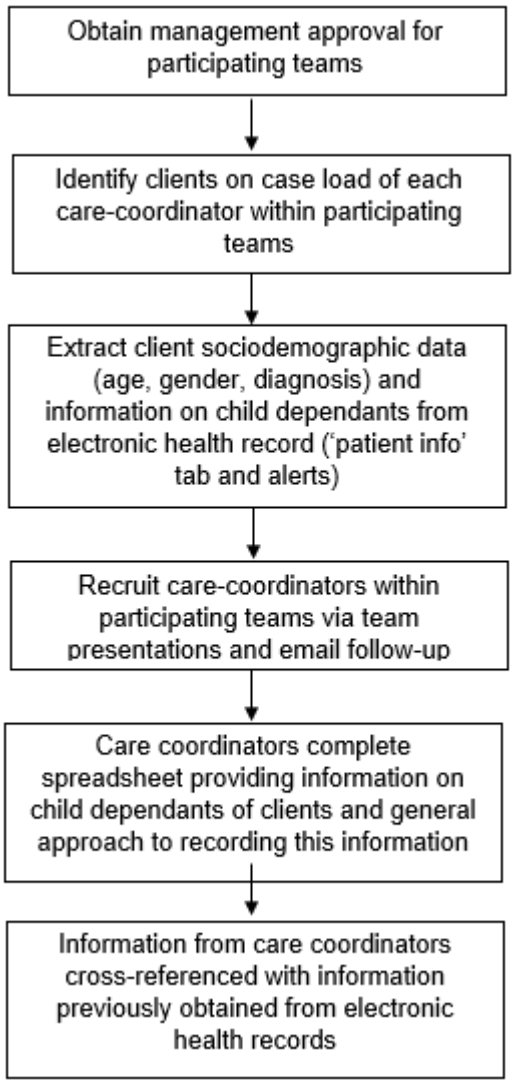
4. To propose potential improvements, sharing findings with relevant stakeholders and decision makers.

Methods

Participants

One community adult mental health team and one specialist team within OHFT participated following consent of team managers. The audit was conducted between August and October 2020 and in total, 37 care-co-ordinators with active caseloads were approached across the two teams. The project received audit and information governance approval from OHFT (see Appendix D). The procedure for data gathering is shown in Figure 1. The information sheet for participants and questions asked are shown in Appendix E. These questions, which were piloted prior to use, were shaped by themes emerging from the literature and discussions with care coordinators in a third team during the design phase. Care coordinators who did not respond were sent several reminders unless a team manager indicated that they were on sick leave or otherwise unable to participate. To protect respondent confidentiality and encourage honest reporting, care coordinator sociodemographic characteristics were not recorded.

Figure 1. Process for obtaining study data



Processing of Quantitative Data

Concordance or non-concordance between information obtained from carenotes and information provided by care-coordinators was established. Where a dependant was noted by a care coordinator but information about the dependant had not been identified in the initial examination of the 'patient info' tab in the Carenotes record, the client's Carenotes record was re-examined to see whether these children were listed in the client's care plan. This back-checking also ensured that there were no cases where a child was mentioned as a dependant in the 'patient info' tab but that this had been

missed due to researcher error. Likewise, where a child dependant had been identified in the Carenotes record, but was not mentioned by a care coordinator, the client's record was re-checked as part of data cleaning to ensure information was accurate. Data was tabulated and descriptive statistics presented.

Analysis of Qualitative Data

Participant responses to open-ended questions were entered into NVIVO (v.12, 2018) verbatim and analysed using thematic analysis (Braun & Clark, 2013). Some deductive codes were established based on key themes identified during the design phase. The trainee coded all participant responses against these deductive codes, adding additional inductive codes as required during the analysis process, to derive a provisional coding frame. The trainee's supervisor then independently coded a subset of responses (*n* = 6 participants, 23%) against this provisional coding frame. Discrepancies between codes assigned by the trainee and supervisor were identified and discussed, resulting in revision of the coding frame to increase parsimony in some areas and to draw out new themes in others. Following this, the trainee reviewed the coding of all participants' data against the finalised coding frame. The findings of qualitative analysis were presented alongside other project data to participating teams, to allow for 'member checking'.

Results

Response Rate

Twenty-six care coordinators (70%) provided data on the presence/absence of child dependants for each of the clients on their caseload (response rate: 69% team 1; 71% team 2). In total, care coordinators provided information on 300 clients (one client

was deceased). Twenty-four care coordinators provided responses to at least some of the open-ended questions, with a minimum of 20 responding to each.

Concordance

Concordance was assessed in terms of degree of agreement between a) the care coordinator reporting that a client had one or more child dependant and b) the Carenotes record including one or more child dependant on the client's 'patient info' tab. The following pre-determined quality targets were set for the audit:

Standard 1. Completeness of Recording of Known Child Dependants

1. 95% (quality rating excellent) of patients who have *known parental responsibility for a child under the age of 18* (a 'dependant'), as reported by the care coordinator, will have that dependant recorded on Carenotes, in the 'patient info' tab (expected standard). In this instance 'recorded' refers to information indicating the presence of the child even if the name and d.o.b. of the child is missing.
2. For patients with multiple child dependants, a record will meet the expected standard if **all known child dependants** are recorded on Carenotes, in the 'patient info' tab.

As shown in Table 1 (below) examination of the data indicated that 16% of clients (*n* = 49) were reported to have a child dependant by their care coordinator. Of these, just under half (47%; *n* = 23) had child dependants recorded in the Carenotes 'patient info' tab. In two cases the child was listed as a 'contact / child' but not 'dependant/child'. These cases were included as records were clearly comprehensible on viewing the 'patient info' tab. In relation to Standard 1, the observation that only 47% of clients with known children

had these children recorded on the ‘patient info’ tab meant that performance fell well below the specified standard. There was 100% agreement between the number of children expected based on care coordinator reports and the number of children listed in the ‘patient info’ tab.

Table 1. Quality Standard 1: Concordance between Carenotes Entry and Care Coordinator Reports

		Care-Coordinator Report		
		No Dependants	Dependants	Not known
Carenotes Entry in ‘Patient Info’ Tab	No Dependants	244	26	4
	Dependants	2	23	-

Note: See Appendix I for futher details

Quality Standard 2 addressed the completeness of child-related data, as described below:

Quality Standard 2: Recording of <u>Name</u> and <u>Age</u> of Child Dependants

- 80% (quality rating good) of patients who have child dependants recorded on Carenotes in the ‘patient info’ tab, will also have the <u>date(s) of birth</u> recorded (at least the month and year) for all these dependants in the ‘patient info’ tab.
- 80% of patients who have child dependants recorded on Carenotes in the ‘patient info’ tab, will also have the <u>names</u> of all children recorded in the ‘patient info’ tab.

Data indicated that where a client's children were recorded on Carenotes, 91% (*n* = 21) had child(ren's) names listed and 83% (*n* = 19) had date of birth recorded. Thus, in relation to Standard 2, performance met the specified criterion.

Other Locations for the Recording of Information about Dependent Children

It was recognised that information about children can be recorded in different places within the Carenotes record. Inspection of care plans and alerts for the remaining 53% of clients (*n* = 26) whose children were not listed as child dependants, suggested that in 88% (*n* = 23) of cases at least partial information was recorded about these children in one or more of these locations (see Table 2).

Table 2. Other locations of information about child dependents

Careplan	Alert	Patient Info Tab (but not listed as child or dependant)	No Record
17	6	2	3

Interestingly, references to children within care plans were often incidental and only rarely was the section of the care plan titled "*is the client a parent, carer or being cared for*" completed with reference to children. Alerts were typically used where there were safeguarding concerns. In two cases a child was noted in an alert and also referenced in a care plan.

Characteristics of Clients with Correctly and Incorrectly Recorded Child Dependants

As shown in Table 3 differences between clients whose children were recorded in line with standards, and those whose children were not, appeared minimal, particularly given the relatively small sample size.

Table 3. Characteristics of clients where recording of children complied with Standard Operating Procedures and those where it did not

	Compliant (n=23)	Non-Compliant (n=26)
Mean Age	39.78 years	40.53 years
% Male	35% (*n* = 8)	42% (*n* = 11)
% psychosis / bipolar	70% (*n* = 16)	77% (*n* = 20)
% one or more pre-school	22% (*n* = 5)	19% (*n* = 5)
% one or more primary	48% (*n* = 11)	38% (*n* = 10)
% one or more secondary	43% (*n* = 10)	31% (*n* = 8)

Care Coordinator Perspectives on Recording Child Dependants

Care coordinators answered a series of open questions exploring their current understanding and confidence in obtaining and recording information about child dependants and contact with non-dependent children, as well as factors that facilitated or acted as barriers to this process (Appendix F). The final coding frame contained six

meta-themes, denoted below in bold, with subthemes denoted in bold italics (Figure 1 and Appendix G).

Figure 1. Final Coding Frame



In the first meta-theme **Confidence** respondents described their confidence obtaining and recording information about child dependants. A majority of those who responded said they ***felt confident***, "*Yes. I feel confident, if I have any difficulties with recording such information, I would seek assistance from our admin staff" [ID 111].*

However, some expressed ***a lack of confidence*** about the processes involved *"…don't feel confident, not sure who to include"* [ID 116].

Confidence related to the theme **Who to Record**. Even amongst participants who expressed confidence, there was wide variation in understandings of which ***dependent children*** should be recorded, varying from "*only children that are subject to MASH/Social services involvement*" [ID 101], to "*any child dependents [sic] or other children under 5 years old with whom the client has regular contact*" [ID 102]. Some specified that level of contact was not important "*my understanding is that all children of clients should be registered on Carenotes, whether they live with the client, have limited contact, or are estranged*" [ID 114].

Fewer respondents commented on recording of ***non-dependent children***, and those who did generally expressed a lack of experience "*I have never recorded other children that they have contact with. I would not know how frequent the contact needs to be for those children to be recorded*" [ID 103] or potential concerns, "*extended family/ friends and other household members it maybe a bit more blurry as who to record. There may also be issues of confidentiality and how far does the family tree stretch? …It might be determining who the service user has substantial and consistent contact with, … but this would need to be made clear"* [ID 109].

The third meta-theme reflected on the role of the **Therapeutic Relationship** between health professional and client. Many respondents suggested that asking about dependants could be difficult due to ***client concerns about disclosing information***. For example, *one said* "*often people have already had dealings with children's services and have a negative view of this so get offended when we ask for details*…[ID 136], whilst another said "[the client] *may feel it's intrusive and that it may be a step towards*

getting social services involved" [ID 135]. As a result, some expressed concerns about the impact of asking about dependants, for example "*it would make me concerned about the impact this may have on our therapeutic relationship*" [ID 118] or that "*I worry about detrimentally impacting on my assessment by asking about children…* [ID 136]. Conversely some respondents commented on the **therapeutic relationship as a facilitator** to obtaining information, "*Having good relationship with whole family makes this process easier/ more natural"* [ID 102] and that "*Building a relationship with the service user … I have found completing genograms or ecomaps often helps*" [ID 105].

The last subtheme under **Therapeutic Relationship** related to issues of ***timing and consent***. Respondents spoke of needing to consider the "*capacity of the client, at the time of the assessment/CPA*" [ID 118] with some suggesting delaying where possible, "*If there is no obvious immediate risk to the children I would delay asking for details until the client is better"* [1D 103] because "[it is difficult] *trying to obtain information when client is in acute MH crisis* [ID 1'28] and *"when people are feeling vulnerable..* [asking about children]. *feels 'surveillancy'* [ID 116].

The next meta-theme, **Obtaining Information**, comprised respondents' reflections on practitioner issues. The subtheme ***remembering and prioritising***, concerned reflections on the challenges of remembering to ask about dependants amongst many competing demands. Respondents said that this is the "*Sort of thing that can get missed*" [ID 116] and that "*sometimes I do just forget to ask*" [ID 136]. Others commented that recording information on dependants is "*Not seen as priority, [seen] as an administrative task"* and that "*some clinicians still may hold,* [the view] *that we only work with the service user primarily and not the children, and this is something other services, like social workers, might address*" [both ID 109].

The sub-theme ***obtaining information from other sources*** addressed participants' reflections on how they liaised with others, "*if the client cannot provide the information then a family member, or Health Visitor/GP/Social Worker, will do so"* [ID 126] and how helpful this could be, "*in my experience this information is rarely included in referrals sent from GPs (which would provide another means of recording the information if it has not been asked at assessment*) [ID 137].

The meta-theme **Barriers to Recording Information**, captured information about factors which prevented translation of knowledge about child dependants into relevant sections of the Carenotes record. These fell into two domains: The first, ***time and workload***, overlapped with the subtheme ***remembering and prioritising***, but related to transfer of information specifically. For example, participants said that "*time and workload get in the way* [of entering data]" [ID 116] and that '*having time'* [ID 109] and *'time and workload'* [ID 114] were issues.

The second subtheme, ***IT systems and software***, related to participants' difficulties "*struggling with the Carenotes system - where and how to input said information may be difficult*" [ID 111]. These difficulties included accessing the system *"... I would [do it] when the IT is behaving itself and running quickly so that I don't get frustrated that I have wasted time*" [ID 103] and knowing where to add information. Specifically, whilst some participants knew that, "*dependant details should be recorded as a contact in client information tab in care notes*" [ID 128] others said "*I am not entirely sure where it should go – on alerts, on client contacts? On risk assessment?*" [ID 136], reporting that they "*often will record this within the initial assessment* …" [ID 132], or will '*generally put it in the care plan. Not sure, might sometimes be in client info'* [ID 110] and "*probably end up recording it in the assessment rather than in the info tab, haven't been putting it in the care plan'* [ID 116]. In summary participants reported difficulties,

suggesting that "[a barrier is] *knowing exactly where to put the info!!"* [ID 101] and that the process was easier when people were "*confident and sure of what you doing, and where to input it*". [ID 109].

The final meta-theme **Making Collection of Information Routine** included participants' reflections on their practice. Participants commented that "*I try to highlight that this is just a routine thing that we ask everybody and nothing to worry*" [ID 136] and that "*Informing client that this is routine, perhaps a form for them to complete would make this seem more formal to them and could help with any potential paranoia or anxiety re sharing this information [ID 112].* Others commented on differences between practice in different services "*In previous Trusts we had to complete a child safeguarding/risk assessment that prompted gathering of this information"* [ID 140] and on broader cultural changes they had observed over time "*Family leads in clinical teams, reiterating and embedding the importance of systemic thinking and family orientated work within standard clinical practice*" [ID 109].

Participating care coordinators were asked about things that might improve recording practices, and their responses are summarised in Figure 2. Figure 3 shows their opinions on five innovations proposed based on initial scoping work. A range of potential improvements including reminders, changes to documentation and processes and changes to IT systems were suggested by care coordinators. Most of the innovations suggested to care coordinators were endorsed by them, with the exception of including the recording of child dependants as a quality target. This evoked some strong responses including "*please, no*!" "*that is just annoying*" and a suggestion that this kind of approach would be "*shaming*" to staff.

Figure 2. Care Coordinator Proposed Improvements

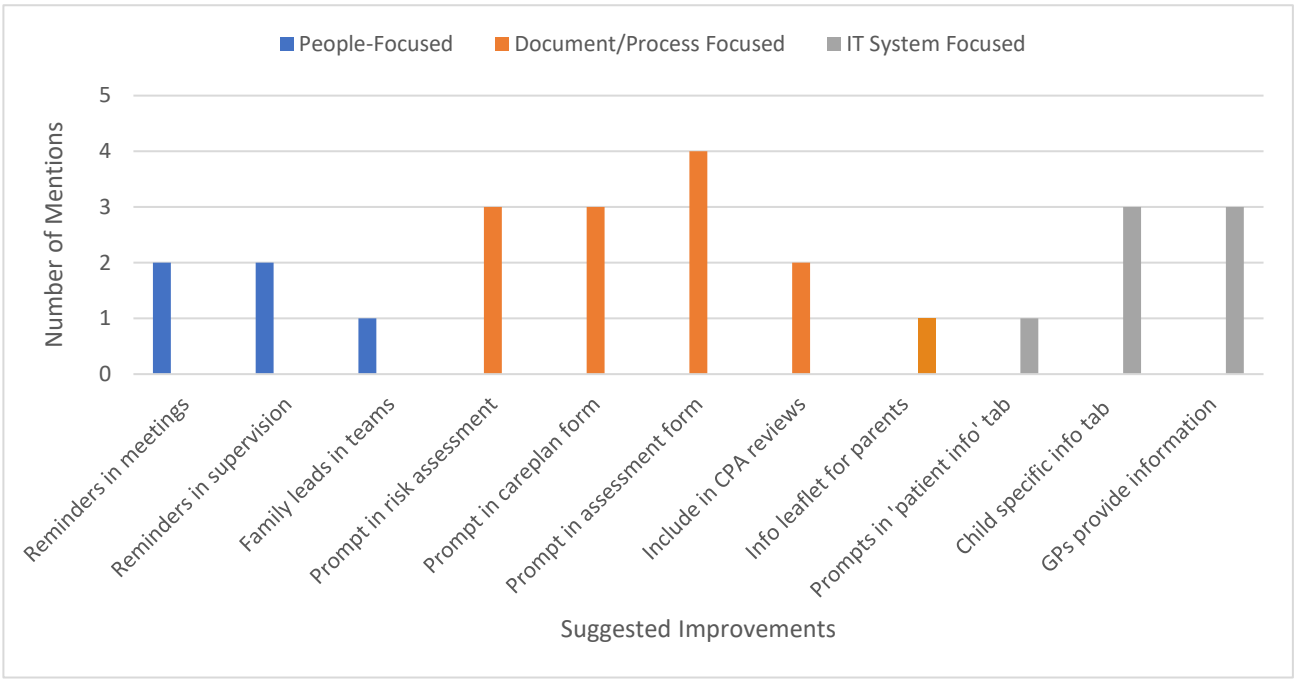
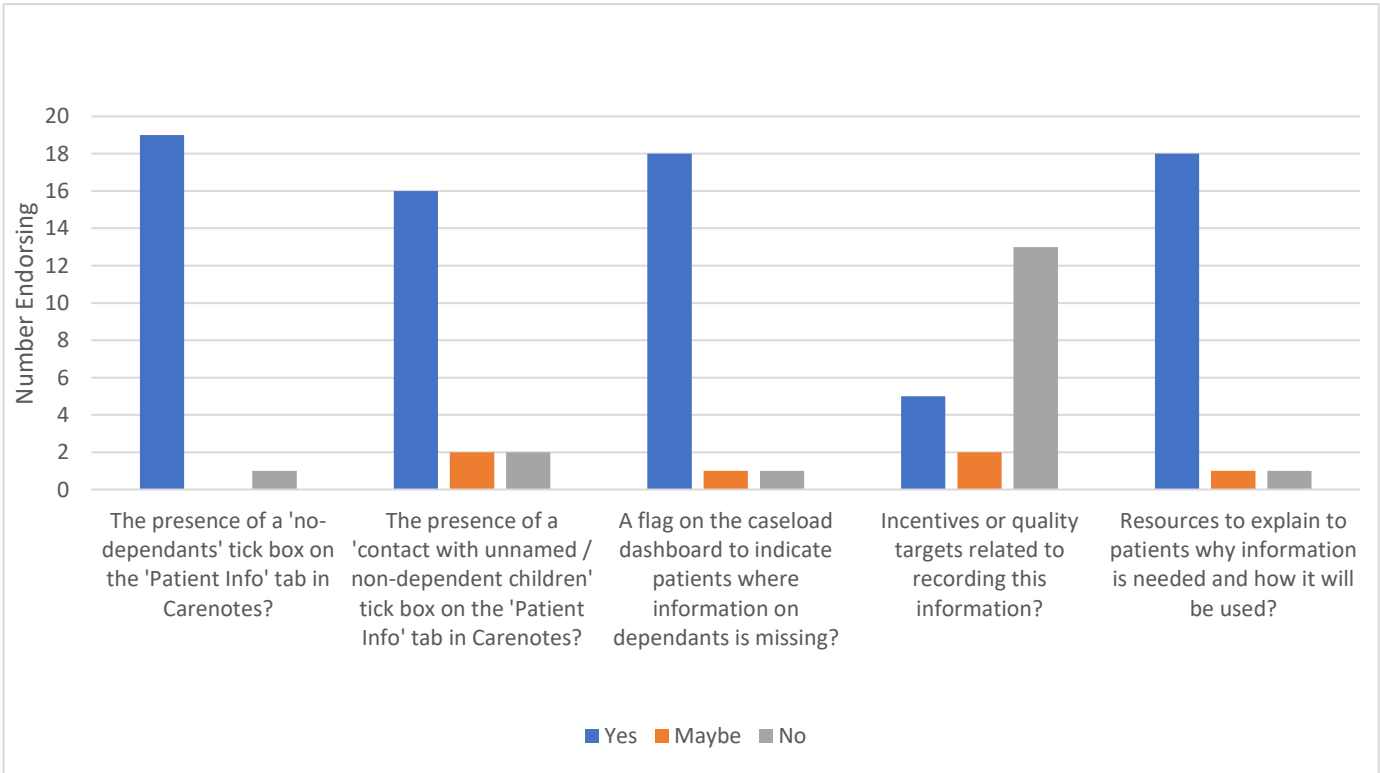


Figure 3. Endorsement of Researcher-Proposed Changes by Care Coordinator



Member Checking

Results of the project were shared formally with each of the participating teams, through an oral presentation and discussion. Members of both teams reflected that the data was a reminder to prioritise recording information about child dependants. They recognised issues raised and both highlighted handover of clients between team members, for example when a client moves from the assessment team to the treatment team, as an area for improvement.

One person (Team 2) suggested that the paucity of training in Carenotes, which was usually by another staff member, might be a factor contributing to the uncertainty some respondents felt about processes. The second issue raised was the belief that clinicians needed to present questions about dependants in the 'right way' and with 'emotional intelligence' in order to reduce stigma and clients' scepticism about responding, and that this was a skill to be learned.

Dissemination of Finding to Stakeholders and Decision Makers

The Oxford Health Improvement Team were contacted to discuss the findings which were also presented to the Trust Families Working Group (which brings together senior professionals with responsibilities for safeguarding and an interest in family working –see Appendix H). Findings were also shared with the Head of Adult Mental Health, and the Trust Safeguarding Committee.

Members of the Families Working Group expressed concern that some respondents had highlighted a perceived lack of priority given to recording information about children, but also reflected that the findings had parallels in an ongoing peer review of records of adults with caring responsibilities being conducted in another county. Some members of the group also queried the 16% of the sample identified as

having child dependants, suggesting that this might reflect the fact that many children are completely unidentified. However, similar studies, e.g., Stallard et al., (2004, who examined a sample of *n* = 303 adult patients within a CMHT), have found an almost identical proportion of adults with dependent children (15.0%), suggesting that this figure is not unexpected.

Discussion focused on how the findings might inform changes. One member commented that in their opinion where an issue is related to the institutional culture, supervision or training alone are rarely effective. Members of the group reflected on how local IAPT services had introduced system-level changes to successfully collect mandatory data on dependants at referral. They suggested that ideally fields within Carenotes would be automatically populated with data on dependants from the Trust registration form (which they had assumed was electronic) and that data might be cross-populated where the same information is enterable in multiple fields of the Carenotes record (e.g. across the client info, careplan, and assessment tabs).

Discussion also focused on the contribution of high levels of agency staff within adult mental health teams to non-compliant practice and lack of confidence asking 'difficult' questions. They highlighted how the health visiting teams had introduced an indicative script for post-birth visits that was used to train new staff within competency frameworks. The senior nurse clinical lead pointed out that the CAMHS Single Point of Access also use a scripted approach during referral, which had the effect of depersonalising sensitive questions and reducing biases. There was also some discussion of unintended negative consequences of potential changes, for example whether making fields relating to child *details* (e.g., d.o.b. and name) mandatory when entering a child would increase provision of this data or in fact prevent children being recorded at all.

An action from the meeting was for the Associate Director of Social Care (Chair) & Deputy Director of Nursing (Mental Health) to consider how the findings of the project might be integrated into the ongoing work plan for the group.

Recommendations

Human factors research suggests that it is beneficial to take a systemic approach which looks beyond improvements aimed only at changing individual knowledge and behaviour. The responses of care coordinators identified both person-level and system-level factors influencing their ability to perform the task of obtaining and recording information about child dependants. Cafazzo & St-Cyr (2012) outline a hierarchy of intervention effectiveness (see Figure 4). Within this hierarchy, system-level changes are regarded as more effective, however they are also likely to be more difficult to implement. A range of possible actions that could be taken to improve the recording of information about child dependants, which emerge from the findings of this project, are detailed in Table 4.

Figure 4. Cafazzo & St-Cyr (2012) Hierarchy of Intervention Effectiveness (adapted from original)

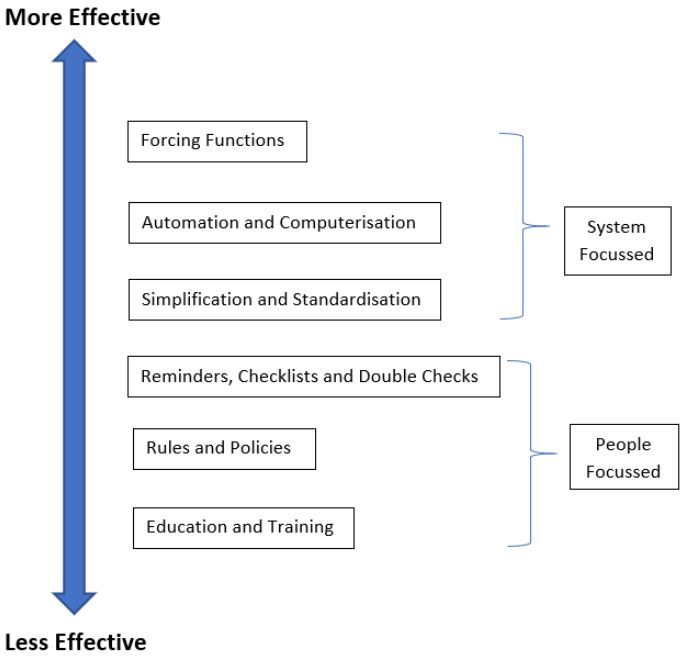


Table 4. Proposed Changes at Each Level of Intervention

Level of Intervention	Proposed Changes
Education and Training	• Clear unambiguous information to staff about which dependant children and non-dependant children should be recorded in carenotes record • Train staff in how and why to record information about dependants • Training at induction with periodic reminders/ refreshers thereafter
Rules, Policies and Procedures	• Policies and procedures exist but are not sufficiently 'visible' to staff. Increase accessibility of information from policies and procedures within teams
Reminders, Checklists and Double Checks	• Ensure reminders to gather information about child dependants are present and visible within all mental health assessment, risk assessment and care planning templates.

	• Where these already exist increase visibility further and ensure staff use templates and proformas during assessment • Make questions about dependant and non-dependant children a standing item on CPA reviews • Add reminders to staff within mental health assessment tabs and care plan tabs on carenotes system to prompt staff to transfer information about dependants to the client info tab. • Include checks of completeness of information about child dependants as standard supervision item and as part of handover of clients between team members.
Simplification and Standardisation	• Create and share leaflet that provides standard information for clients about why information on child dependants and non-dependant children is requested and how it is used to support their care • Provide staff with an indicative script that supports them to ask sensitively about children and to explain why this information is sought. Use this as part of induction training for new staff.
Automation and Computerisation	• Simplify processes for recording information about children within Carenotes. Consider a separate ‘child dependant’ tab to make recording simple and visibly accessible

	• Add a field which makes it possible to indicate that a client has been asked whether they have child dependants and has indicated that they do not. Require this field to be re-completed periodically as circumstances may change (see below). • Add a flag to the Carenotes dashboard to indicate that information about child dependants is missing or has not been updated within the last 12 months.
Forcing Functions	• Redesign systems so that they do not allow mental health assessments, care plans or risk assessments to be confirmed until information about child dependants is completed (i.e., make completion of these fields mandatory) • Redesign systems to ensure that referrals to mental health services cannot be made without provision of information about child dependants • Redesign systems to that where information is entered about a child dependant in one tab this information is cross populated to other tabs in full, or to indicate the presence of a child dependant.

Quality improvement in healthcare often follows a rapid and iterative Plan Do Study Act (PDSA) cycle in which changes are initially implemented on a small scale to study both their positive and negative effects. Any intervention designed to improve a healthcare system may also have unintended consequences. For example, respondents highlighted the sensitivity of timing enquiries about dependants. Introducing a scripted approach or making provision of information about children a requirement for referral may increase data completeness, but at a cost to engagement or trust. Likewise, increasing pressure on staff to ask about dependent children during time-limited assessments may leave less time to explore other important aspects of risk.

Various forms of IT system change are proposed. However, although potentially efficacious, these changes are not ideally suited to a PDSA approach as they typically need to be implemented at scale and without the possibility of retraction if they are not effective. During a discussion with a member of the Oxford Healthcare Improvement Team it was suggested that it was unlikely that the recording of information about child dependants would be regarded as of sufficient priority to justify prompt changes in the Carenotes interface, highlighting the role of institutional culture. Where there is a shared, top-down, commitment to 'think family', openness to implementation of system changes may be greater. In contrast, where workload pressures are acute and other issues are prioritised, even person-level changes may be less willingly adopted or effective. Workload issues were highlighted by substantial numbers of respondents as representing a barrier to compliant practice, and quality targets imposed upon a stressed workforce, although potentially an effective way to incentivise compliance, were widely rejected as irritating and shaming by staff.

Conclusions

The findings suggest that recording of information about the children of parents with mental health problems currently falls short of good practice as defined by OHFT. Although data were only gathered within two teams, the findings were consistent with both a previous safeguarding audit of recording, and ongoing peer review of health records suggesting that it is likely that further actions to improve recording of child dependants are required. Qualitative findings were also consistent with those of a recent study exploring staff attitudes to parents with psychosis (Radley, Barlow & Johns, 2021). There was considerable uncertainty about recording of contact with non-dependent children (an area where the Families Working Group reported that requirements are currently being defined) but encouragingly, no evidence of bias towards more or less accurate recording of the children of clients with particular sociodemographic characteristics.

This project focused on gathering information that addressed the preparatory questions which would underlie a further piece of quality improvement research, establishing a useful baseline of current practice against which future improvement efforts could be benchmarked. The project also outlined a range of potential changes that could be implemented and evaluated through iterative PDSA cycles, based on data gathered from care coordinators and the reflections of relevant stakeholders within OHFT. The findings and recommendations of this report have been disseminated to relevant decision makers, and it is hoped they will provide a useful contribution to ongoing efforts to increase the effectiveness of child safeguarding and parenting support for adults with mental health problems within OHFT.

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Use of the ACT Matrix to Support Fluid Restriction and Quality of Life in People Receiving Haemodialysis for End-Stage Renal Disease

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Please note: To protect participant confidentiality, participant descriptions have been altered whilst retaining the overall sample characteristics and information important to interpretation of data.

Abstract

Many people receiving haemodialysis for end-stage renal disease struggle with adherence to fluid intake restrictions. This study explored the feasibility, acceptability and outcomes of a four-session intervention using the ACT Matrix targeting fluid restriction and valued living in people experiencing difficulties managing fluid intake on dialysis. Eight participants were randomised in two blocks in a concurrent multiple baseline single case experimental design. Participants were allocated to baselines of 6- 8- or 10-weeks, followed by a four-week intervention and four-week follow-up. Participants provided self-report data on fluid adherence and valued living throughout the study period. Data on interdialytic weight gain data was obtained from medical records for the 12 weeks prior to the start of the self-report baseline and for the duration of the study thereafter. Participants rated the intervention as moderately credible and had modest expectations for change. Six of the eight participants were admitted to hospital as inpatients during the intervention phase and only three completed both the intervention and self-report follow-up, complicating interpretation of data on fluid restriction. Two participants showed reliable improvements in psychological distress (assessed at baseline, intervention sessions 1 and 4, and at follow-up) and three showed significant shifts in aspects of valued living, although these were modest in size. There was no evidence of change on the measure assessing ACT processes (compACT). This study suggests that further work is required to tailor the format of the intervention to meet the needs of patients on renal dialysis, for example triaging patients to different intervention durations based on degree of complexity and orientation to active behavioural change. Timing of the intervention and delivery during periods of relatively physical stability is also likely to be key to intervention success.

Highlights

- Many people receiving haemodialysis struggle with adherence to fluid intake restrictions.
- We explored the feasibility, acceptability and outcomes of a brief four-session intervention using the ACT matrix for people struggling with fluid adherence on haemodialysis, using a concurrent multiple baseline single case experimental design.
- Significant feasibility issues affected delivery of the intervention, mostly relating to participant health problems requiring inpatient admission, compromising interpretation of data on fluid adherence.
- Participants reported that the intervention was credible and had modest expectations for change. There was some evidence of positive change on measures of psychological distress and valued living.
- Future research should consider intervention timing and matching of intervention format (brief / extended) to participant complexity.

Introduction

Haemodialysis is the main treatment for End-Stage Renal Disease (ESRD). However, dialysis can only partially replace the function of damaged kidneys and most people are required to adjust their diet and significantly reduce fluid intake to limit strain on body organs, and pre- and post-dialysis symptoms. Given these demands, and the fact that ESRD may develop in people who have already struggled with managing other underlying conditions such as diabetes, non-adherence to aspects of treatment is common, affecting between 25% and 86% of people (Vlaminck, Maes, Jacobs, Reyntiens & Evers., 2001). A recent systematic review (Oquendo, Asencio & Bonill de las Nieves, 2017) identified a range of intrinsic and extrinsic factors associated with (non)adherence.

Interdialytic weight gain (IDWG) reflects fluid consumption between dialysis sessions and higher IDWG is associated with increased risk of morbidity and mortality (Wong et al., 2017). Bossola, Pepe & Vulpio (2018) reviewed research on four categories of intervention to target IDWG: interventions to limit sodium intake through diet, adjustment of dialysate (both intended to reduce thirst); efforts to target dry mouth, and behavioural interventions to reduce fluid consumption (e.g., self-monitoring, behavioural contracting, motivation-focussed, and CBT-based interventions). They concluded that whilst uncertainty remained about the benefits of therapeutic interventions for fluid restriction, behavioural interventions have led to encouraging, albeit short-term, changes. Despite this, behavioural interventions are not routinely offered to dialysis patients struggling with fluid adherence in hospital settings and there is little consensus concerning what type of intervention could be employed.

The final common pathway for factors influencing adherence is through the behavioural decisions an individual makes day to day, when behaviours consistent with adherence (e.g., saying no to a drink) compete, explicitly or implicitly, with behaviours

consistent with other goals and values (e.g., being a polite guest, quenching thirst). One psychological approach to help people live well with chronic physical and mental health problems and to promote positive health behaviour change is Acceptance and Commitment Therapy (ACT; Hayes et al., 2004; Graham, Gouick, Krahe & Gillanders, 2016; Zhang et al., 2017). ACT is a third-wave cognitive behavioural therapy developed in parallel with relational frame theory (Hayes, Barnes-Holmes, & Roche, 2001) , a theory of human language and cognition which assumes that private internal events (e.g., verbal thoughts, mental images, body sensations) can, through a process of derived relational responding, develop appetitive or aversive functions that influence behaviour. It aims to support people to develop greater 'psychological flexibility' in contexts in which they would previously have responded inflexibly due to excessive and unhelpful regulation of behaviour by verbal processes (Hayes, Luoma, Bond, Masuda & Lillis, 2006).

Recently, the rationale for using ACT to address treatment non-adherence has been elaborated by Graham, McCracken, Harrison, Walburn & Weinmann (2022). They describe emerging evidence of associations between psychological flexibility and adherence and suggest that ACT has the potential to complement other forms of behaviour change intervention. They argue that ACT can support people to link choices around adherence to their broader priorities through value clarification ('is attending dialysis a step towards or away from how you want to live your life?) and that where adherence behaviours are limited by experiential avoidance, increasing a person's openness to experience through metaphors and defusion skills may be beneficial. They also suggest that increasing awareness of links between behavioural antecedents and consequences can support people to recognise points of choice, and that ACT, by encouraging behavioural awareness through tracking, and teaching mindfulness and grounding skills, can support greater awareness and shifts in perspective.

Despite some evidence of a direct association between ACT processes (e.g., acceptance) and physical and psychological functioning in patients with ESRD (e.g., Lida et al., 2020, Poppe, Crombez, Hanoulle, Vogelaers & Petrovic, 2013) there are relatively few published studies exploring the use of ACT in this population. Rzeszut (2011) described the use of ACT with an individual struggling to adhere to dialysis. After 15 sessions the client demonstrated improved adherence and emotional regulation and had reoriented towards engagement with non-dialysis life goals. However, Rzeszut highlighted the extent of the challenges faced by people with ESRD and their need for continuing support. This high-level of need was also evident in a feasibility randomised controlled trial conducted by Vogt, Nair, Moghaddam, Proctor & Coyne (2016), who explored a 6-week ACT self-help intervention for depression in people with ESRD. Of 276 participants screened, only 99 returned the screening measure and of these, only nine reported depression *and* were willing to take part. Four were randomised to treatment, but only one completed the self-help book. Participants explained that health problems were the main barrier to engagement and a larger trial was judged unfeasible. Finally, Kalbasi, Hatami, Seyrafi, Hakemi & Sabet (2021) described an 8-session group ACT intervention targeting quality of life and blood pressure in people on dialysis, reporting that it led to significant improvement in quality of life and blood pressure. However, this study was small with limited detail provided, and should be considered preliminary.

There are significant practical barriers to overcome if an ACT intervention is to be integrated into busy renal services and delivered routinely to people struggling with treatment adherence. The ACT Matrix (Polk, Schoendorff, Webster and Olaz, 2016) provides an accessible way of quickly communicating ACT concepts and processes, based around a visual tool which is used to ‘map’ relevant dimensions of a person’s

values, values-consistent behaviour, internal experiences which get in the way of values-consistent behaviour, and the behavioural responses these evoke (see Appendix J). Reflecting its potential efficiency, a single-session protocol based on the ACT Matrix has recently been used with some success in a study of health-behaviour change in college students (Barreto, Tran & Gaynor, 2019). The matrix can also be used as a platform for more extended pieces of therapeutic work, which expand on each ACT process.

In this study, we examined the feasibility, acceptability and outcomes of a four-session protocol based on the ACT Matrix, for people struggling with fluid adherence using a concurrent multiple baseline single case experimental design (SCED). Reflecting the balance between adherence and quality of life, outcomes related to both fluid restriction (self-reported adherence and IDWG) and valued living. Give high rates of depression in dialysis (Palmer et al., 2013), and their association with poor adherence (e.g., Kauric-Klein, 2017), psychological distress was also assessed as a secondary outcome.

Method

Setting

Recruitment took place in two hospital haemodialysis centres managed by a single NHS Trust.

Involvement of People with Lived Experience

Four people with lived experience of dialysis recruited from kidney disease associations reviewed study documents and participated in a focus group. These individuals talked about the culture of dialysis units, camaraderie between patients and relationships with staff. They discussed the benefits of completing study activities during dialysis versus at another time. They agreed they preferred to keep dialysis-related

discussions to the renal unit and suggested that sessions were offered there, with measures completed during sessions too. Few concerns were expressed about confidentiality as people said they discussed symptoms freely. No concerns were raised about study documents but during ethical review the lay member requested changes to emphasise the non-judgemental nature of the intervention. These discussions were particularly valuable given that the study was developed during the Covid-19 lockdowns at a time when it was impossible for the trainee to visit the dialysis units and experience the research context directly.

Eligibility

Eligibility criteria, developed in consultation with renal unit staff, were as follows:

Inclusion Criteria

- Receiving haemodialysis for ESRD
- Aged 18+
- Fluency in written / spoken English to undertake the intervention and complete measures
- Willing to participate in face-to-face and/or digital delivery of a psychological intervention.
- Identified by clinical staff as having difficulty with fluid adherence.
- Consents to participation and audio recording of sessions

Exclusion Criteria

- Lack of capacity to consent
- Poorly controlled diabetes resulting in recent hospital admissions for hypo/hyperglycaemic episode(s)

- Intellectual disability

Procedure

Potential participants were approached by clinical staff and given brief written information about the study. Those who were interested were contacted by the researcher who explained the study and provided the full patient information sheet. Those who wished to participate provided written informed consent. Twenty-six people received full information and eight (31%) consented. Following consent, participants completed an intake questionnaire and when all participants at a single site had completed this, randomisation took place (to a six-, eight- or ten-week baseline). During baseline, questionnaire booklets were distributed to participants weekly. The four intervention sessions were offered over four consecutive weeks, with a single four-week follow-up. All participants received a £10 gift voucher. Measures are described in Table 1, with full details in Appendix K.

Table 1. Measures

Measure	Purpose	Psychometrics	Administration Points
End-Stage Renal Disease Adherence Questionnaire, (ESRD-AQ, Kim et al., 2010)	46-item measure assessing aspects of adherence to medication, diet, fluid restrictions and dialysis sessions.	Measure has excellent content validity and test-re-test reliability (Kim et al., 2010).	Study intake
Dialysis Diet and Fluid Intake Non-Adherence	Four-item measure assessing subjective adherence to diet and fluid requirements (see Appendix K).	Evaluation in n= 564 patients across 10 renal units (Vlamink et al.,). Significant correlation between self-report ratings of	Administered bi-weekly for the duration of the study, starting in self-report baseline week 2. Items relating to fluid

Questionnaire (DDFNAQ, Vlamink et al., 2001)		days of fluid non-adherence and IDWG, (r=0.24, p <.0001) and between severity of deviation from fluid guidelines and IDWG (r=.25, p <.0001).	adherence were used for analysis.
Interdialytic weight gain (IDWG) in kgs.	Obtained from medical records for each dialysis session attended.	n/a – see Appendix K for treatment of missing data on this measure.	Collected for12 weeks prior to self-report baseline week 1 (to control for possible effects of self-monitoring on IDWG), with continued collection throughout the baseline, intervention and follow-up phases.

Valuing Questionnaire (Smout, Davis, Burns & Christie, 2014)	10-item questionnaire. The items load on one of two subscales: Progress towards Values ("*I made progress in the areas of life I care most about*") and Obstacles to Progress ("*Difficult thoughts, feelings or memories got in the way of what I really wanted to do*").	Each item is rated from 1 (not at all true) to 7 (completely true). The subscales have good internal consistency (progress: alpha=.81; obstacles: alpha=.79) and convergent and discriminant validity.	Administered weekly from self-report baseline week 1.
The Clinical Outcomes Routine Evaluation (CORE -10,	Assesses severity of psychological distress, across 10 items, each rated 0-4.	Differentiates clinical samples from non-clinical populations. Adequate convergent validity when correlated with other clinical measures. Good internal reliability (alpha > .80)	Self-report baseline week 1, intervention week 1, intervention week 4 and follow-up.

Barkham et al., 2013)		and sensitivity to change (Connell & Barkham, 2007).	
Comprehensive Assessment of Acceptance and Commitment Therapy Processes (CompACT Francis, Dawson & Golijani-Moghaddam, 2016)	Questionnaire assessing psychological flexibility, yielding total score, and three subscale scores: openness to experience, behavioural awareness and valued action.	Good internal consistency (average inter-item correlation = .34, *n*=352) and convergent and discriminant validity e.g., a correlation with the AAQ of *r* = .79 and a correlation with the Marlowe Crowne Social Desirability scale of *r* <.03.	Self-report baseline week 1, intervention week 1, intervention week 4 and follow-up.

Intervention Credibility and Expectancy Questionnaire (adapted for a renal population from Devilly & Borkovec, 2000)	Assesses participants perceptions of intervention credibility with items rated on a scale from 1, not at all-9 extremely, and expectations (anticipated percentage improvement)	Items can be combined to create two subscales: credibility (items 1-3) and expectancy (items 4-6) as well as a total score (internal reliability, alpha = .85). However, in the current study items were examined individually to assess participant attitudes to the treatment rather than being used to predict treatment outcome.	Administered after intervention session 1 and at follow-up.
EQ-5D-5L (EuroQuol	Assesses quality of life across five domains: mobility, self-care,	The measure was found to have excellent psychometric	Self-report baseline week 1, intervention week 1,

Group, 2009, *data reported in Appendix L).*	usual activities, pain / discomfort, anxiety/depression. In this study the raw total score for items assessing impairment in each domain, and health thermometer score (rated 0 – 100) were reported.	properties in a systematic review of m=99 studies across a range of populations and contexts (Feng, Kohlmann, Janssen & Buchholz, 2021).	intervention week 4 and follow-up.

Randomisation

Randomisation occurred by site, in two blocks and was conducted by the student's academic supervisor, who was not involved in day-to-day aspects of the study (see Appendix M). Participants were provided with the outcome of randomisation and details of the study timetable.

Intervention Protocol

The protocol was developed by the trainee and clinical supervisor, based on the ACT Matrix (e.g., Polk et al., 2016). Sessions were delivered by the trainee, under supervision of Dr Louise Hankinson, Clinical Psychologist in Renal and Transplant Medicine. The intervention was designed to be relatively straightforward so that it might ultimately be delivered by dieticians under the supervision of a clinical psychologist.

Table 2. Outline of Intervention Content

Session	Core Aims and Session Elements
1	**Aims** *Introduce and populate the ACT Matrix in relation to overall values and health. Introduce the idea of towards and away moves and encourage noticing internal experiences and behavioural responses* **Session Elements** • Gain verbal consent for session

- Reminder of approach and structure of sessions
- Explain Matrix as a paper and pencil exercise to give a different perspective
- Explain towards / away (action can look the same but feel different)
- Explain inside / outside (difficult to be in both places at once)
- Populate Matrix – unrestricted, starting with bottom right (probe domains)
- Explain noticing position and draw attention to balance of left side / right side
- Second round focusing on health / fluids (if not mentioned in first round)
- Validate and normalise participant's experience
- Validate difficult emotions that show up for participant and encourage them to acknowledge and make space for them
- Introduce concept of stuck loop
- Introduce a brief grounding practice – notice 5 things (if time)

<u>Taking it forward after Session 1</u> – Notice towards and away moves (emphasising that neither is good / bad; right/wrong)

2 **Aims**

Reinforce participant's attempts at noticing, introduce the concept of short-term versus long-term workability, help participant identify

some new towards moves in relation to a) fluid restriction and b) life in general

Session Elements

- Gain verbal consent
- Check in (in relation to health/dialysis/general wellbeing)
- Revisit Matrix from Session 1
- Explore a towards move and an away move participant noticed during the week and reinforce noticing
- Explore workability of an away move short term / long term
- Validate difficult emotions that show up for client and encourage them to acknowledge and make space for them
- If participant is struggling to contemplate behavioural change, continue to identify internal barriers and place them in bottom left of matrix, with corresponding away moves.
- Identify at least one potential towards moves a participant could make in relation to a) fluid restriction (gently explore participant's current knowledge and techniques used to manage fluids and suggest next steps if they are unsure, including providing written resources) and b) other things that are important to the client.

Depending on Participant Presentation (in this and subsequent sessions)

- Introduce metaphors and skills to support defusion: Passengers on the bus; chessboard; beachball (thought

suppression and intrusions); grounding (notice 5 things); Labelling ‘stories’ that repeatedly show up; “I’m having the thought that…”. These skills were supported by written resources and links to online materials, although in practice only some participants were confident using digital resources.

- Introduce temporal framing (supported conversation with imagined future self, engaging in planned towards move, or future self who has / has not made behavioural changes)
- Introduce concept and practice of urge surfing
- Introduce concept of hierarchy / step ladder of valued actions

Taking it forward after Session 2: Put into practice planned towards moves and observe what happens (see examples in Table 4).

3 **Aims**

To continue to support the participant in noticing towards and away moves in relation to managing fluid restriction and dialysis and in identifying potential incremental towards moves. Reinforce any attempts at behavioural change the client is making, trouble shoot potential barriers and support client to identify next steps.

Session Elements

- Check consent to continue with intervention
- Check in (in relation to health/dialysis/general wellbeing)

- Review any towards moves made during the week, or if none made, revisit intended towards moves and explore what happened
- Identify any internal barriers to behavioural change
- Introduce or revisit metaphors / skills (as described above) to support valued action in the presence of internal obstacles

Taking it forward after Session 3: Put into practice planned towards moves and observe what happens. Practise skills introduced (e.g., urge surfing).

4 **Aims**

Consolidate steps participant has taken to increase awareness of towards and away moves in relation to managing fluid restriction and dialysis and reinforce any behavioural changes they have made that move them in the direction of what matters. Identify future goals.

Session Elements

- Revisit and revise matrix from previous sessions and reinforce towards moves made
- Encourage client to summarise any things they have learned and changes they have made over the intervention period
- Identify any next steps the participant would like to make, setting goals for the future (next week, next month).

Taking it Forward after Session 4: Encourage participant to continue to use Matrix and related skills to support management of ongoing challenges related to dialysis

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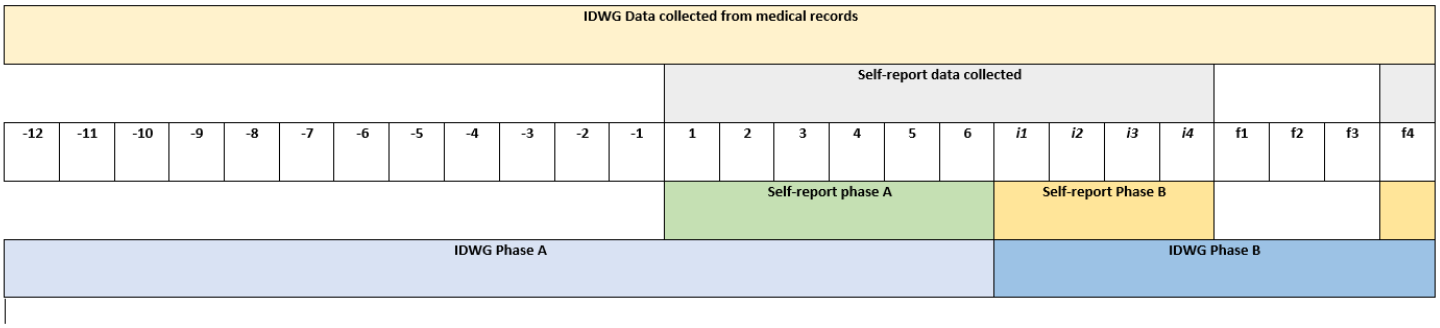
Supervision

The trainee received regular supervision during the intervention phase, including via review of audio recordings of sessions. Supervision was used to consider how to shape the intervention in response to challenges raised by participants, for example a participant at the end of life and a participant with limited motivation to change.

Study Design and Data Analysis

The study employed a concurrent multiple baseline single case experimental design. The study was initially conceptualised as including three phases: baseline, intervention, follow-up (A, B, C). However, due to incompleteness in IDWG data and low rates of follow-up self-report data, intervention and follow-up were collapsed for Tau U analysis, simplifying to an A (baseline), B (intervention and follow-up) design. Figure 1 illustrates the weeks of data collection contributing to phase A and phase B for IDWG and self-report data respectively. For IDWG, phase A included data collected for the 12 weeks prior to commencement of weekly self-report to partially address the potential impact of self-monitoring on fluid adherence during the baseline phase (e.g., a Hawthorne effect – McCarney et al., 2007). IDWG data was also collected for the full four-week follow-up period, whereas self-report data was collected at a single 4-week follow-up point only.

Figure 1. Data contributing to Phase A and Phase B for IDWG and self-report data.



Data Presentation

IDWG, self-reported fluid adherence and Valuing subscale scores were graphed for each participant. For graphed IDWG data, pre-study baseline is shown in green, the within-study baseline in blue (together phase A) the intervention phase in red and the follow-up in orange (together phase B). IDWG data points were blue, except for weeks that included one or more missing data point, which were coloured purple. Self-report fluid non-adherence was represented on a single chart and the y axis reflecting score on each respective measure (days out of 14 the participant was non-adherent; degree of deviation, none = 0 to 4 = very severe). Valuing subscales were also represented on a single chart. Visual inspection was used to examine apparent stability of baselines, and any evidence of treatment effects (within and between phase trends). Graphs are presented together for each measure, rather than each participant, to explore potential staggering of any treatment effects in line with staggered start dates (e.g., Morley, 2018).

The Tau U statistic was employed to examine statistical evidence of intervention effects (Parker, Vannest, Davis, Sauber, 2011, see Appendix N) from phase A to phase B, and to control for phase A trends where present, using the online Tau U calculator (Parker, Vannest & Gonert, 2011).

Reliable change in psychological distress (CORE) was examined using the published threshold (Barkham et al., 2013), and the Leeds Reliable Change Index (Morely & Dowzer, 2014) was used to determine reliable change for the CompACT and Valuing Questionnaire. Finally, participants' ratings of intervention acceptability were summarised.

Ethical Approval and Serious Adverse Events

The study received ethical approved from East Midlands – Leicester South NRES and HRA Ref: 21/EM/0025 and research governance approval from Oxford University Hospitals NHS Foundation Trust. Two substantial and three non-substantial amendments were issued. Six participants were admitted as inpatients on one or more occasion during the study and one participant died during the four-week follow-up period. None of these serious adverse events were judged to be related to study procedures. Two participants reported suicidal ideation on a questionnaire and were reviewed by the site Principal Investigator. Again, these episodes were judged to be unrelated to study procedures. Study approvals and information and consent documents are shown in Appendix O.

Results

Participant Characteristics

Eight people participated in the study. Six were male, with ages ranging from thirties to late eighties. Three had previously received a kidney transplant, which had failed, requiring reinstatement of dialysis. All participants were invited by staff because they were regarded as having relatively high IDWG. ESRD-AQ data indicated that all

participants recognised the importance of fluid restriction but described varying degrees of difficulty with adherence (see Table 3).

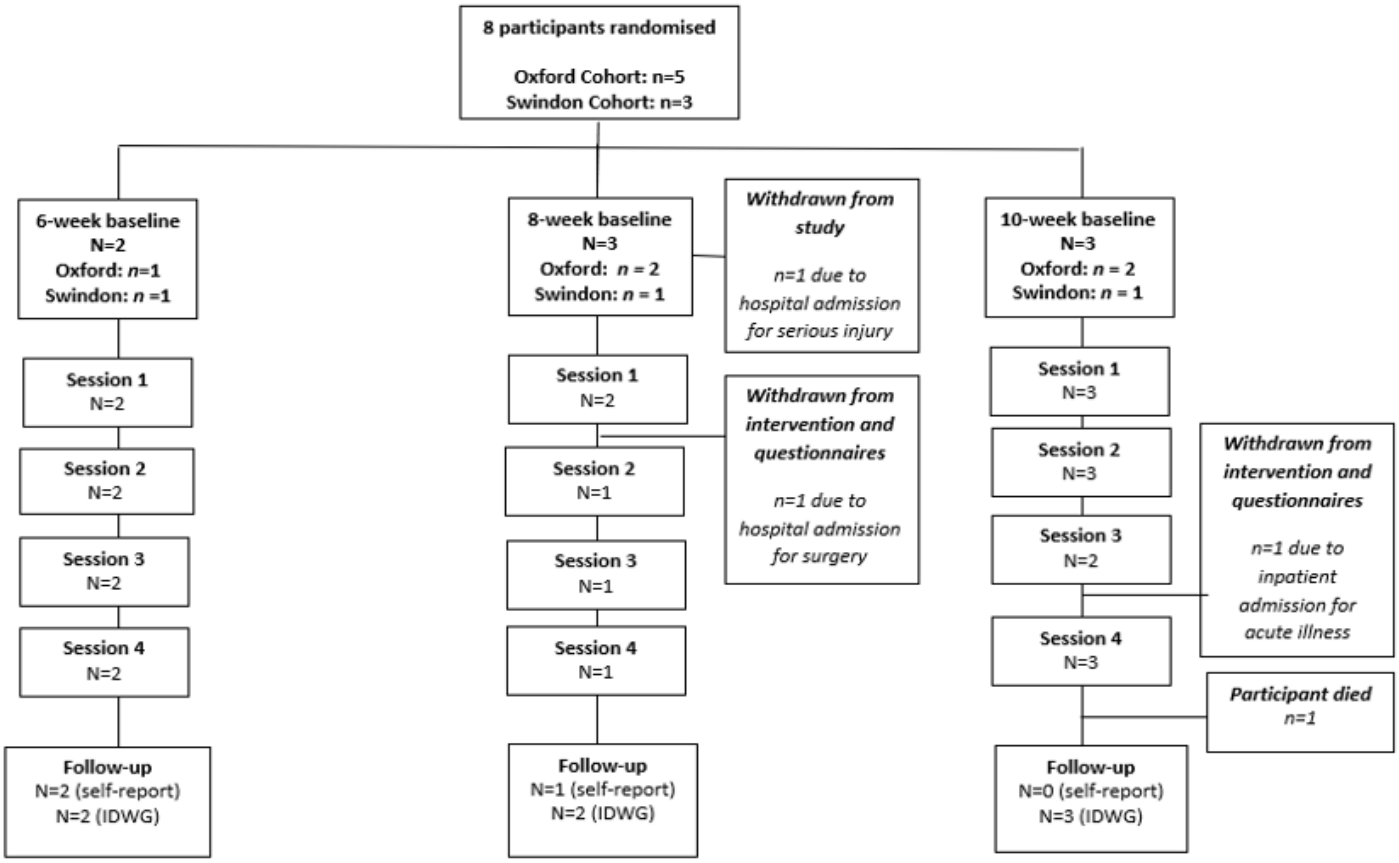
Table 3: Participant Characteristics and ESRD-AQ Responses to Items Addressing Fluid Adherence

	Gender	Age	Ethnicity	Years on Dialysis	Co-occurring conditions	Transplant listing (Suspended if comorbidities currently prevent transplantation)	Perceived importance of fluid restriction	Reported difficulty remaining on dialysis	Reported fluid adherence past week	Reported difficulty with fluid adherence
105	F	30s	White British	< 1	Diabetes	Living Donor (suspended)	Very	No difficulty	Very seldom	A lot of difficulty
107	M	70s	White British	5.5	Diabetes	No	Very	A little	Most of the time	A lot of difficulty
108	M	80s	White British	1	Diabetes	No	Highly	No difficulty	Always	No difficulty
109	M	60s	Black British	1.5	Diabetes, Hypertension	No	Highly	No difficulty	Most of the time	A lot of difficulty
111	M	30s	South Asian	< 1	Congenital small kidneys	Deceased Donor transplant	Highly	No difficulty	Very seldom	A lot of difficulty
201	M	60s	White British	< 1	Diabetes, High Blood Pressure	Deceased Donor Transplant (suspended)	Highly	A little	Most of the time	Moderate difficulty
203	F	40s	White Other	< 1	Cardiac Disease, IAG neuropathy,	Living Donor (suspended)	Highly	A little	None of the time	I could not control fluids at all

209	M	50s	White British	6	Hypertension, Diabetes High blood pressure	No	Very	No difficulty	Very seldom	A lot of difficulty

Figure 2 shows participant flow through the study and reasons for participant withdrawal. As illustrated, seven participants completed at least one intervention session, with five completing all sessions. One participant was withdrawn by the clinical team due to a prolonged hospital admission and two of the remaining participants withdrew from self-report aspects of the study. Three participants completed the four-week follow-up questionnaire.

Figure 2. Participant Flow



Intervention Delivery

To protect participant confidentiality individualised descriptions of clinical sessions are not provided. However, Appendix J provides anonymised examples of participant matrices, and illustrative examples of in-session and between-session activities are show in Table 4.

Table 4. Examples of In and Out of Session Activities

Examples of activities aimed at increasing awareness and behavioural tracking

- Noticing towards and away moves during week
- Practising grounding (e.g., 5-4-3-2-1)
- In session – 'retrospective mini-matrix' – based on situations from previous week
- In session - 'prospective mini matrix' – to explore internal obstacles to future valued action
- Tuning in to body to differentiate body signs of thirst from thought "I need a drink"

Examples of planned towards moves aimed at reducing fluid consumption

- Choosing a smaller cup
- Practising urge surfing when feeling an urge to drink
- Talking to family about fluid restriction
- Reading patient information leaflets about diet and fluid restriction
- Gradually increasing attention to role of fluid-rich foods in IDWG
- Melting ice to see how much fluid volume it has when melted, rather than guessing
- Changing to regularly drinking small amounts, rather than infrequent high-volume drinks
- Speaking to partner about cooking and making different foods with less salt
- Starting to weigh oneself regularly at home to monitor fluid consumption more closely
- Measuring the volume of the water jug during hospital admission
- Switching from high volume, high sugar drinks to a lower volume drink

Examples of planned towards moves addressing experiential avoidance

- Talking to partner about end-of-life preferences
- Having a conversation with a health professional about an ESRD-related concern

- Attending to, rather than ignoring, bodily signs of fluid overload (e.g., breathlessness)
- Sharing fears and worries about ESRD and dialysis with a family member
- Using a wheelchair when out and about
- Replacing computer time with shared cooking although this might cause pain

Examples of towards moves directed at other values

- Asking a family member to play a board game
- Explore travelling whilst on dialysis and dialysis away from home
- Going for a walk in the neighbourhood
- Creating a graded hierarchy to support gradual increase in valued activity
- Exploring ways to swim safely
- Researching a new evening class
- Calling family, texting friends

Actions to Increase Defusion

- Trying to take position of the chess board rather than chess pieces in challenging situations
- Using 'passengers on the bus' 'visual' to spot 'regular passengers' showing up during week
- Noticing and naming familiar 'stories' e.g., "*the story of its not as easy as it should be*…" the book of "*expect the worst and you won't be disappointed*"
- Using "I'm having the thought that" technique
- Watch video on managing intrusive thoughts
- Naming the character that says "I won't do what you tell me" and noticing when they show up

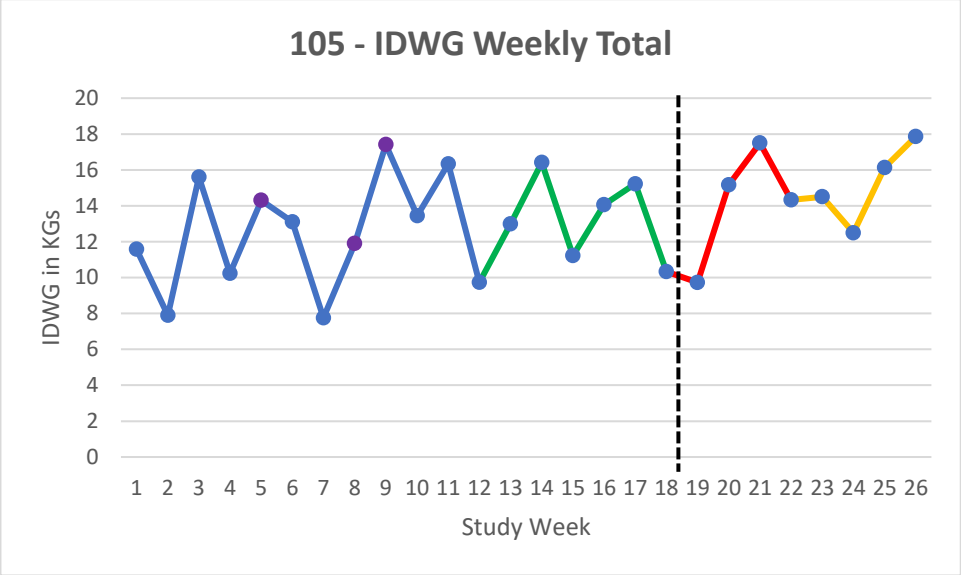
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Main Outcomes – Objective Fluid Adherence: Interdialytic Weight Gain

In the following figures, data on interdialytic weight gain is presented alongside a brief summary of the Tau-U analysis. In each figure the data series from the unmonitored baseline phase are shown in blue, the data series from the self-report baseline in green (together Phase A), the data series from the intervention phase are shown in red and from the follow-up in orange (together Phase B). Purple dots represent weeks with suspected missing IDWG data (e.g., a null reading or completely missing data).

Figures 3a to 3g: Interdialytic Weight Gain

Figure 3a.



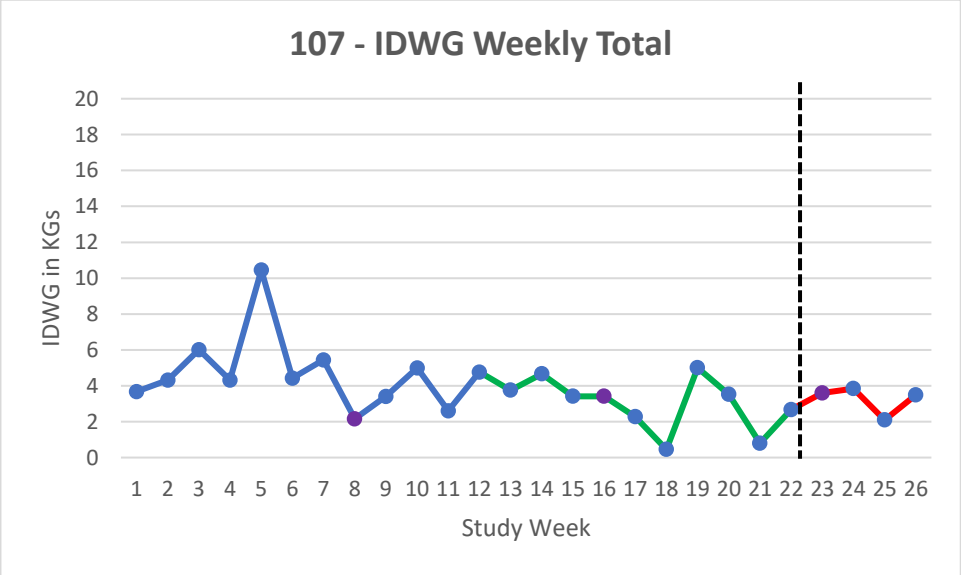
Summary

Tau-U Analysis

No statistically significant phase A or phase B trends.

No statistically significant between-phase shift.

Figure 3b.



Summary

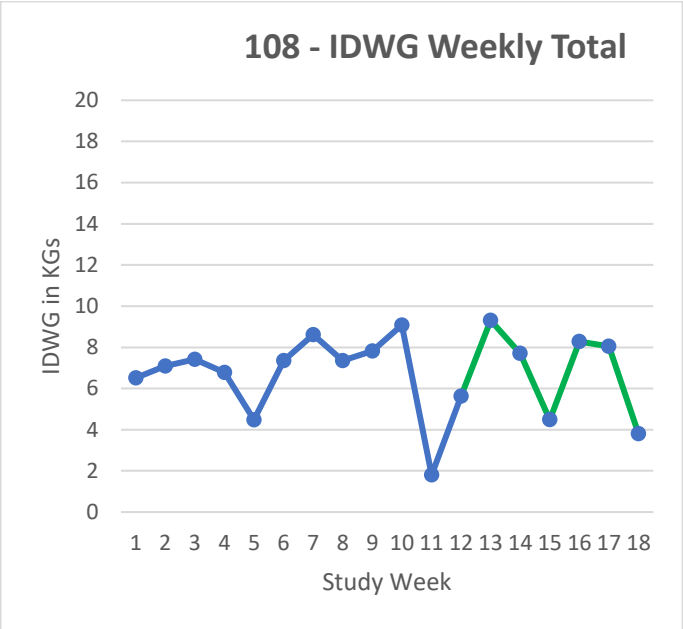
Tau-U Analysis

No statistically significant phase A or phase B trends.

Statistically significant between-phase shift, $p = .047$

Note: Participant died in the week following the final intervention session.

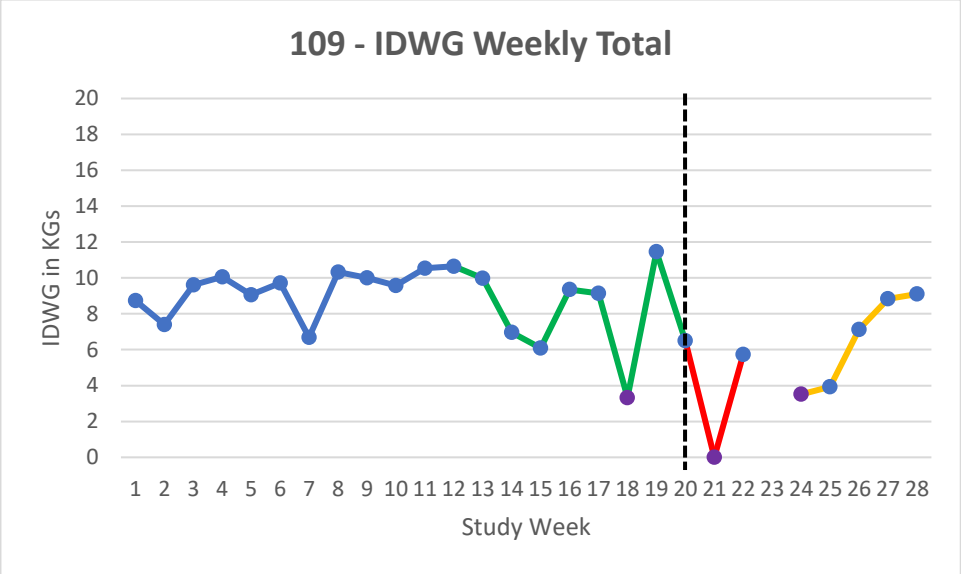
Figure 3c.



Summary

Participant withdrawn by clinical team due to serious injury sustained during baseline phase resulting in prolonged hospital admission.

Figure 3d



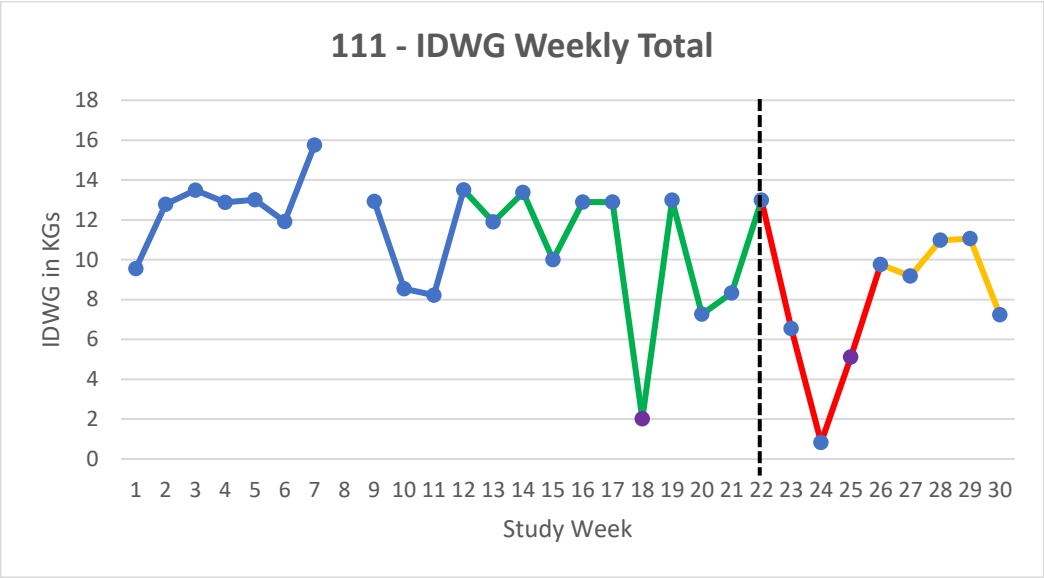
Note: Participant admitted for surgery after session 1 (week 22).

Summary

Tau-U Analysis

Statistically significant phase B trend (p = .01). Statistically significant between-phase shift, p = .009.

Figure 3e



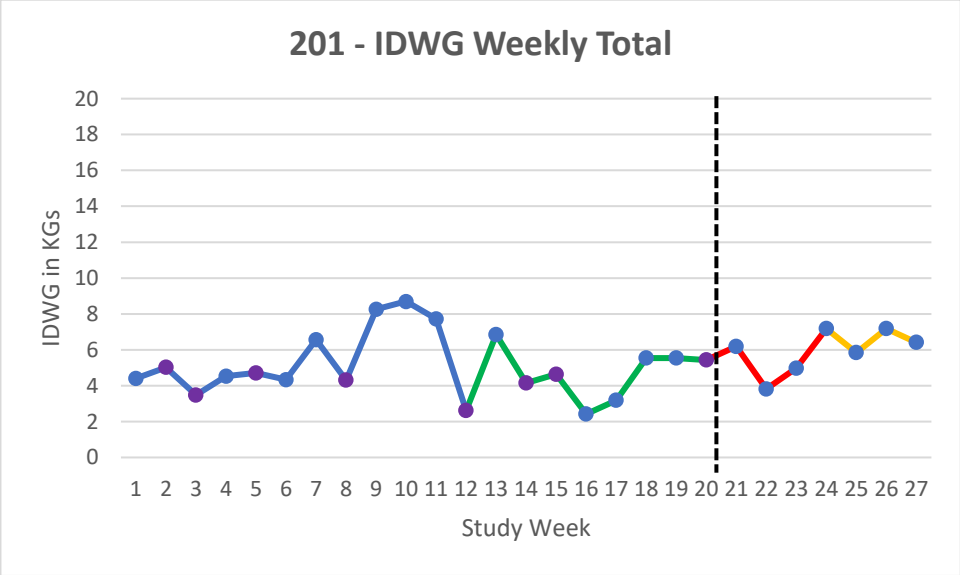
Summary

Tau-U Analysis

Significant phase A trend (p=.03). trend. Significant between-phase shift, p = .006 controlling for phase A trend.

Note: Participant hospitalised after session 1 (week 22) due to gastroenteritis.

Figure 3f



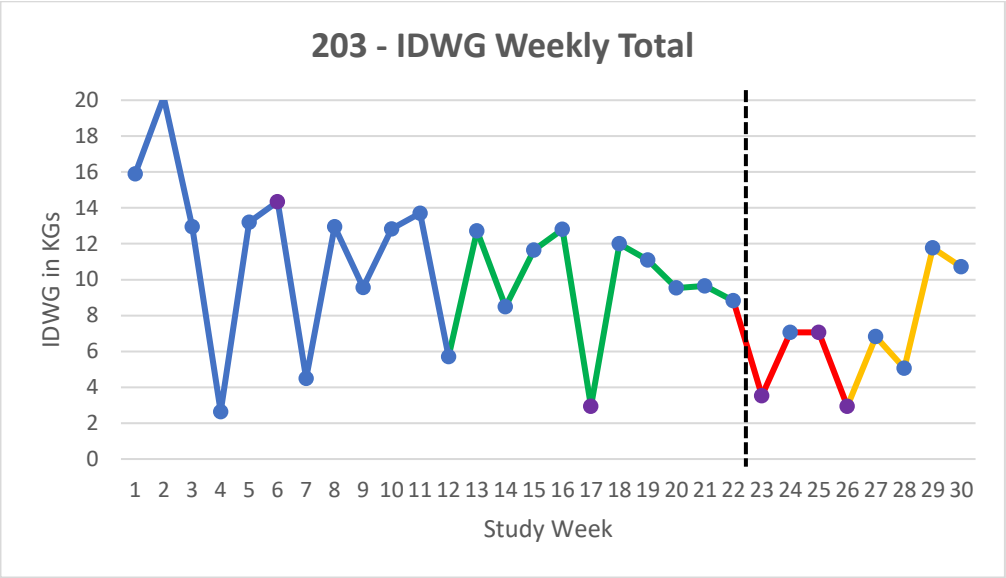
Summary

Tau-U Analysis

No statistically significant phase A or phase B trends. No statistically significant between-phase shift.

Note: Participant admitted for vascular surgery during phase B

Figure 3g



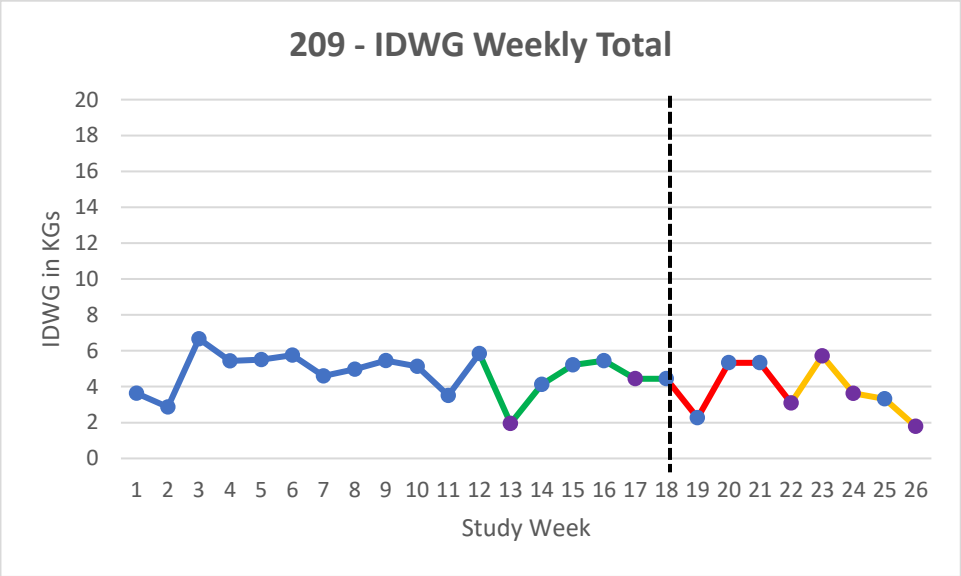
Summary

Tau-U Analysis

Statistically significant phase A trend (p = .02) and statistically significant between-phase shift controlling for phase A trend (p=.02).

Note: significant missing data in phase B due to participant's hospital admission for ruptured bowel.

Figure 3h



Summary

Tau-U Analysis

No statistically significant phase A or phase B trends. No statistically significant between-phase shift.

IDWG Summary In summary participants 107, 109, 111 and 203 showed evidence of statistically significant non-overlap between phases in IDWG data (see

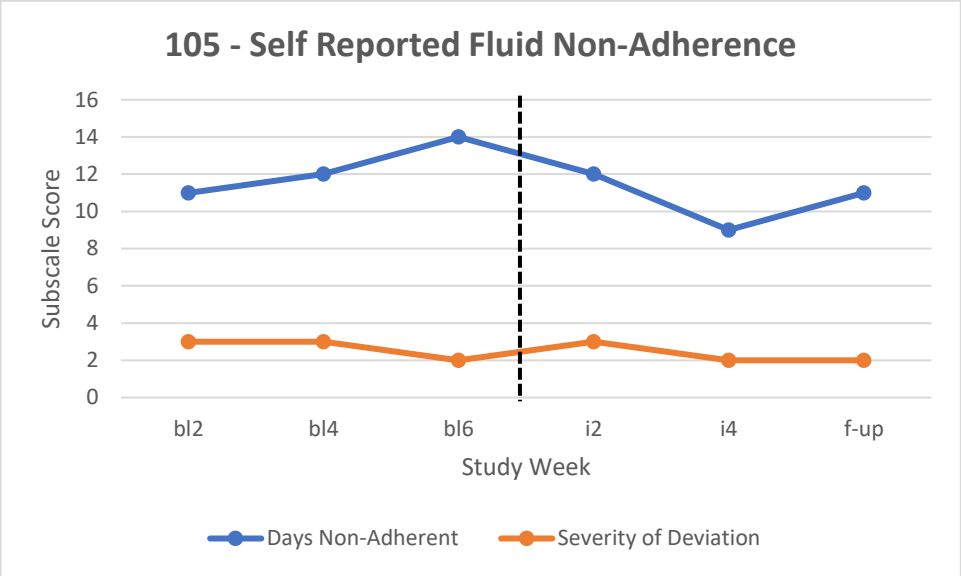
Appendix P). However, contextual information suggests the observed phase shifts may be artifacts. Specifically, participant 107 was approaching end of life and it is likely that reduced IDWG reflected reduced food and fluid intake. Participants 109, 111 and 203 were also hospitalised during the intervention phase, impacting data quality and validity (for example due to administration of IV fluids). It is probable that the statistically significant changes are the result of these confounding factors. .

Main Outcomes – Subjective Fluid Adherence

Figures 4a to 4h show data for self-reported / subjective fluid non-adherence. The vertical line on each graph represents the shift from phase A to phase B. A brief description of the outcomes of Tau-U analysis and any confounding factors are provided beside each figure (full details of Tau-U analysis are provided in Appendix P. Only one participant, ID 111 showed a statistically significant phase A trend (p=.03) and statistically significant between phase shift (p=.007) for number of days non-adherent to fluid restrictions, and a trend towards a similar between-phase shift in degree of deviation (p=.052). However, the participant did not provide follow-up data limiting confidence in this finding.

Figures 4a – 4h Self-reported non-adherence to fluid restrictions

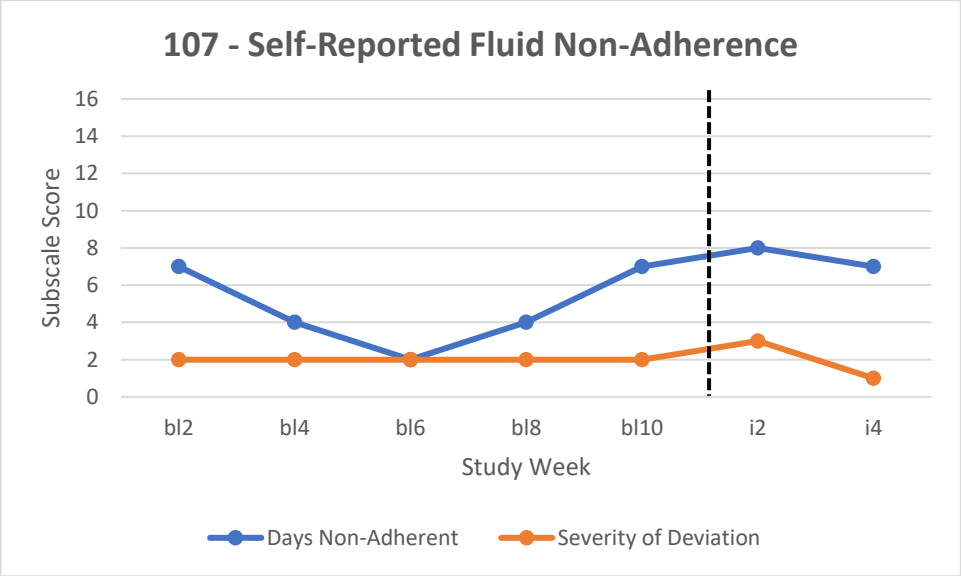
Figure 4a



Summary

Tau-U Analysis
No statistically significant phase A or phase B trends. No statistically significant between-phase shift.

Figure 4b

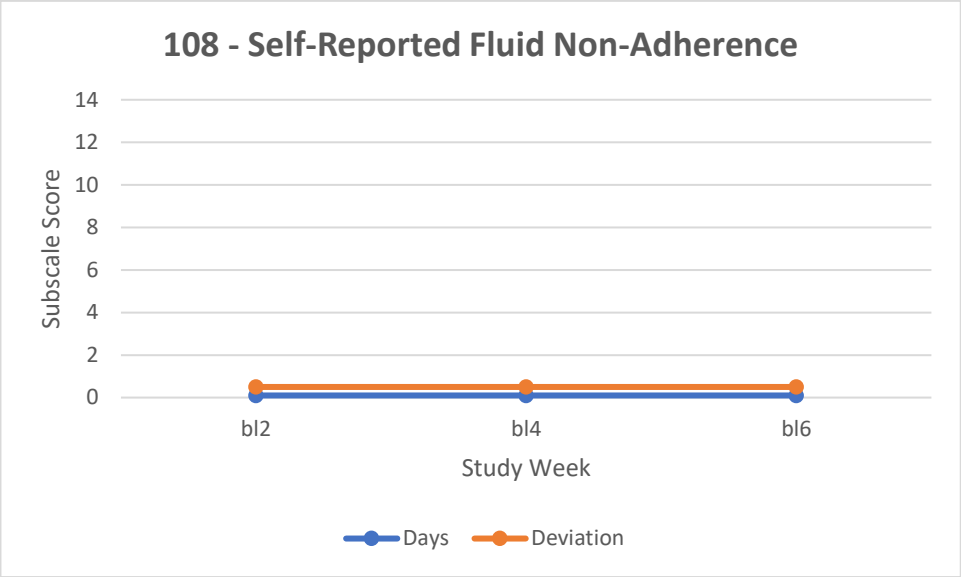


Summary

Tau-U Analysis
No statistically significant phase A or phase B trends. No statistically significant between-phase shift.

Note: Participant died of complications of ESRD prior to follow-up assessment.

Figure 4c

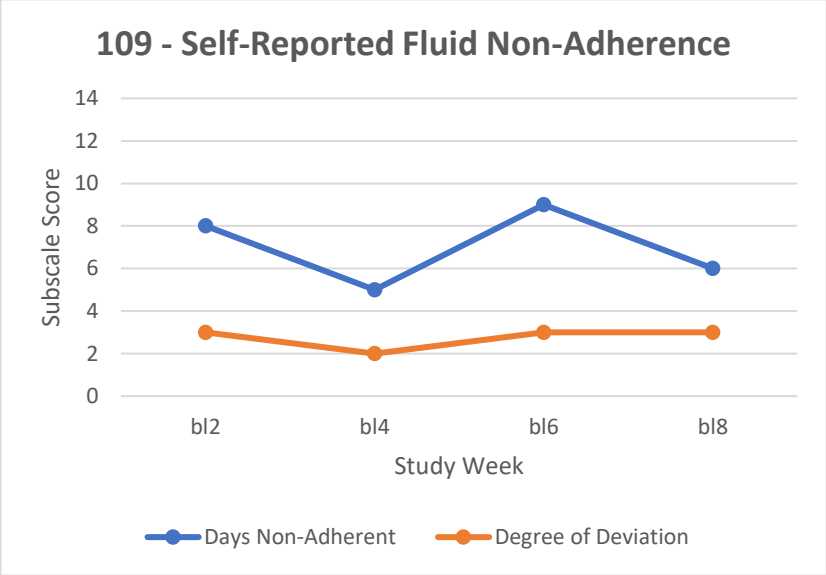


Summary

Tau-U Analysis
No statistically significant phase A trend.

Note: Participant withdrawn by clinical team due to serious injury sustained during baseline phase resulting in prolonged hospital admission.

Figure 4d

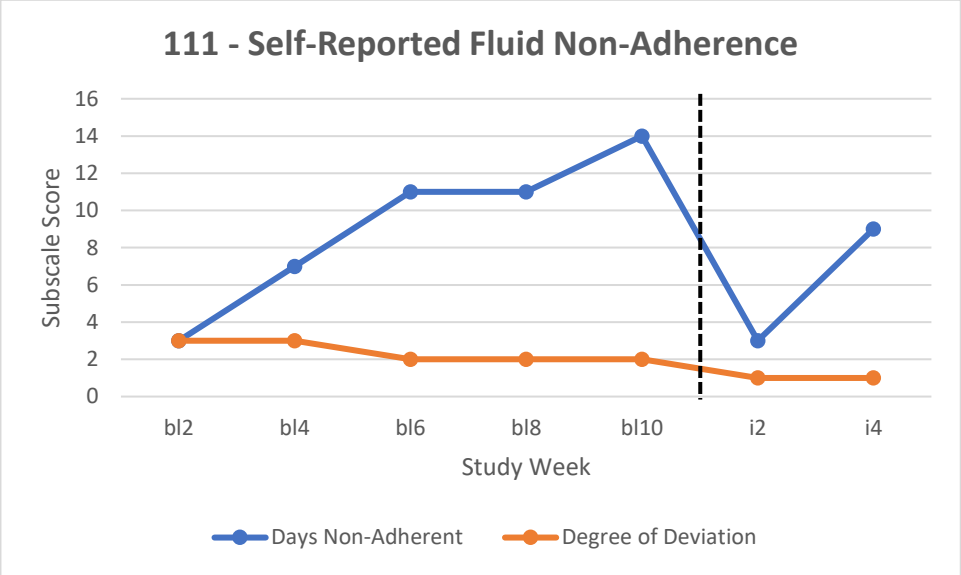


Summary

Tau-U Analysis
No statistically significant phase A trend.

Note: Participant admitted to hospital between intervention weeks 1 and 2 for surgery and withdrew from self-report aspects of study.

Figure 4e

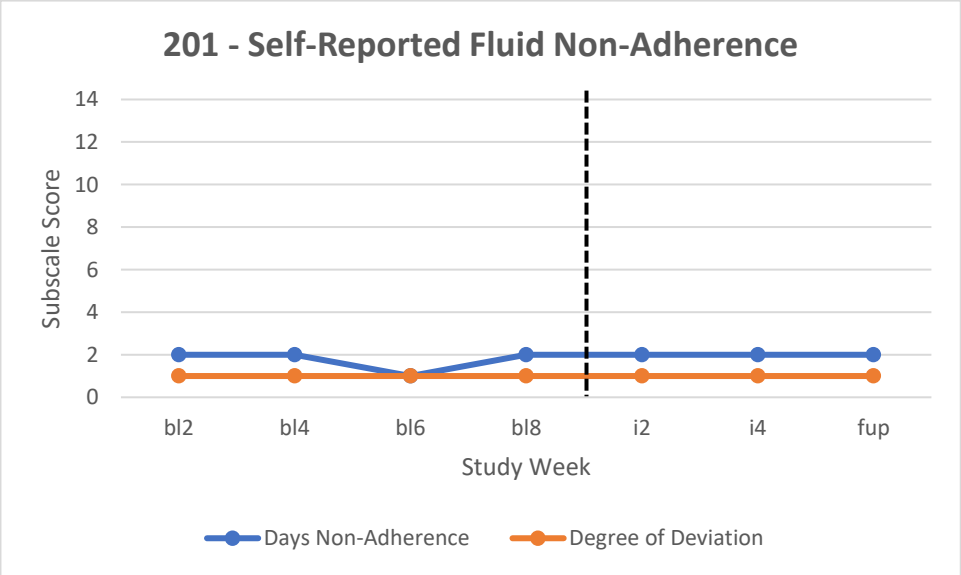


Summary

Tau-U Analysis
Statistically significant phase A trend for days non-adherent (p = .03). Statistically significant between-phase shift for days non-adherent (p=.007) but only two data points in phase B.

Note: participant admitted to hospital for gastroenteritis at intervention week 2 (i2).

Figure 4f

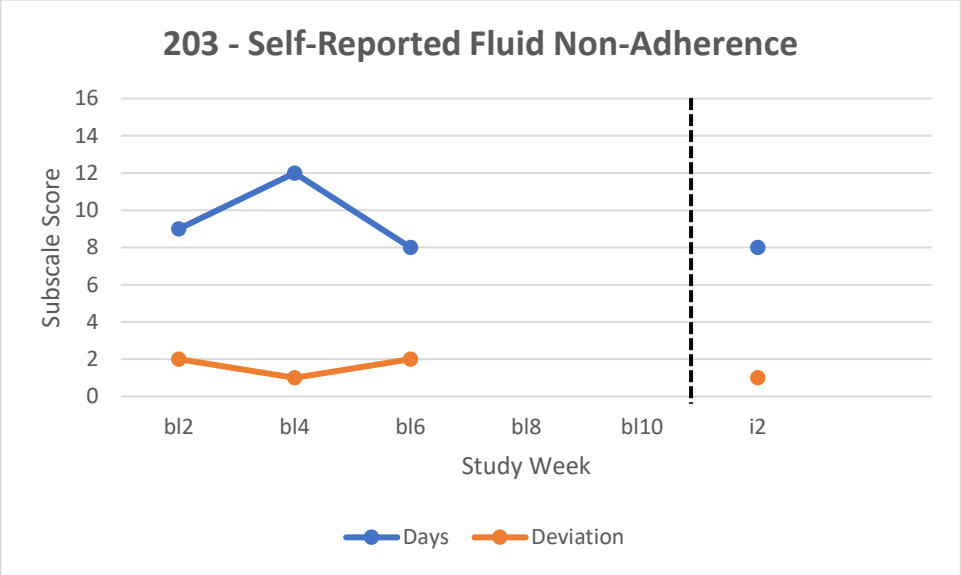


Summary

Tau-U Analysis
No statistically significant phase A or phase B trends. No statistically significant between-phase shift.

Note: Participant was hospitalised for vascular surgery on two occasions during phase B.

Figure 4g

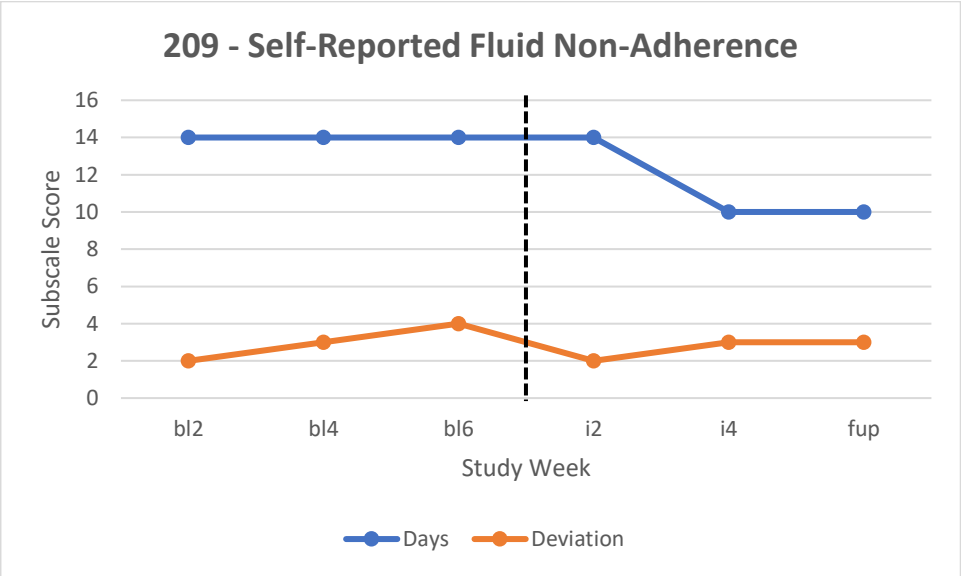


Summary Tau-U Analysis

No statistically significant phase A or phase B trends. No statistically significant between-phase shift

Note: Participant experienced hospitalisation for ruptured bowel after intervention session two (i2) and discontinued self-report measures.

Figure 4h



Summary

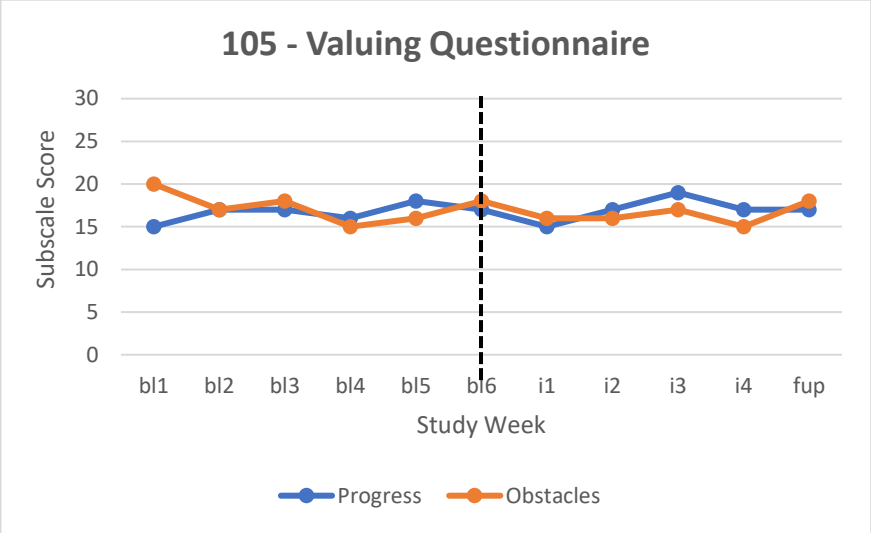
Tau-U Analysis
No statistically significant phase A or phase B trends. No statistically significant between-phase shift

Main Outcomes - Valuing Questionnaire

Figures 5a to 5h shows participant reports of *Progress towards values* and *obstacles to progress* assessed by the Valuing Questionnaire. A brief summary of the findings is provided by each figure, with details of Tau U analysis provided in Appendix P. In summary, analysis identified a significant downward shift in perceived obstacles from phase A to phase B for participant 111 (p=.005), a significant upward shift in perceived progress from phase A to phase B for participant 201, controlling for a significant phase A trend (p = .03) and a significant increase in perceived progress towards values from phase A to phase B for participant 209 (p=.04). These changes were broadly consistent with visual inspection. Reliable change indices for the two valued living subscales (calculated using information on internal reliability and standard deviation from previous publications, e.g., Carvalho, Palmer, Pinto-Gouveia, Gillanders & Castilho, 2018; Smout et al., 2013) suggests a change of 8 points on the Progress subscale and a change of 6 points on the Obstacles subscale are indicative of reliable change. Using these values to contextualise the magnitude of the shifts observed in these participants, it is clear they are modest.

Figures 5a to 5h. Valuing Questionnaire Subscale Scores

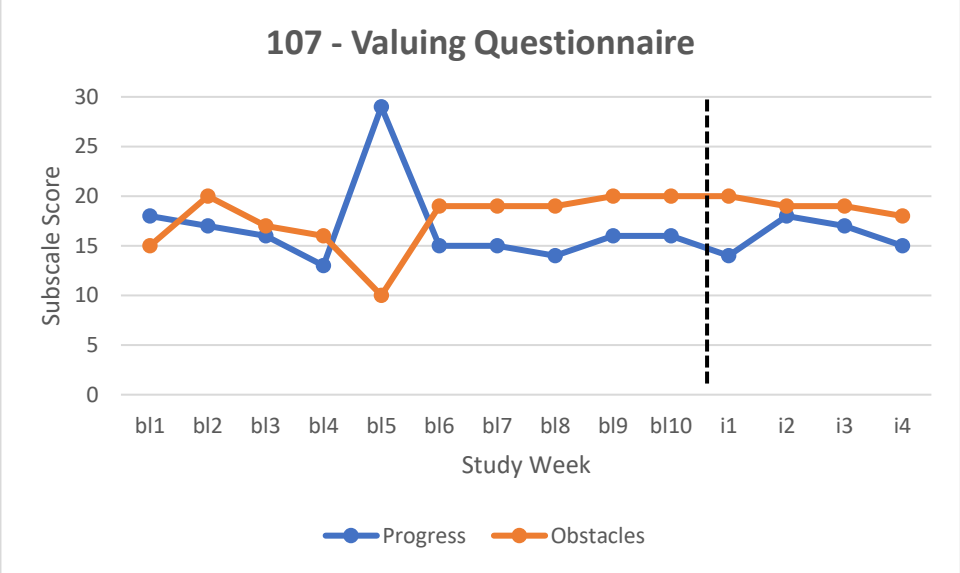
Figure 5a



Summary

Tau-U analysis identified no statistically significant phase A or phase B trends and no statistically significant between-phase shift.

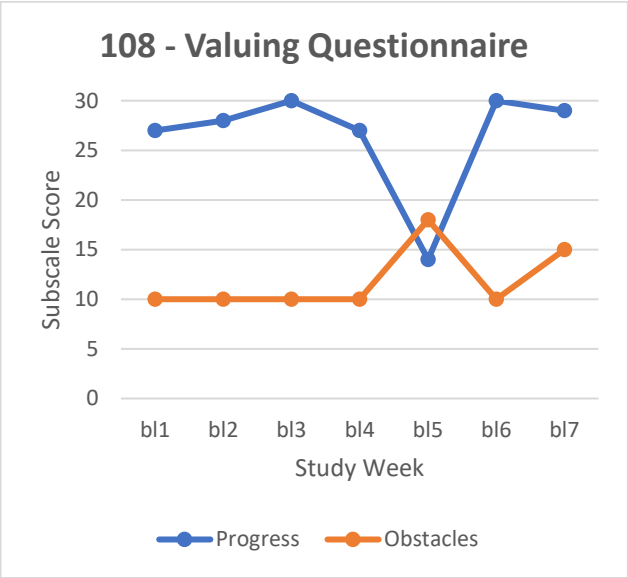
Figure 5b



Summary

Tau-U analysis identified no statistically significant phase A or phase B trends and no statistically significant between-phase shift.

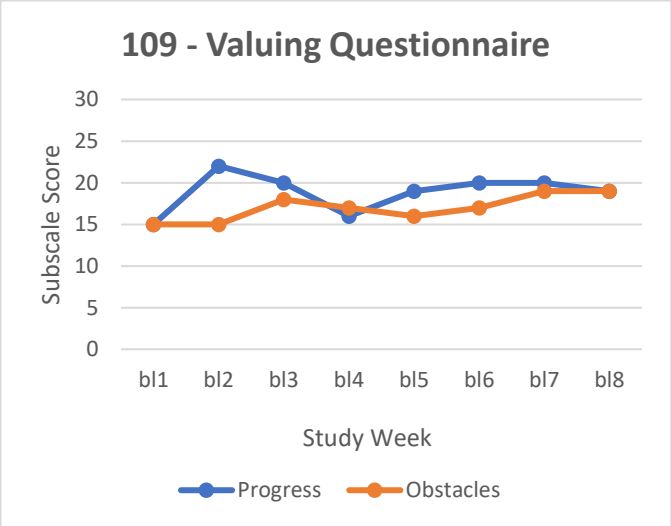
Figure 5c



Summary

No Tau U analysis conducted as participant withdrawn by clinical team.

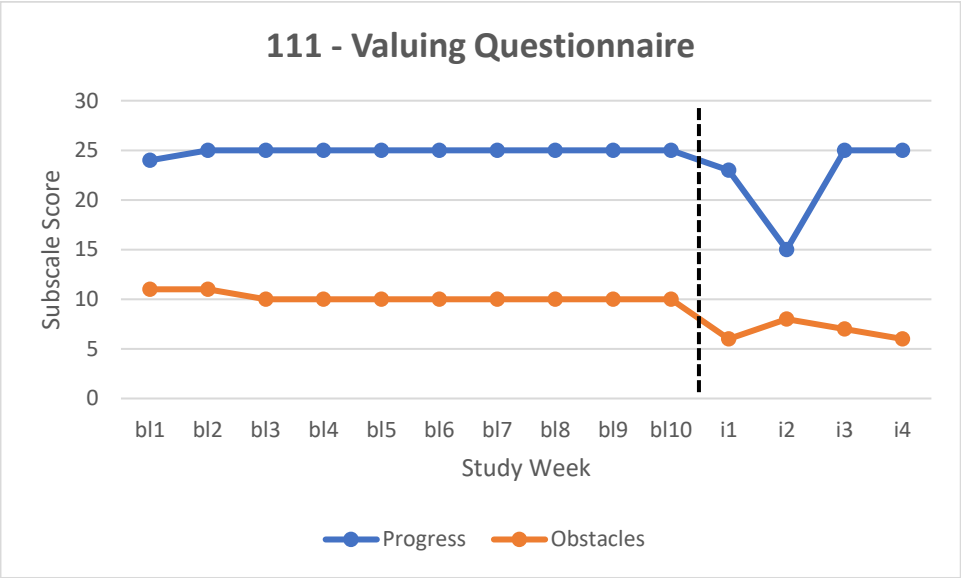
Figure 5d



Summary

No phase B data collected.

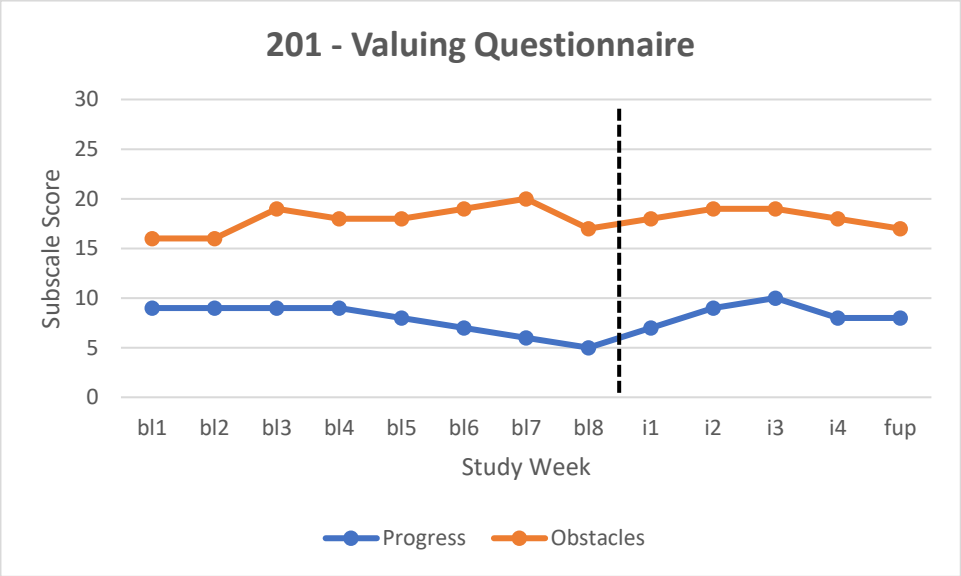
Figure 5e



Summary

No statistically significant phase A or phase B trends. Statistically significant between phase shift in perceived obstacles (p = .001).

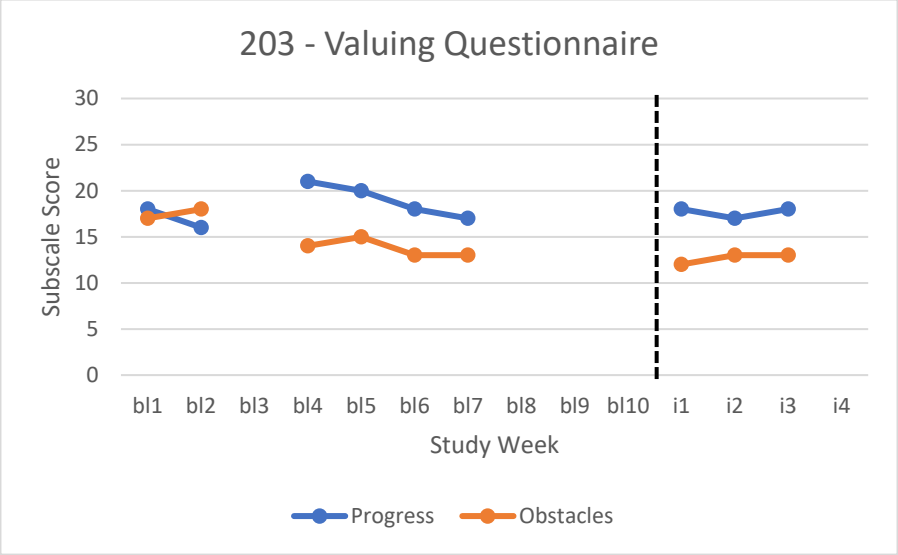
Figure 5f



Summary

Significant phase shift from phase A to phase B in perceived progress towards values (p = .03).

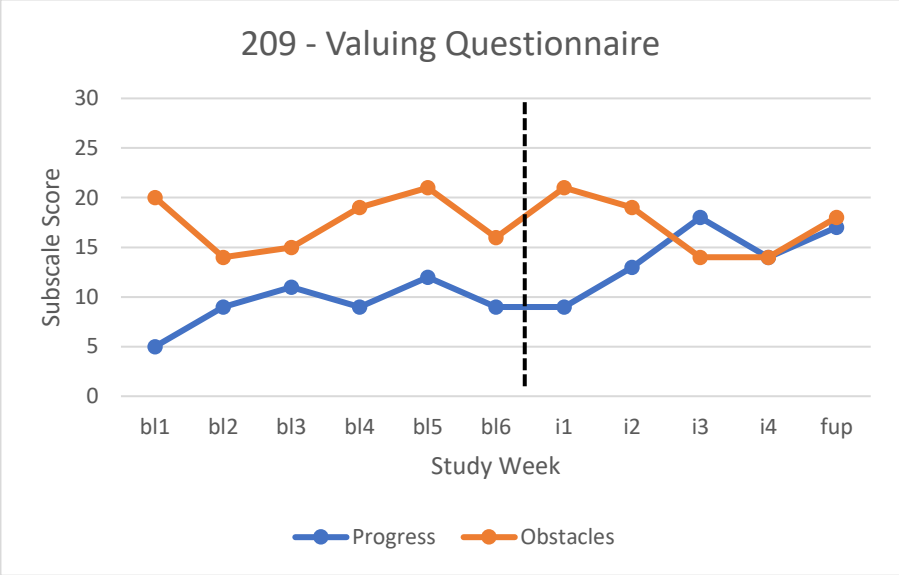
Figure 5g



Summary

No statistically significant phase trends or between-phase shifts in the context of very high levels of missing data.

Figure 5h



Summary

Statistically significant between phase shift from phase A to phase B corresponding to an increase in perceived progress towards values ($p = .04$).

Psychological Distress

Four participants commenced the study with CORE scores in the moderate-severe or severe range (see Table 6). Of these, one withdrew, and one died and the remaining two showed improvements reaching the threshold for statistically reliable change (moving from moderate-severe to mild and moderate severe to moderate symptom levels. Two participants scored in the mild and low-levels respectively and showed slight reductions in distress which did not reach the threshold for reliable change. Two participants were in the healthy range at the outset of the study, with no evidence of deterioration in the participant who completed measures at subsequent time points.

Process of Change

Table 6 also shows participant total scores on CompACT. Scores for participants 105 and 201 were remarkably stable. Participant 107 showed a deterioration on the final measure completed, just one week before he died. Participant 111 scored almost at ceiling during baseline, declined after intervention session 1 and returned almost to ceiling by the end of the intervention. Participant 203 showed a small decline from baseline to session 1. Participant 209 showed an increase from session 1 to session 4 in excess of the threshold for reliable change, calculated as a change of 12.23 using data on standard deviation and internal reliability from Francis et al., (2016) and Trindale et al., (2021), but showed a subsequent deterioration at follow-up. Overall, there was little evidence of an effect of the intervention on ACT processes.

Table 6. Participant Scores on CORE and CompACT at each assessment point

	Clinical Outcomes Routine Evaluation				Comprehensive Assessment of Acceptance and Commitment Therapy Processes			
	Start Baseline	**Session 1**	**Session 4**	**Follow-up**	**Start Baseline**	**Session 1**	**Session 4**	**Follow-up**
105	24	22	21	*18**	70	67	71	69
107	26	24	28	*Deceased*	71	71	59	*Deceased*
108	1	-	-	-	111	-	-	-
109	21	-	-	-	66	-	-	-
111	2	4	2	**-**	130	113	132	
201	11	11	12	9	66	60	64	64
203	9	7	-	-	82	73	-	-
209	24	18	11	10*	57	57	84	65

* Participant shows reliable improvement from baseline to follow-up

Summary of Findings

Table 6 shows a summary of the statistically significant findings across the key outcome measures. Where evidence of an intervention effect was identified this is indicated by '+'. Where such an effect was observed but was likely to be attributable to confounding factors this is marked (+). Where there was no evidence of an intervention effect this is marked by a dash. For participant 108 who was withdrawn prior to intervention these comparisons are marked not applicable 'n/a'.

Table 6. Summary of Findings

ID	Subjective Fluids	Objective Fluids (IDWG)	Progress to Values	Obstacles to Values	Mood (CORE-10)
105	-	-	-	-	+
107	-	(+)	-	-	-
108	n/a	n/a	n/a	n/a	n/a
109	-	(+)	-	-	-
111	+	(+)	-	+	-
201	-	-	+	-	-
203	-	(+)	-	-	-
209	-	-	+	-	+

Acceptability

Six participants completed credibility and expectancy items after session 1. Items were rated on a scale from 1 (not at all logical/successful/confident) to 9 (extremely logical/successful/confident) as well as rating percentage anticipated

improvement. Three completed the same measures at follow-up with two additional participants providing verbal feedback at last contact. Data suggest that participants varied in their expectations for the intervention but felt moderately positive about its logic and had modest expectations for the success of sessions in supporting them to live well (see Table 6). Those who completed the intervention rated it more positively at completion, although there was a decrease from anticipated to actual improvement for two participants and an increase for one.

Table 7. Intervention Credibility and Expectancy Ratings Session 1 and Follow-up

	After Session 1						Follow-Up				
ID	Logic	Success	Recommend	Improve %	'feel success'	'feel improve'	Logic	Success	Recommend	Improve %	*Comments*
105	5	5	5	80	9	90	7	7	8	40	"*it was nice to talk to someone about what was happening in my life*"
107	5	2	6	10	2	10					'*enjoyed having our conversations'* '*less keen on the paperwork'*.
111	9	7	9	50	6	40					"*the questionnaires were useful in helping me reflect on things and getting me ready to complete the matrix*"
201	6	4	6	20	5	20	6	6	7	30	"*the sessions made me stop*

											and think about my approach to dialysis. Helpful to have someone to talk to"
											"I found it difficult to see the relevance of some of the questionnaires"
203	5	5	5	50	5	50					*'I've never enjoyed doing homework'*
209	6	5	7	50	6	80	7	7	8	40	"*Talking things out to someone who isn't family"*
Mean (SD)	6 (1.55)	4.65 (1.62)	6 (1.54)	43.33 (25.03)	5.00 (2.26)	46.67 (29.43)	6.67 (0.58)	6.67 (0.58)	7.67 (0.58)	36.67 (5.77)	

Discussion

Many people who are receiving dialysis for ESRD struggle to adhere to fluid intake recommendations (Vlaminck et al., 2001). This study explored the acceptability, feasibility and outcomes of a brief four-session intervention based on the ACT Matrix (Polk et al., 2016).

Acceptability Participants found the intervention moderately acceptable. Ratings of intervention logic, success and likelihood of recommendation improved from session 1 to follow-up amongst participants providing this data, with these participants describing a 30-40% improvement in their ability to live well on dialysis. Premature termination of sessions, affecting two participants, occurred due to acute illness, highlighting the challenge of delivering an intervention to people experiencing an unpredictable health condition. Indeed, the level of physical health complications additional to or arising from ESRD that participants were experiencing was greater than anticipated and this resulted in difficulty interpreting the data. Most participants experienced at least one serious adverse event during the study, but there was no evidence that the intervention itself, or the associated research procedures, caused harm. Due to Covid-19, consultation during study design was challenging. However, it would have been advantageous to refine the intervention more to meet the needs of people on dialysis. Indeed, after approval of this study, Elander et al. (2021) published research describing the development of an adapted version of ACT for renal dialysis patients incorporating substantial patient input which is yet to be trialled.

Feasibility Busy dialysis units are a challenging environment to deliver psychological therapy. Sessions were regularly interrupted by nursing staff adjusting equipment and during one session a participant became unresponsive. Participants

were sometimes limited in their capacity to focus during sessions and to engage in behavioural changes between. Three participants moved between dialysis units during the intervention phase and six experienced an inpatient admission. Considerable flexibility was required to maintain weekly sessions. One possibility would be to explore whether offering the intervention through telehealth, with an accompanying workbook, might increase accessibility (e.g., Herbert et al., 2022) although previous research using this format with ESRD patients has been unsuccessful (e.g., Vogt., 2016).

The four-session intervention was designed to be relatively brief and straightforward. However, most participants recruited had longstanding difficulties with treatment adherence. It is likely that their internal obstacles to adherence were psychologically complex. For example avoidance of powerful emotions such as guilt and shame may contribute to patterns of responding that deny the reality of ESRD, and depression, uncertainty and feelings of futility can contribute to engagement in unworkable behaviours. It is also hypothesised that for some participants powerful cultural associations with non-adherent behaviours andwider systemic issues influenced adherence. Likewise in some instances ways of responding to the advice of powerful others may have develop as functional adaptations to particular early life experiences but be less adaptive whenfacing the challenge of managing a chronic health condition. In these circumstances it may be unrealistic to expect sustainable behaviour change from a brief intervention (e.g., Rzeszut, 2011). If such an approach were to be trialled again, it would be beneficial to establish a mechanism for screening participants, to identify those who were medically stable and in a position to benefit from a brief and focused psychological intervention to support adherence. Additionally, brief psychological screening might support triaging of

people according to their suitability for an intervention delivered by an allied health professional (including those without extensive psychological training), or to more sustained input from an experienced renal clinical psychologist.

Outcomes Inspection of study data showed no clear and consistent picture of benefit. Tau-U analysis identifies statistically significant non-overlap of baseline and intervention phase data but not the degree of separation beyond this (Parker et al., 2011). Although four participants showed improvements on IDWG which yielded significant Tau-U values, in each case confidence in their reliability was undermined either by poor data quality or the occurrence of medical events, and visual inspection suggested that these shifts were relatively small. Likewise, whilst three participants showed statistically significant non-overlap in valued living, the degree of change was not substantial. Two participants met criteria for reliable change in psychological distress. However, there was no evidence of change on the measure of ACT processes, consistent with some previous research (Lavelle et al., 2022). The challenges faced by participants, for example the participant at the end of life, also highlighted the ethical tension between remaining person-centred and adhering strictly to a study protocol, the efficacy of which was to be assessed in terms of a relatively narrow outcomes. In a larger sample per-protocol omnibus analysis could have been conducted, excluding participants who required very substantial intervention adaptations to meet their needs.

Limitations This study under-recruited, and the level of physical morbidity of participants was higher than anticipated. Although it would have been logistically challenging to manage more participants concurrently across three hospital sites, it would have improved the study. Additionally, in hindsight it would have been advantageous to limit recruitment to participants who were in the contemplation or

preparation stages of change (e.g., Prochaska & DiClemente, 1992). The relative inexperience of the trainee in using ACT with renal patients and their dual role taking consent, distributing questionnaires, and then delivering the intervention, may have introduced bias and reduced intervention efficacy relative to delivery by an experienced clinician. In future research it would be advantageous to separate these roles, although the conduct of this study likely reflects the reality of conducting small-scale research in clinical practice. Lastly, with hindsight, many improvements could have been made to study design. For example, the self-report measure of fluid adherence was selected as the only identified validated measure in the literature. However, because it was designed for administration bi-weekly this reduced the number of data points and meant that for participants who did not complete follow-up, the number of post intervention measures was insufficient to be confident in the reliability of any observed changes. In future research it is recommended that a brief weekly self-report adherence measure, or even a measure completed at each hospital visit, might be trialled. Additionally, whilst visual inspection considered potential changes between the unmonitored and monitored baseline and whether any intervention phase changes persisted, increased or diminished during follow-up, statistical analysis was based on an A/B design due to issues with data quality and completeness. In future research it would be advantageous to increase the number of measurement points, maintaining weekly measurement during a follow-up phase (see Smith, 2012 for SCED quality indicators). This would support exploration of the persistence (or otherwise) of any intervention effects. However, it should also be noted that even the measurement schedule employed in this study placed a considerable burden on participants and improvements to study design need to be balanced with consideration of participant burden. Reliance on IDWG overcomes

problems with participant burden, but in the current study, this data, collected in routine clinical practice, was of variable quality.

This brief ACT intervention targeting fluid adherence and valued living was broadly acceptable, but its benefits were ambiguous. A more sustained intervention, including follow-up sessions to support consolidation of ACT concepts and embed behavioural changes, may be more efficacious, at least for those with complex difficulties. Previous research has tested a range of behavioural interventions, with no clear superiority of one intervention over another (e.g., Bossola et al., 2018). Participants commented primarily on the helpfulness of having someone to talk to and future research might usefully consider whether an ACT intervention implemented has incremental benefit over brief supportive counselling, particularly on behavioural outcomes. There is ongoing work exploring how best to meet the psychological needs of people on dialysis. It is hoped that this research, by highlighting some of the challenges, will contribute in a small way to this broader endeavour.

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Executive Lay Summary

Study Context: This study explored the feasibility, acceptability and outcomes of a four-session psychological intervention for people experiencing difficulties with fluid restriction on dialysis. The study was developed with input from four people with lived experience of kidney disease and dialysis. These people reviewed study documents and discussed issues relating to the planned delivery of the intervention within renal units. The study received ethical approval from the Leicester South Research Ethics Committee and was sponsored by the University of Oxford. The study was registered at www.clinicaltrials.gov (ref: NCT05264220). Participants were recruited from two haemodialysis units operated by Oxford University Hospitals NHS Trust. We are extremely grateful to our participants and lay advisers for their contribution to this project and to renal unit staff for their support with recruitment.

Background: Fluid restriction during dialysis treatment is important because dialysis cannot completely replace the function of damaged kidneys. Fluid restriction limits the build-up of excess fluids within bodily tissues, reducing strain on organs such as the heart and lungs. However, many people struggle with this and other recommended dietary and lifestyle changes. This study used an intervention based on a paper and pencil tool called the ACT Matrix (see Polk, Schoendorrf, Webster & Olaz, 2016). The aim of the ACT matrix is to support people to clarify their values, both broadly and in relation to health and wellbeing, to become aware of internal obstacles to values-consistent behaviour and develop strategies to support them to

act in ways that were more consistent with their values, even when internal or external factors make this challenging.

Methods: Eight people were recruited and consented to take part in the case series. They were randomly allocated to a baseline of 6, 8 or 10 weeks and during this baseline period completed weekly questionnaires. At the end of the baseline, participants were offered four therapy sessions, one per week for four weeks. Sessions were offered by a trainee clinical psychologist under supervision of an experienced renal clinical psychologist. Participants completed further questionnaires during the intervention and at four weeks follow-up. Interdialytic weight gain data was obtained from medical records for the 12 weeks prior to the start of the self-report baseline phase, and for the duration of the study to the end of follow-up. Participants also provided feedback on the intervention.

Results: Of the eight people who participated in the case series, seven received at least one intervention session and three completed the full study including four-week follow-up. Six participants experienced at least one inpatient admission during their period of involvement in the study. One participant was withdrawn by the clinical team during the baseline due to serious illness, two withdrew from self-report aspects of the study during the intervention as a result of acute health problems. One participant died of complications of ESRD during the follow-up period. None of these events were related to study procedures, but they illustrate the feasibility challenges of offering an intervention to improve fluid restriction in this clinical group.

Analysis of data related to intervention acceptability suggested that participants had moderate expectations of intervention success and those who completed the intervention viewed it positively, particularly commenting on the benefits of talking to someone who was independent of family and could help them look at issues from a different perspective. There was tentative evidence of some isolated improvements in study participants. For example, one participant showed improvement subjective fluid restriction, four showed improvements in interdialytic weight gain and three reported living more in line with what mattered to them. However, the combination of poor data quality, the small absolute magnitude of changes observed and co-occurring medical events that may have influenced fluid restriction, mean that confidence in the findings is severely compromised. Two participants showed statistically reliable improvements in psychological distress. Some participants reported that completing study measures burdensome whilst one said they found the measures a useful tool for reflection. There was no evidence of change in psychological processes thought to be cultivated by the therapeutic approach.

Discussion: This study has highlighted the challenges of managing the demands of dialysis alongside other related health problems. Although some people appeared to experience limited benefits from the intervention, these were very modest, and it is unclear whether the benefits observed would have exceeded those achieved through simple social support. Our data suggest that any intervention offered to support people with fluid restriction on dialysis needs to be flexible enough to accommodate interruptions and to be respectful of the fact that as a person's

health status changes improving fluid control may no longer be a significant priority. If the intervention was to be trialled again it is suggested that it be offered people who are keen to work actively towards increased fluid control and are experiencing a period of relative stability in any concurrent health problems. Sessions occurring over a longer duration, alongside the provision of tapered follow-up, might also be required to enable people to establish and maintain challenging behavioural change.

Dissemination: Findings of the study will be disseminated to participants, clinical staff within participating renal units and to the organisations whose members contributed to the initial development of the study. We will consider whether the findings are appropriate for presentation at a conference or submission to a peer review journal at this stage, or whether they are best regarded as pilot data used to inform ongoing clinical and research activity.

Reflective Connecting Narrative

The three studies I conducted: a critical review of the literature on the relationship between readiness to change and outcome in CBT; a service improvement project focused on staff recording of clients' child dependants; and a study of fluid adherence on dialysis, initially appear completely unrelated. I chose projects in different clinical areas that interested me and that would allow me to develop new research skills. However, as time has gone on, I have become aware of their common thread: a focus on understanding the initiation and maintenance of behaviours in the face of intrapersonal, contextual and systemic challenges. I have also come to see completion of the research itself in similar terms and this perspective has helped me keep going when progress has been slow.

Critical Review of the Literature I was initially drawn to the topic of readiness to change and therapy outcome when observing triage meetings in the adult mental health team where I spent the first year of training. In the context of limited resources many discussions focussed on whether a given referred person was 'ready for therapy'. I wondered how different members of the team were conceptualising this and how it might be assessed objectively. I also wondered what the evidence was that 'readiness' related in a meaningful way to therapy outcome. It was challenging to approach a new and unfamiliar literature and rapidly make the precise decisions required to define the scope of the review. I realised how much I valued collaborative working and was very grateful to my supervisors Becca Knowles Bevis and Matt Hotton, as well as Lucas Shelemy, my second reviewer, for helping clarify the scope of the review and being willing to discuss the decisions along the way. The outcomes of the review were inconclusive and brought home to me the

strengths and limitations of systematic review methodology in addressing complex questions that go beyond intervention efficacy.

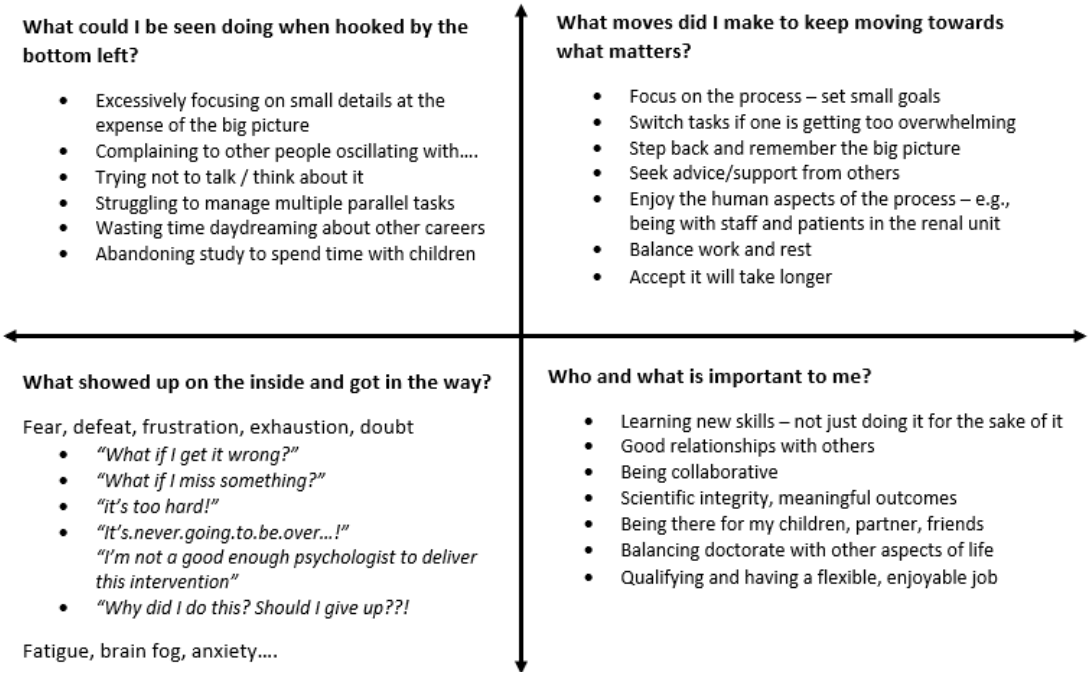
Service Improvement Project As a parent I often found myself thinking of service users' parenting role, so I was very keen when the opportunity arose to update and then conduct a project on recording information about child dependants that had been planned but not initiated by my project supervisor Louise Johns. Initially I hoped to include the perspectives of service users as well as staff. However, the project was taking place in the middle of the Covid-19 pandemic, and it was decided that it was more feasible to focus on staff perspectives only.

Data collection was challenging as staff in the two teams were under high levels of stress. I was grateful to my supervisor for helping facilitate buy-in from the teams and also in supporting me to later present the findings to the various trust working groups focussed on children, families and safeguarding. Both the findings, and the discussions in these meetings, highlighted the incredible challenges that exist in trying to implement changes within a complex system that is under strain and how individual behavioural decisions (to ask about children, to input relevant data) are so heavily shaped by the interaction between individual level and system level factors. This is something that will be at the forefront of my mind in any future service improvement work I conduct in learning disability services.

Main Research Project The motivation for my main research project was the desire to learn new clinical skills and new research methods. I had never conducted case series research and I was keen gain further experience using ACT, as well working with people experiencing chronic illness. The pandemic compromised some aspects of the study: I was unable to visit the renal units during the design phase,

which would have provided a better sense of the patient group, and the approval process took almost 18 months from first applying for sponsorship to receiving the go-ahead to start, which delayed recruitment by a year. Delivering therapy as part of the research study had seemed like a good idea in theory and felt like a lot of pressure in practice! I had to use the ACT Matrix regularly with myself to keep taking steps forward when we met inevitable obstacles and had to adjust (see Figure 1).

An ACT Matrix of the Thesis Experience!



Although this was the most challenging project I undertook and the findings were equivocal, I was not disappointed. It was evident when delivering the intervention that, given the complexity of the participants' situations, expecting them to make dramatic behavioural changes over a short timeframe was probably unrealistic. However, the approach did not feel invalidating to their struggles and allowed for the flexibility to respond to events that occurred from week to week. I would have liked to

revisit participants for follow-up sessions to get a better sense of whether they could embed the ideas and practices we had discussed into their daily lives with more support and time. One of the challenges of writing up the study was realising that even in a case series it was necessary to let go of so much individual detail in order to summarise the data. Ideally it would have been possible to learn from the first group of participants, make changes and implement a second phase in an iterative design. Although I cannot do this myself, I hope the findings will be useful to the clinical team where I conducted the research. Exploring this type of research has led me to appreciate the sophistication of case series methodology and I know that there is much more to learn. I hope that in my future work in learning disabilities I will be able to apply these techniques to improve clinical practice in a population where single case research is more widely used and may be particularly useful.

In summary, conducting these research projects has been a formative experience. I have learned a lot about the realities of conducting research alongside clinical work and balancing scientific and pragmatic considerations, I am looking forward to taking this learning in my future career.

Acknowledgements

First, I would like to acknowledge all the participants who took part in the research described here. They gave their energy and shared their thoughts with such grace and commitment at a difficult time and I am extremely grateful for their contribution. Thank you also to the staff in the Mental Health teams and Renal units who supported this research during a period of unprecedented stress.

I would also like to thank my research supervisors. I chose the projects described here at least as much because I wanted to work with you, as because of the research topics themselves and I have learned so much. Thank you all for your wisdom, sense of humour, and pragmatism and thank you Louise for sharing your office, your time, your enthusiasm and for making me feel so welcome. It has kept me going when things have been tough.

A big thank you also goes to the 2019 cohort and especially all the other ‘year 4s’.- I’ve really appreciated working with you these last few months – although it would have been nice to finish ‘on time’, I wouldn’t have missed spending this extra time together in real life, after so much training online.

Lastly thank you to my family and friends. You’ve supported and encouraged me and kept me grounded. Thank you to James for the late-night playlists and refreshments and to Bethan, Seth and Kit for being so patient over the last three years. I can’t wait to spend more time with you!

Appendices

Appendix A

Full PsycInfo Search

# ▲	Searches	Results	Type
1	readiness to change.mp. or exp Readiness to Change/	2979	Advanced
2	limit 1 to (english language and yr="1980 -Current")	2848	Advanced
3	stages of change.mp. or exp "Stages of Change"/	2812	Advanced
4	limit 3 to (english language and yr="1980 -Current")	2690	Advanced
5	transtheoretical model.mp. or exp Transtheoretical Model/	2454	Advanced
6	limit 5 to (english language and yr="1980 -Current")	2347	Advanced
7	exp Motivation/	142952	Advanced
8	limit 7 to (english language and yr="1980 -Current")	117477	Advanced
9	exp Readiness to Change/ or readiness ruler.mp.	1597	Advanced
10	limit 9 to (english language and yr="1980 -Current")	1522	Advanced
11	exp "Stages of Change"/ or exp Behavior Change/ or exp Readiness to Change/ or exp Motivation/ or URICA.mp.	155838	Advanced
12	limit 11 to (english language and yr="1980 -Current")	129245	Advanced
13	exp "Stages of Change"/ or exp Motivation/ or exp Readiness to Change/ or SOCRATES.mp.	145468	Advanced
14	limit 13 to (english language and yr="1980 -Current")	119657	Advanced
15	CONTEMPLATION LADDER.mp.	116	Advanced
16	limit 15 to (english language and yr="1980 -Current")	115	Advanced
17	2 or 4 or 6 or 8 or 10 or 12 or 14 or 16	132224	Advanced
18	exp Cognitive Behavior Therapy/ or cognitive behavio$ therapy.mp.	31760	Advanced
19	limit 18 to (english language and yr="1980 -Current")	28881	Advanced
20	cognitive therap$.mp. or exp Cognitive Behavior Therapy/	42427	Advanced
21	limit 20 to (english language and yr="1980 -Current")	39246	
22	exp Cognitive Behavior Therapy/ or exp Cognitive Therapy/ or CBT.mp.	37821	
23	limit 22 to (english language and yr="1980 -Current")	34588	
24	19 or 21 or 23	44817	
25	exp "Treatment Process and Outcome Measures"/ or exp Patient Reported Outcome Measures/ or outcome$.mp.	431283	
26	limit 25 to (english language and yr="1980 -Current")	403617	
27	effect$.mp.	1440511	
28	limit 27 to (english language and yr="1980 -Current")	1224540	
29	prognos$.mp.	38120	
30	limit 29 to (english language and yr="1980 -Current")	29768	
31	impact$.mp.	384871	
32	limit 31 to (english language and yr="1980 -Current")	360863	
33	exp Treatment Duration/ or exp Treatment Refusal/ or exp Treatment/ or treatment$.mp. or exp Treatment Barriers/ or exp Treatment Dropouts/ or exp Treatment Compliance/ or exp "Treatment Process and Outcome Measures"/ or exp Treatment Outcomes/	1325908	
34	limit 33 to (english language and yr="1980 -Current")	1125602	
35	benefi$.mp.	238498	
36	limit 35 to (english language and yr="1980 -Current")	221689	
37	engag$.mp.	206963	
38	limit 37 to (english language and yr="1980 -Current")	194007	
39	26 or 28 or 30 or 32 or 34 or 36 or 38	2308283	
40	17 and 24 and 39	1414	

Appendix B

Detailed Title/Abstract and Full Text Screening Criteria

Detailed Title/Abstract Screening Criteria

All titles and abstracts were screened against the following **exclusion criteria**. They were excluded if ANY of the following applied. If there is no reason for exclusion at this stage progress to full text screening.

Criteria
Study does not include a CBT arm. At this stage studies that do not include an active psychological intervention at all, or which include an active intervention other than CBT are excluded. Excluded studies include those offering derivatives of CBT (e.g. MBCT, ACT, DBT, CST, BA, CBSAP) and those offering alternative psychotherapeutic interventions (e.g. psychodynamic psychotherapy, peer support, counselling). If the details of the psychotherapeutic intervention are unclear from the abstract the paper should be progressed to full-text screening.
The population under investigation is not defined by the presence of a mental health problem. Studies are excluded if the population of interest is defined by the presence of an addictive behaviour (e.g., to gambling, pornography, smoking) or other forms of substance abuse / dependence. Studies are excluded if the population under investigation is defined by the presence of traumatic brain injury, chronic pain, insomnia, physical health problems including diabetes, cancer, obesity, sexual dysfunction or other similar conditions. Studies on forensic populations are excluded due to the likelihood of different drivers of motivations for treatment in these populations.
The clinical target of the intervention is not a mental health problem. Studies where the clinical target is related to an addictive behaviour (e.g., craving, abstinence), are excluded.
The study does not include original data (e.g., a commentary, opinion piece or protocol), or was a qualitative study, a case study or case series, a cross-sectional study or a review.

Detailed Full Text Screening Criteria

Exclude if:

1. **Meets title/abstract exclusion criteria** (if includes people with dual diagnosis outcome and readiness measures must relate to non-substance misuse outcomes)

2. **Study does not include a measure of motivational readiness linked to transtheoretical model of stages of change**

Eligible measures including, but not limited to ....URICA, Change Questionnaire, Stages of Change Questionnaire/Scale, Anorexia Nervosa/Bulimia Nervosa Stages of Change Questionnaire, Readiness Ruler, etc

Ineligible measures: measures such as Nijmegen Motivation List (NML/NML-2/NML-child version), Willingness Scale, or measures focused on Treatment Expectancy, Treatment Credibility, Treatment Efficacy or Importance, or Therapeutic Alliance/Resistance, etc)

3. **Measure of motivational readiness is not taken prior to intervention or session 1** (initial measure must be taken at baseline or session 1 only)

4**. Study does not include a CBT intervention** (note: ERP included for OCD spectrum disorders). CBT plus medication or CBT as main psychological treatment in context of inpatient admission where there are other adjunctive psychological interventions included. Combined CBT and Motivational interviewing not included. Unguided (pure self-help) CBT bibliotherapy not included.

5. **Study does not report analysis which directly examines link between motivational readiness and outcome/engagement.** NOTE: if study includes multiple treatment arms comprising a CBT treatment arm and other non-CBT treatment arms analysis must either examine the association between motivational readiness and CBT outcome separately or examine the overall association across treatment arms and report the interaction between motivation and treatment arm on outcome.

3. **No measure of clinical symptoms post intervention or engagement with intervention** symptom outcome, attendance, duration of treatment etc included- e.g. needs to have one or the other to be included, but does not need both.

6**. No original data included**

Appendix C

Quality Appraisal Tool: Selection and Implementation

The Down and Black Quality Appraisal Tool, used in this review, is intended for appraisal of both randomised and non-randomised healthcare interventions. Despite this, it had some limitations as a tool to appraise studies with respect to the exploration of within-group associations between variables of interest, rather than efficacy of a treatment interventions. As a result, other potential quality assessment measures were also considered, but these also had limitations. For example, use of the Newcastle Ottawa Scales or Cochrane Quality Assessment Tools would have necessitated the use of different tools for different studies, making it difficult to compare ratings. The Standard Quality Assessment Criteria (Kmet et al., 2003), whilst simpler than Downs and Black, provides less guidance on scoring of items and assimilates items addressed separately in the Downs and Black measure, which may conceal areas of difficulty in rating. Finally, whilst the recently published Quality of Survey Studies in Psychology (QSSP, Protogerou & Hagger, 2020) is potentially better suited to addressing the relationship of interest to this review (placing less weight on design features characteristic of randomised controlled trials) it has not yet been having been validated for use. As a result, the decision was made to use Down and Black but to state clearly how items relating to features of multi-arm studies or intended to capture quality features of randomised controlled trials were scored for studies where these were not relevant. Below the procedures for scoring items on the Down and Black Scale for Single Group Pre-Post Studies are outlined. Numbers refer to the item numbers on the scale.

Item Number and Coding Approach

5. Are the distributions of principle confounders in each group of subjects to be compared clearly described (reporting) – interpreted as consideration of relevant covariates in within-group analyses

14. Was an attempt made to blind study subjects to the intervention they have received? (internal validity, bias) – not particularly relevant in case of psychological interventions but answered for all studies

21. Were patients in different intervention groups recruited from the same population (internal validity, confounding, selection bias)- answered yes for single group studies

22. Were study subjects in different intervention groups recruited over the same period (internal validity, confounding, selection bias)- answered yes for single group studies

23. Were study subjects randomised to intervention groups? – answered no for single group studies

24. Was the randomised intervention assignment concealed from both patients and health care staff until complete and irrevocable – answered no for non-randomised/single group studies.

25. Were there adequate adjustments for confounding in the analyses from which the main results were drawn – in many studies potential confounders are not easy to identify – in RCTs guidance requires ITT to answer yes alongside adjustment for identified confounders – for single group studies answered yes if there are no relevant covariates identified (either theoretically it is not clear what might be

relevant, or if assessed and none significant in initial exploratory analysis, or if there is adequate control for identified covariates.

Discussions Emerging from Assessment of Inter-Rater Reliability for Quality Rating

During the establishment of inter-rater reliability two items prompted discussion. The first, **item 16**, related to 'data dredging'. This item asks whether, if any results were based on 'data dredging', this was made clear. This is difficult to determine for studies that are not based on published protocols and so ratings were based on the extent to which the study was described as exploratory, opportunistic, hypothesis generating, as designed from the outset to address the research question, or as uncertain, with some potential for rater interpretation.

The second item that generated discussion was **item 19,** 'was compliance with the intervention reliable'? Sometimes analyses were based on treatment completers with information provided about minimum session attendance, but often information on compliance was not available. The item guidelines suggest that "for studies where the effect of any misclassification was likely to bias any association to the null, the question should be answered 'yes' [as reliable intervention compliance]. This guidance appears to be consistent with judging quality in studies trying to establish intervention efficacy. However, it might be hypothesised that treatment non-compliance would be influenced by degree of readiness, and indeed some studies explored this explicitly. Therefore, for the research question under investigation, over constraining compliance (as might occur in an efficacy trial) would not be consistent with optimal interrogation of the relationship between readiness and outcome in naturalistic clinical settings and this item was interpreted quite

liberally with non-compliance being considered more in terms of marked deviations from the treatment protocol (e.g., equivalent to lack of receipt of intervention or switching trial arms) rather than variations in engagement / lack of homework compliance etc which might be recorded in primary efficacy trials.

Appendix D

Email Trail Confirming Audit Approvals

From: Rhodes Katie (RNU) Oxford Health <Katie.Rhodes@oxfordhealth.nhs.uk>
Sent: Monday, July 27, 2020 10:22:52 AM
To: Crane Catherine (RNU) Oxford Health <Catherine.Crane@oxfordhealth.nhs.uk>; Lofthouse Emma (RNU) Oxford Health <Emma.Lofthouse@oxfordhealth.nhs.uk>
Cc: Johns Louise (RNU) Oxford Health <Louise.Johns@oxfordhealth.nhs.uk>
Subject: RE: Audit and DPIA form - revised

Good morning Catherine,

The below changes within the questions are ok to go ahead.

Kind Regards,

Katie Rhodes
Senior Team Administrator
Oxford Health NHS Foundation Trust
The Whiteleaf Centre
Bierton Road
Aylesbury
HP20 1EG

From: Crane Catherine (RNU) Oxford Health <Catherine.Crane@oxfordhealth.nhs.uk>
Sent: 24 July 2020 16:51
To: Rhodes Katie (RNU) Oxford Health <Katie.Rhodes@oxfordhealth.nhs.uk>; Lofthouse Emma (RNU) Oxford Health <Emma.Lofthouse@oxfordhealth.nhs.uk>
Cc: Johns Louise (RNU) Oxford Health <Louise.Johns@oxfordhealth.nhs.uk>
Subject: Re: Audit and DPIA form - revised

Dear Katie,
Many thanks for notifying us of approving our audit proposal (see below). Following approval
we have now piloted the audit and would like to request one minor change.

The existing approval enables us to identity the number of children of each client falling within pre school, primary, and secondary age ranges, based on data from Carenotes. However, we have realised that we also need to obtain this information directly from care coordinators, to cover situations in which a child's d.o.b. is not included in the electronic health record.

We would therefore like to add the questions in yellow, to be answered when care coordinators indicate that a client has children.

If yes, how many does the patient have?

How many pre-school age?
How many primary school age?
How many secondary school age?

I have also added these questions to the amended audit form, attached.

We hope this minor change is acceptable, but please do let me know if you need any further information,

With thanks and best wishes,

Catherine

Get Outlook for iOS

From: Rhodes Katie (RNU) Oxford Health <Katie.Rhodes@oxfordhealth.nhs.uk>
Sent: Thursday, July 16, 2020 2:35 pm
To: Lofthouse Emma (RNU) Oxford Health
Cc: Crane Catherine (RNU) Oxford Health
Subject: FW: Audit and DPIA form - revised

Good afternoon,

Your audit proposal has now been approved.

Please see attached copy of an Audit Report Template in which will need to be completed and returned once the project is complete.

Kind Regards,

Katie Rhodes
Senior Team Administrator
Oxford Health NHS Foundation Trust
The Whiteleaf Centre
Bierton Road
Aylesbury
HP20 1EG

From: Lofthouse Emma (RNU) Oxford Health <Emma.Lofthouse@oxfordhealth.nhs.uk>
Sent: 29 June 2020 09:09
To: Ampofo Jelena (RNU) Oxford Health <Jelena.Ampofo@oxfordhealth.nhs.uk>
Cc: Crane Catherine (RNU) Oxford Health <Catherine.Crane@oxfordhealth.nhs.uk>; Johns Louise (RNU) Oxford Health <Louise.Johns@oxfordhealth.nhs.uk>
Subject: FW: Audit and DPIA form - revised

Hi Jelena

This requires approval from the directorate.

BW
Emma

From: Crane Catherine (RNU) Oxford Health <Catherine.Crane@oxfordhealth.nhs.uk>
Sent: 26 June 2020 16:56
To: Clinical Audit (RNU) Oxford Health <Clinical.Audit@oxfordhealth.nhs.uk>
Cc: Johns Louise (RNU) Oxford Health <Louise.Johns@oxfordhealth.nhs.uk>
Subject: Audit and DPIA form - revised

Dear Audit Team
Approximately one year ago Rob Bale granted management approval for a planned audit to improve the recording of service users' dependants within carenotes. The original title of the audit was "An audit to determine whether standards of recording dependants of patients in adult mental health teams are currently being met". At the time the project was to be undertaken by Jessica Radley, a post graduate student, under the supervision of Dr Louise Johns. Due to time constraints Jessica was unable to undertake the review. I am now hoping to take forward this project. As some things have changed in the intervening year we have updated the audit proposal, and DPIA form (both attached), to build on the findings of a recent safeguarding children audit, and to make the project feasible within the context of Covid-19.

We have sought Mark Underwood's approval for the revised plans and he has agreed this (see email trail below). We could be extremely grateful if the revised forms could be reviewed to seek management approval for the updated plans. I hope this is clear, but please to not hesitate to contact me if you have any questions,

With many thanks in advance for your help,

Yours Sincerely

Dr Catherine Crane, Clinical Psychologist in Training

This email has been scanned by BullGuard antivirus protection.
For more info visit www.bullguard.com

This email has been scanned by BullGuard antivirus protection.
For more info visit www.bullguard.com

From: Underwood Mark (RNU) Oxford Health <Mark.Underwood@oxfordhealth.nhs.uk>
Sent: Wednesday, June 24, 2020 4:40 pm
To: Crane Catherine (RNU) Oxford Health

Cc: Johns Louise (RNU) Oxford Health
Subject: RE: Audit and DPIA form - revised

Dear Catherine,

Thank you for getting back to me, and for your time earlier. Perfect, happy to support the audit, I hope it goes well for you. Very best wishes.

regards. *Mark M. Underwood*.

Mark M. Underwood
Head of Information Governance

IM&T Department, Oxford Health NHS Foundation Trust
The White Building, Littlemore MHC, 33 Sandford Road, Oxford, OX4 4XN
direct dial: 07810 040307
email: mark.underwood@oxfordhealth.nhs.uk





Appendix E

Information Sheet for Service Improvement Project

Recording Information about the Child Dependants of People Using Adult Mental Health Services: A Quality Improvement Project

Project Aims

- We are conducting a project within OHFT to understand how information about patients' child dependants and any contact with other children is recorded in electronic health records.
- We know that this information can be recorded in Carenotes in different ways.
- We would like to understand any barriers to obtaining and recording this information.
- We hope the things we discover can be used to make improvements to recording systems, to identify people who might benefit from parenting support and better safeguard children.

Who is Conducting the Project?

- This project is being conducted by Dr Catherine Crane, a clinical psychologist in training, supervised by Dr Rebecca Knowles-Bevis, OxCIPTR Research Tutor and Dr Louise Johns, Consultant Clinical Psychologist, Oxford Early Intervention Team. The project is being carried out with the support of the Oxford Health Safeguarding team.

What am I being asked to do?

- You will be asked to provide some brief information about child dependants for each of the patients on your caseload who is on CPA, entering the information into a simple spreadsheet.
- We would also ask you a few questions about whether anything makes obtaining and recording information about children difficult, and any suggestions you might have for improvements to current systems.
- The information we obtain **will be stored securely and will not be linked back to you individually in our audit report.**

Who has approved the project?

- The project has received DPIA approval for processing of patient data. Additionally, the project has received audit approval from Mark Underwood, OHFT Head of Information Governance.

What happens now?

Catherine Crane will contact you by email to discuss the next steps. We very much hope you will be willing to take part. If you have any questions you can contact Catherine by email at Catherine.crane@oxfordhealth.nhs.uk

Is there any benefit to me taking part?

- We realise how precious your time is and we hope that what we learn from this project will help improve safeguarding systems in the future. In recognition of your contribution each team taking part will receive a token of appreciation for their involvement.

Appendix F

Questions for Care Coordinators

Questions asked for each client on caseload:

Item #		Response Options
1	Client ID	*Pre-completed by researcher*
2	Does this patient have child dependants? (e.g. children for whom they have parental responsibility)	Y / N / Don't Know
3	If yes, how many does the patient have?	0, ___, Don't Know
4	How many pre-school age?	0, ___, Don't Know
5	How many primary school age?	0, ___, Don't Know
6	How many secondary school age?	0, ___, Don't Know
7	If yes, what is the patient's relationship* with these children?	Free text.
8	Is the patient in regular contact with any *other* children? (e.g. younger siblings, cousins, nieces/nephews, children of girl/boy friends, through workplace)	Y / N / Don't Know
9	If yes, what is/are the patient's relationship* with these children?	Free text.
10	Are you aware of any caring responsibilities any of the above children might have for the patient? (NOTE: Included for another trainee project, not analysed)	Y/N/DK
**These items were intended to capture whether the client was mother, father, sibling, step-parent etc. However, some respondents misunderstood and reported on the quality of the relationship. Responses to these items were not analysed.*		

Open-Ended Questions

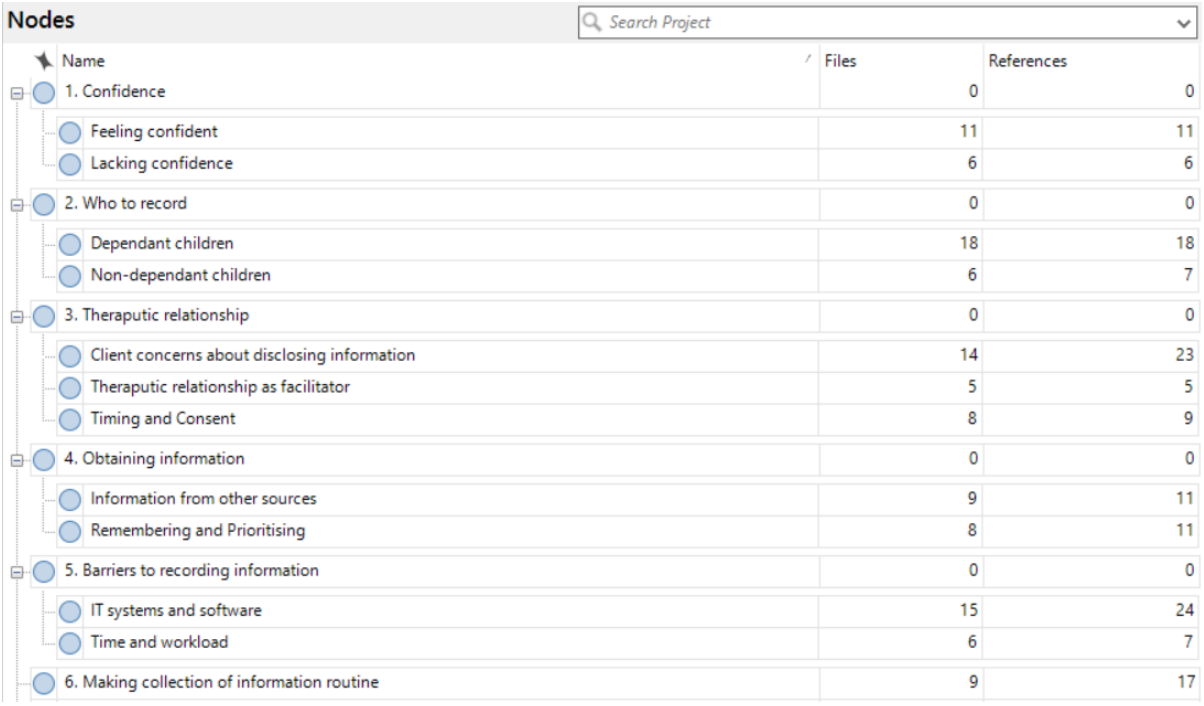
We would like to use the findings of this project to make recommendations that could help improve the recording of information about patients' child dependants and contact with other children, within Carenotes. We would really appreciate your feedback concerning things that affect the gathering and recording of information about contact with children:

1. Do you feel confident in deciding which children should be recorded on a patient's Carenotes record? Y/N/ Please describe your understanding of this and any concerns you have:
2. Could you tell us about anything that gets in the way of gathering information about patients' child dependants and contact with children?
3. Could you tell us about anything that gets in the way of recording information about patients' child dependants and contact with children on Carenotes?
4. What helps with obtaining and recording this information (including information about D.O.B and names of children)?
5. Do you have suggestions for any improvements to systems, or any resources, that might support the accurate recording of information about patients' contact with children? If yes, please describe…
6. In addition to suggestions above, do you think any of the following changes might be helpful?
    a. Presence of a 'no-dependants' tick box on the Patient Info tab in Carenotes
    b. Presence of a 'contact with un-named / non-dependant children' tick box on the Patient info tab in Carenotes?
    c. A flag on the caseload dashboard to indicate patients where info on dependants is missing?
    d. Incentives or quality targets related to the recording of this information?
    e. Resources to help explain to patients why information is needed and how it will be used?
    f. Anything else, in addition to info above:

Appendix G

Nvivo Coding

NVIVO coding showing themes, with associated number of *files* (number of respondents whose replies included content coded to the theme) and *references* (total number of discrete response elements coded to the theme).



Nodes

Search Project

Name	Files	References
1. Confidence	0	0
Feeling confident	11	11
Lacking confidence	6	6
2. Who to record	0	0
Dependant children	18	18
Non-dependant children	6	7
3. Theraputic relationship	0	0
Client concerns about disclosing information	14	23
Theraputic relationship as facilitator	5	5
Timing and Consent	8	9
4. Obtaining information	0	0
Information from other sources	9	11
Remembering and Prioritising	8	11
5. Barriers to recording information	0	0
IT systems and software	15	24
Time and workload	6	7
6. Making collection of information routine	9	17

Appendix H

Members of Families Working Group in Attendance at Presentation of Findings

- Associate Director of Social Care (Chair)
- Deputy Director of Nursing Mental Health
- Senior Nurse Clinical Lead- CAMHS Community Services-Oxon
- Lead Nurse Safeguarding Children
- Matron/Clinical Lead for Health Visiting
- Lead Nurse Older Adult Mental Health
- Trust Lead Nurse for Safeguarding Children
- Specialist Health Visitor Perinatal Mental Health
- Social Care Professional Lead
- Administrator

Appendix I

Table Notes and Supplementary Information for Service Improvement Project

Table 1 Note

In two cases a child dependant was listed on Carenotes but was not identified by a care coordinator. These comprised one case in which a client was listed as the guardian for a grandchild and one in which there was information on the ‘patient info’ tab indicating two named dependants aged 16 and 17, who were not reported by the care coordinator. One client was deceased at the time the care coordinator completed the audit.

Table 3 Note

Age bands as reported by care coordinator Information on child age was missing for *n* = 1 client in the formally recorded group and *n* = 4 clients in the informally recorded group. Percentages are computed based on the total number of clients and do not add to 100 due to clients with children in more than one age band and clients for whom this information is missing.

Appendix J

Description of the ACT Matrix

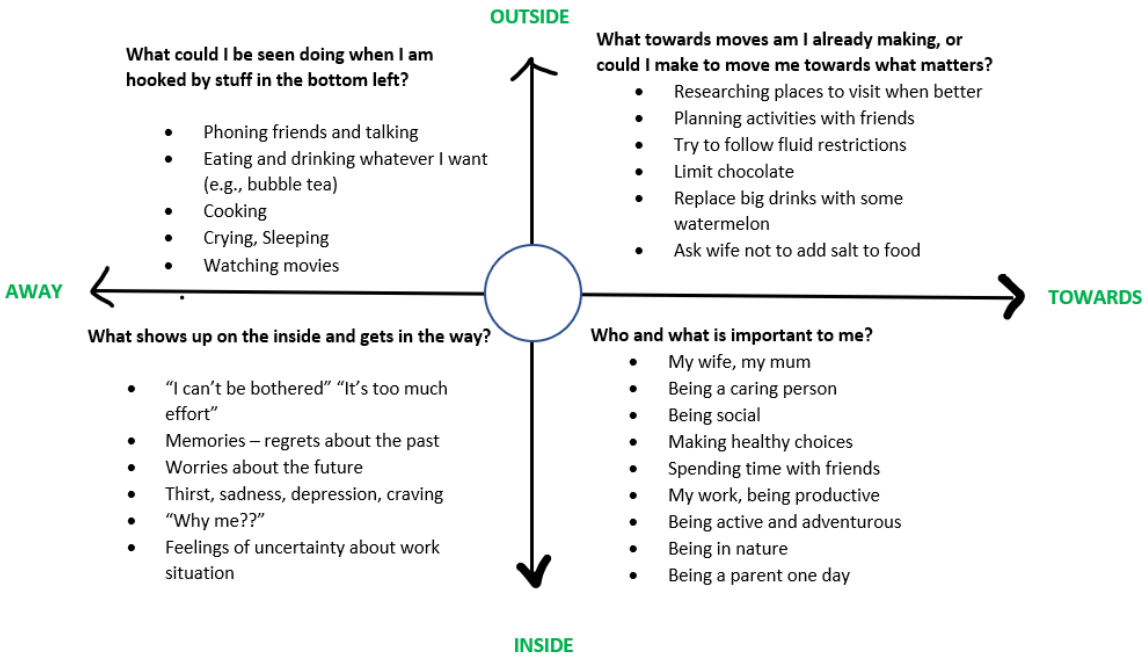
The ACT Matrix is a simple clinical tool used to guide brief interventions. The matrix is structured around four quadrants formed by two intersecting lines. These lines represent two dimensions of experience: the distinction between internal to external experiencing, and the distinction between behaviours directed at 'moving away' from unwanted internal experiences as compared to behaviours directed at 'moving towards' things that matter to a person (see illustrated examples below). Individuals are guided to populate the matrix to represent their important values, current unwanted internal experiences that get in the way of connecting with these goals and values, their actions in response to any unwanted internal experiences, and actions that can move them towards things that matter.

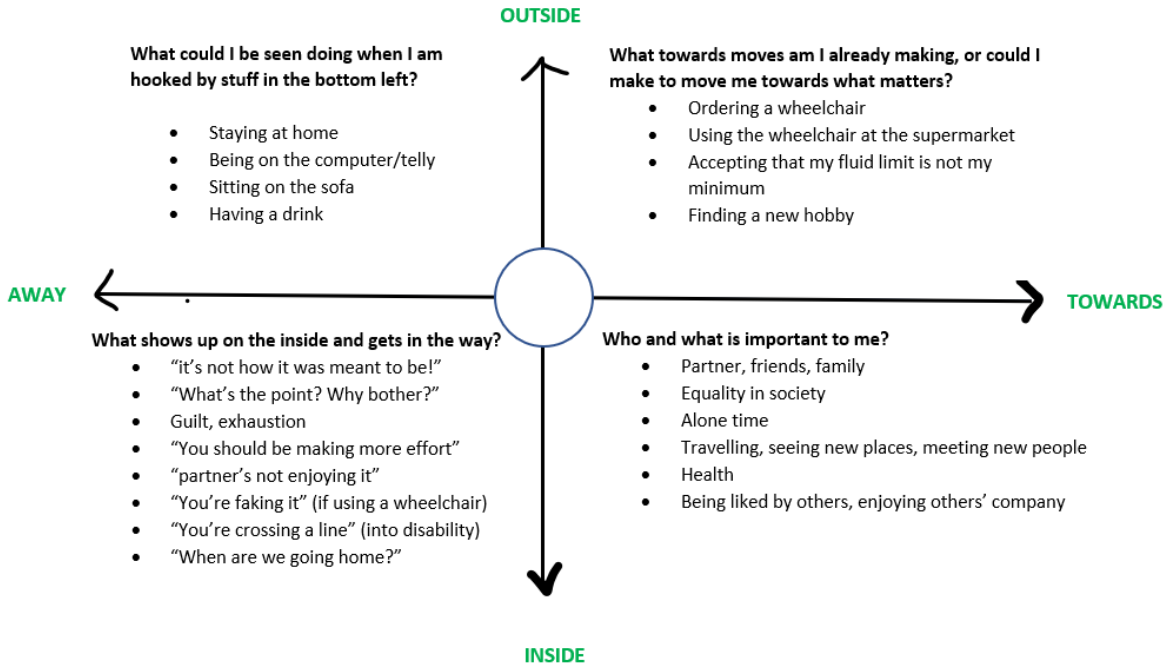
Once constructed, the matrix is initially used as a tool to help people 'sort' their experiences, noticing times when they are making 'towards' or 'away' moves, and becoming aware of the context-dependent 'workability' of behaviours (the extent to which, in a particular context, a particular behaviour is moving the person towards things that they value, both in the short term and the longer term). The matrix captures both values and committed action in the right-hand quadrants. The left-hand quadrants capture aspects of experiential avoidance (as opposed to acceptance) and cognitive fusion (as opposed to defusion). The remaining aspects of psychological flexibility: contact with the present moment, and self-as-context are cultivated through use of the matrix. Encouragement to take an observer / self-as-context perspective is often illustrated on the matrix by a central circle labelled 'me noticing' - highlighting the role of the participant as observer of their internal experiences and external behaviours. Likewise, the vertical axis is used to illustrate the shift from conceptual thinking to in

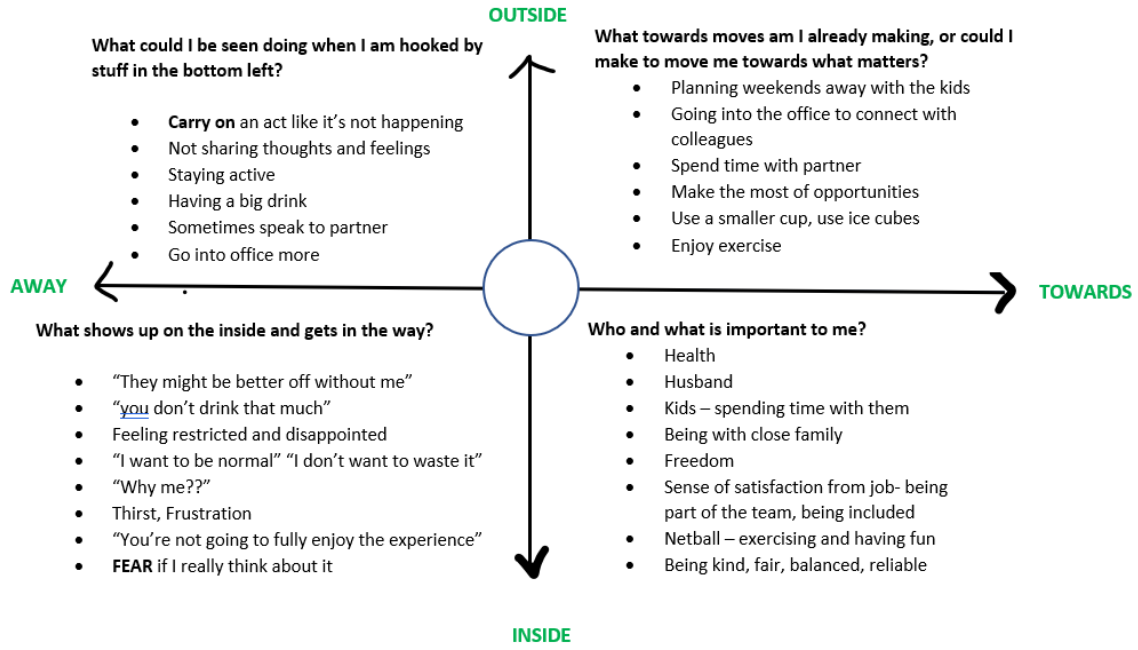
the moment experience. In- and out-of-session activities encourage people to notice times when they are making moves towards goals and values, or away from unwanted internal experiences, and to exercise a greater degree of choice in engaging in workable behaviours, even in the presence of unwanted internal experiences, or when habitual patterns of avoidance behaviour (in ACT referred to as 'stuck loops') might be operating.

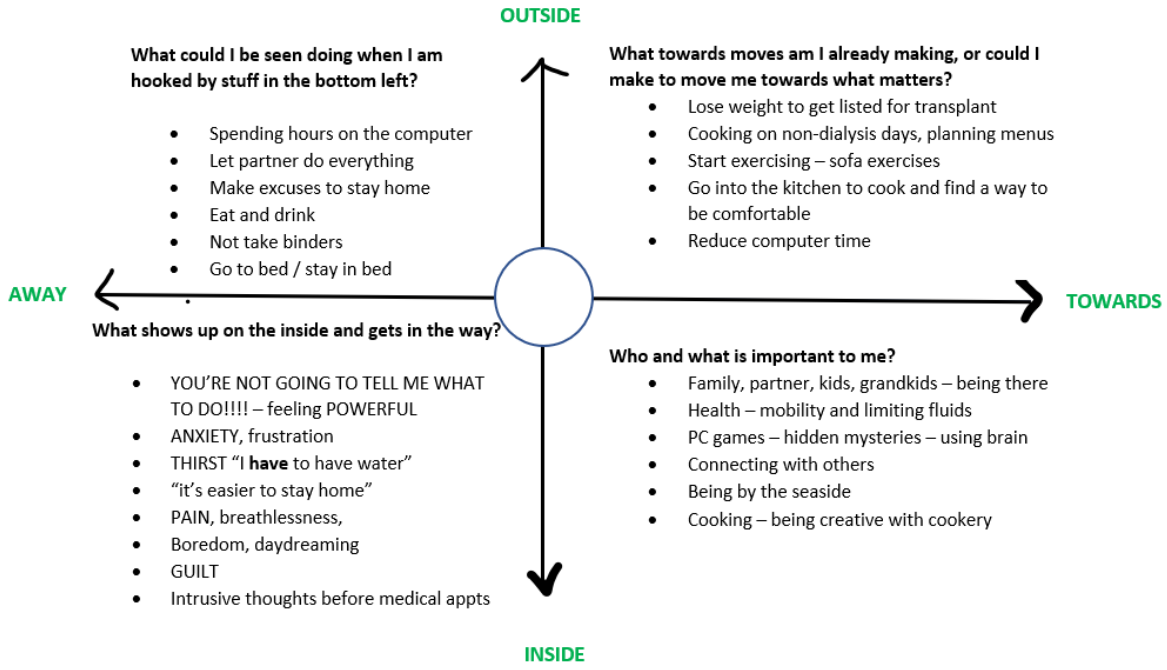
In the current study participants completed a matrix in session 1, which was added to throughout the remaining sessions. Additionally, the same matrix format was sometimes used to map what was happening during a particular event that had been difficult for the participant, to encourage increased insight into the internal and external contextual determinants of non-adherence behaviours. Anonymised examples of participant session 1 matrices and an example of a 'mini-matrix'' mapping a particular incident are shown below:

Anonymised Session 1 matrices completed with study participants:

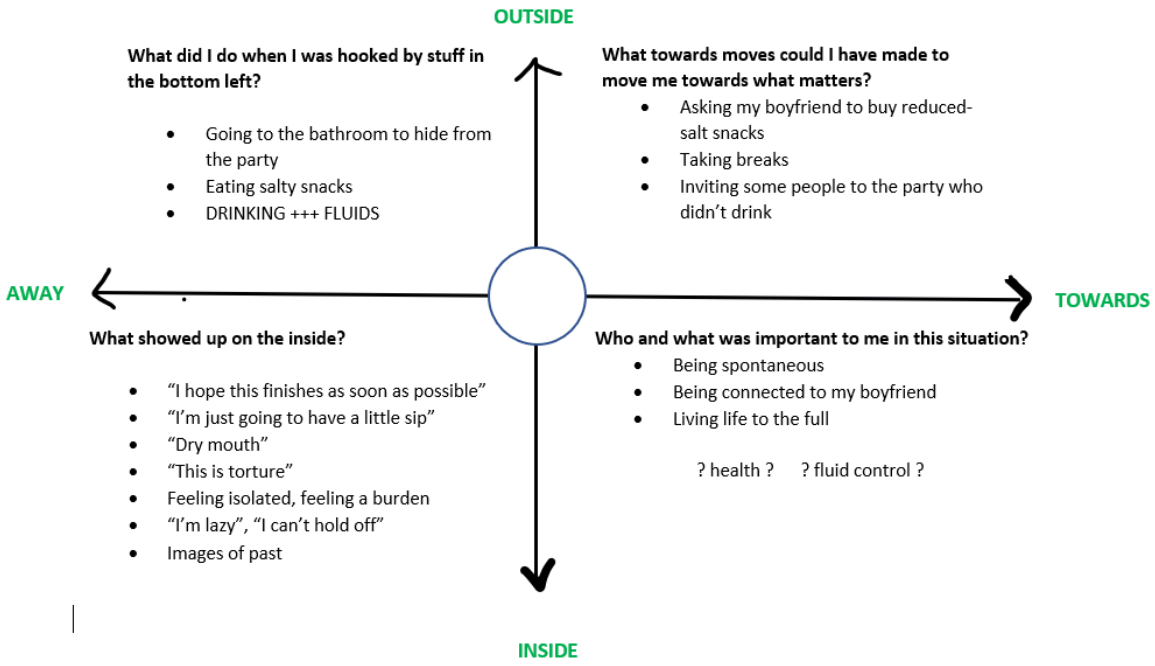



OUTSIDE
What could I be seen doing when I am hooked by stuff in the bottom left?
Staying at home
Being on the computer/telly
Sitting on the sofa
Having a drink
What towards moves am I already making, or could I make to move me towards what matters?
Ordering a wheelchair
Using the wheelchair at the supermarket
Accepting that my fluid limit is not my minimum
Finding a new hobby
AWAY
TOWARDS
What shows up on the inside and gets in the way?
"it's not how it was meant to be!"
"What's the point? Why bother?"
Guilt, exhaustion
"You should be making more effort"
"partner's not enjoying it"
"You're faking it" (if using a wheelchair)
"You're crossing a line" (into disability)
"When are we going home?"
Who and what is important to me?
Partner, friends, family
Equality in society
Alone time
Travelling, seeing new places, meeting new people
Health
Being liked by others, enjoying others' company
INSIDE


OUTSIDE
What could I be seen doing when I am hooked by stuff in the bottom left?
Carry on an act like it's not happening
Not sharing thoughts and feelings
Staying active
Having a big drink
Sometimes speak to partner
Go into office more
What towards moves am I already making, or could I make to move me towards what matters?
Planning weekends away with the kids
Going into the office to connect with colleagues
Spend time with partner
Make the most of opportunities
Use a smaller cup, use ice cubes
Enjoy exercise
AWAY
TOWARDS
What shows up on the inside and gets in the way?
"They might be better off without me"
"you don't drink that much"
Feeling restricted and disappointed
"I want to be normal" "I don't want to waste it"
"Why me??"
Thirst, Frustration
"You're not going to fully enjoy the experience"
FEAR if I really think about it
Who and what is important to me?
Health
Husband
Kids – spending time with them
Being with close family
Freedom
Sense of satisfaction from job- being part of the team, being included
Netball – exercising and having fun
Being kind, fair, balanced, reliable
INSIDE



A 'mini-matrix' mapping an occasion where a participant broke their fluid restriction guidelines:



Appendix K

Questionnaire Administration Schedule and Details of Measures

K1. Table illustrating questionnaire administration schedule for a participant with a six-week baseline

		Phase A (baseline)						Phase B (intervention / follow-up)				
Measure	Set-up	1	2	3	4	5	6	I1	I2	I3	I4	F-Up
Consent	X											
Randomisation	X											
Sociodemographics	X											
ESRD-AQ	X											
DDFNAQ			x		X		x		x		x	x
Valuing Questionnaire		x	x	x	X	x	x	x	x	x	x	x
CORE		x						x			x	x
CompACT		x						x			x	x
Intervention Credibility								x				x
EQ-5D-5L		x						x			x	x

Table Note: ESRD-AQ = End Stage Renal Disease Adherence Questionnaire; DDFNAQ = Diet and Fluid Non-Adherence Questionnaire; CompACT = Comprehensive Assessment of Acceptance and Commitment Therapy Processes. Interdialytic Weight Gain also obtained with consent retrospectively at end of study period for the 12 weeks prior to study week 1, and throughout phase A and phase B.

Appendix K2. Study Measures – Detailed Information

Sociodemographics Information about participant age, gender, ethnicity, co-morbid medical conditions, and previous experience of mental health difficulties were obtained.

End-Stage Renal Disease Adherence Questionnaire (ESRD-AQ; Kim et al., 2010) This 46-item measure assesses attitudes and behaviour related to adherence to medication, diet, fluid restrictions and dialysis sessions. It provided descriptive data to characterise participants. The measure has excellent content validity and test-re-test reliability (Kim et al., 2010).

Outcome Measures

Dialysis Diet and Fluid Intake Non-Adherence Questionnaire (Vlamink et al., 2001) This four-item measure assesses subjective adherence to diet and fluid requirements. It includes the following items: 1) On how many days during the last 14 didn't you follow your diet guidelines? 2) To what degree did you deviate from your diet guidelines? (0-no deviation to 4 – very severe deviation) 3) On how many days during the last 14 didn't you follow your fluid guidelines? 4) To what degree did you deviate from your fluid guidelines? (0-no deviation to 4 – very severe deviation). It was administered bi-weekly for the duration of the study with items relating to fluid adherence were used for analysis. Evaluation in a study of 564 patients across 10

renal units (Vlamink et al.,) indicated a significant positive correlation (r=0.24, p <.0001) between self-report ratings of days of fluid non-adherence and IDWG and a significant positive correlation (r=.25, p <.0001) between severity of deviation from fluid guidelines and IDWG.

Interdialytic weight gain (IDWG). Interdialytic weight gain data from each dialysis session was obtained retrospectively from clinical records for the 12 weeks prior to study week 1 (to establish a baseline prior to monitoring of adherence) and for the duration of the study period up to and including the week of follow-up. Dialysis occurs several times a week, and IDWG is typically recorded each visit. Occasionally dialysis schedules varied (for example due to hospitalisation) and during the study there was a major equipment outage at one of the dialysis units which resulted in participants being sent to dialyse elsewhere. Additionally, sometimes IDWG was not recorded due to technical / recording errors or because of events occurring on dialysis (e.g., access difficulties). Number of dialysis sessions per week also varied between participants and within participants across the study because where participants were experiencing very poor fluid control, they were sometimes offered additional dialysis sessions. For analysis IDWG data was summed across the dialysis sessions occurring within each single study week to provide an index of total weekly IDWG. Where data were not available for a session (casting doubt on the accuracy of the weekly total), the remaining data were still summed, but the uncertainty is illustrated on the graphed data by fading the corresponding bar. Weeks with potentially missing data points were included in analysis of phase overlap and trend, but with caveats around their interpretation. Weeks with a complete absence of data were omitted.

Valuing Questionnaire (Smout, Davis, Burns & Christie, 2014) This 10-item questionnaire assesses a person's ability to live a life in accordance with their values.

It is designed for weekly administration. Each item is rated from 1 (not at all true) to 7 (completely true). The items load on two subscales: Progress towards Values ("*I made progress in the areas of life I care most about*") and Obstacles to Progress ("*Difficult thoughts, feelings or memories got in the way of what I really wanted to do*"). The subscales have good internal consistency (progress: □=.81; obstacles: □=.79) and convergent and discriminant validity.

The Clinical Outcomes Routine Evaluation (CORE) -10 (Barkham et al., 2013) assesses severity of psychological distress, across 10 items, each rated 0-4. The measure differentiates clinical samples from non-clinical populations. It has adequate convergent validity when correlated with other clinical measures, and good internal reliability (Cronbach's alpha > .80) and sensitivity to change (see Connell & Barkham, 2007). A change on the CORE-10 of five or more points corresponds to statistically reliable change (Barkham et al). Scores on the measure are interpreted as follows: 0-5 (healthy); 6-10 (low level); 11-15 (mild); 16-20 (moderate); 21-25 (moderately severe); 26 + (severe).

EQ-5D-5L (EuroQuol Group, 2009). This widely used measure assesses quality of life across five domains: mobility, self-care, usual activities, pain / discomfort, anxiety/depression. Each domain is rated on a five-level scale: no problems, slight problems, moderate problems, severe problems, unable to/extreme problems.

Process Measure

CompACT (Francis, Dawson & Golijani-Moghaddam, 2016); This 23-item questionnaire assesses psychological flexibility. It yields a total score, and three subscale scores: openness to experience, behavioural awareness and valued action. Each item is rated on a scale ranging from 0 (strongly disagree) to 6 (strongly agree).

The measure is reported to have good internal consistency and convergent and discriminant validity (Francis et al.).

Intervention Acceptability

Intervention Credibility and Expectancy (adapted from Devilly & Borkovec, 2000) – This measure was administered after session 1 and at follow-up. Participants were asked six questions to assess their perceptions of the credibility of the intervention: 1) How logical do the sessions offered to you seem? 2) How successful do you think these sessions will be in helping you live well with dialysis/ kidney disease? 3) How confident would you be in recommending these sessions to a friend? 4) How much improvement in your ability to live well with dialysis/kidney disease do you think will occur? 5) How much do you *really feel* that the sessions will help you live well with dialysis/kidney disease? 6) How much improvement in your ability to live well with dialysis/kidney disease do you *really feel* will occur? At the final follow-up participants were asked the same questions, worded in the past tense, and were additionally asked to describe any positives and negatives of the sessions and study process and to give any other feedback.

Note: A final measure, The **Dialysis Symptoms Index** (Weisbord et al., 2004) was also administered. This measure assesses how much a person has been bothered by a range of physical and psychological symptoms associated with dialysis-managed end stage kidney disease, a number of which are likely to be exacerbated by poor adherence. However more than half the participants completed the measure incorrectly at the first assessment point making the data uninterpretable. The measure was dropped from the analysis.

Appendix L

EQ5D5L Supplementary Data

EQ5D-5L (Raw score: high score reflects greater disability) and Health Thermometer Score (high score reflects greater health)

L1. EQ5D5L- Raw Sumscore

	Baseline	Session 1	Session 4	Follow-up
105	15	14	13	12
107	21	21	20	Deceased
108	6	-	-	-
109	13	-	-	-
111	6	7	5	-
201	15	14	15	19
203	8	10	-	-
209	18	17	14	16

On the EQ5D-5L measure participants 105, 111 and 209 showed changes across measurements points in the direction of improved health-related quality of life. Participant 107 showed stable quality of life prior to death. Participant 201 showed stable quality of life during the baseline and intervention phase, with a deterioration at follow-up corresponding to a period of hospitalisation for toe amputation due to gangrene. Remaining participants only provided one or two measurements.

L2. EQ5D5L- Health Thermometer (0 = worst health you can imagine; 100 = best health you can imagine)

ID	Baseline	Session 1	Session 4	Follow-up
105	30	35	45	45
107	5	20	15	
108	100			
109	40			
111	90	80	90	
201	30	25	30	10
203	55	55		
209	50	40	55	45

A.

Appendix M

Explanation of Randomisation Protocol

Randomisation to one of three baseline durations (6, 8, 10 weeks) was conducted by an individual blind to participant characteristics using an Excel algorithm. Randomisation occurred following completion of intake questionnaires by all participants at a single site. Each participant ID was allocated a random number between 0 and 1. These were then ranked, to assign participants to baselines of 6, 8 and 10 weeks. For example, for the cohort of three participants in Swindon the smallest number was allocated to 6 weeks, the second smallest to 8 weeks, and the largest to 10 weeks. For the five participants in the Oxford cohort a dummy participant was added, to ensure near equal and random allocation of participants across baseline durations.

Appendix N

Tau U Statistic

The Tau U statistic is derived from Kendall's Tau and the Mann Whitney U Statistic. It can be used to test the separation between data points in the baseline and intervention phases of a SCED and indicates the degree of non-overlap of the data points in each phase. Tau U can also be used to assess baseline and intervention phase trend. The online calculator (Parker et al., 2011b) allows for evaluation of phase A and phase B trend and calculation of $TauU_{a-b}$ adjusting for phase A trend where required. Brossart et al., (2018) argue that controlling for baseline trend should occur when there is both theoretical and empirical justification. In the current study controlling for phase A trend where a significant trend was identified was important given the long baseline, which involved a period of self-monitoring, and the potential deterioration of participant health over time. Tau U analysis is described as robust to data fluctuations and although it is based on an assumption of lack of autocorrelation, Parker et al., argue that it is robust to varying levels of autocorrelation within the data. The online Tau-U calculator does not adjust for tied values but these were negligible in the current data sets.

Appendix O

Study Documents and Approvals

O1. Patient Information Sheet

Oxford University Hospitals
NHS Foundation Trust

UNIVERSITY OF OXFORD

Oxford Institute of Clinical Psychology Training
Isis Education Centre, Warneford Hospital
Oxford, OX3 7JX

Lead Researcher: Dr Catherine Crane

Supervisors: Dr Louise Johns and Dr Louise Hankinson

IRAS Reference: 290048

Supporting Fluid Restriction and Quality of Life on Dialysis

Invitation to Participate

You are being invited to participate in a research study. To help you decide whether you would like to take part, it is important for you to understand why the research is being done and what it will involve. Please read this information sheet carefully and ask us if anything is not clear or if you would like more information. You may want to discuss the research with others, including your medical team, but it is up to you to decide whether to take part. If you do decide to take part, you will be asked to sign a consent form. Thank you for taking the time to consider this research.

What is the research about?

Around 30,000 people in the UK receive dialysis because they have kidney disease. People on dialysis often have to make big changes to their diet, daily routine, and fluid intake in order to dialyse effectively. Although making these changes helps with dialysis, the restrictions on daily life, including drinking much less than before, can be very hard to stick to and can affect people's quality of life.

This study will examine a brief individually delivered intervention for people who are finding it hard to stick to fluid intake restrictions whilst on dialysis. The intervention, which will consist of four sessions, offered once a week for four weeks. The aim of the intervention is not to judge people's levels of adherence and information about adherence will not be fed back to the renal clinical team. Instead, it aims to help people think differently about managing fluids, and to take steps to live a more meaningful life while on dialysis, whatever that might look like for them.

Patient Information Leaflet

Study Title: Exploring the effect of a brief values-based intervention on adherence to fluid restriction and quality of life in haemodialysis.

Chief Investigator: Catherine Crane
IRAS Project number: 290048
REC Reference number: 21/EM/0025
Version/Date: v2.2. 21.09.21

We intend to offer the intervention to about 12 people and study each person's individual experiences in detail. Everyone who takes part will be asked to complete some questionnaires regularly before and during the programme, as well as one month after finishing it. The research will help us understand whether the sessions are helpful to people, and if so, in what ways. This is a feasibility/pilot study and if its results look promising it could inform a larger study in the future. The study is being conducted in partial fulfilment of a doctoral degree in clinical psychology being completed by Dr Catherine Crane.

Covid-19 Adaptations

Due to the ongoing Covid-19 pandemic this research may be conducted digitally. In this instance all aspects of the study would be completed remotely. Study consent forms and completion of study questionnaires would occur via Qualtircs, a secure online data collection platform, or by post. The intervention itself would be completed through MS Teams, a secure online video conferencing platform. If safe to do so we will offer participants the choice of either completing the intervention digitally or in person.

Why have I been invited to take part?

You have been invited to take part in this study because your medical team have been supporting you in managing fluids and think that you might be interested in the programme. We are looking for people to take part who:

- Are currently receiving haemodialysis for end-stage kidney disease
- Are aged 18 or over
- Are interested in and could benefit from support in managing their fluid intake
- Have an email address and are willing and able to participate in a psychological intervention delivered via a digital platform (e.g. through a smart phone, tablet or computer) rather than face-to-face, if required
-

What will happen to me if I take part?

If you are interested in taking part, please tell a member of the clinical team or contact the research team directly using the contact details at the end of this information sheet. You will then be contacted by Catherine Crane to discuss the study in more detail, check that it is likely to be a good fit for you, and to answer any questions you have. If you remain interested and are eligible you would be asked to sign a consent form and complete some questionnaires to tell us more about your experiences. We estimate that these questionnaires would take no more than 30 minutes to complete. All questionnaires can be completed either online or by post if preferred.

Once 12 people have consented to participate, or on a specific date no more than 6-8 weeks after expressing an interest, you would be assigned to a start date for your sessions. Participants will be randomly assigned to one of three intervention start dates by a computer, approximately 6, 8 or 10 weeks after randomisation.

Once people have been assigned to their start dates, everyone will complete some more questionnaires – the first week these will also take around 30 minutes, but in subsequent weeks these should take only 5 to 10 minutes maximum. In the week of the first and last session of the intervention a few additional questionnaires will be added,

increasing the time required to complete them to around half an hour. Four weeks after completing the sessions participants will be asked to complete a final questionnaire pack, again of about half an hour, to let us know how they are doing and to give feedback on their experiences.
Participants will receive a £10 gift voucher on completion of the study, as a small token of appreciation for their participation.

What will the sessions involve?
There will be two weekly face-to-face or video sessions of up to an hour duration, followed by up to two follow-up sessions of around 45 minutes duration. Each session will be conducted 1-to-1 with Catherine, the psychologist in training running the project. The intervention sessions are based on a psychological approach called Acceptance and Commitment Therapy (ACT), which has been shown to help people living with a chronic health condition. In the sessions you will invited to take a step back, and look at things from a different perspective, using a simple paper and pencil exercise that we will work on together in the sessions. This allows you to start to see what is working for you, and what isn't, and with support, make changes where you can see this might be helpful. Whilst the focus will be on supporting you to manage your fluids and overall health, we may also explore some other areas of your life during this process. This is quite an active therapy in that it invites you to put things into practice in between sessions. This may be practising a brief exercise we have shared in the session or taking steps towards a goal you have chosen for yourself.

As with the research as a whole, during sessions **you would only be asked to share what feels comfortable to you**, and **you can choose to discontinue at any time**, and without giving a reason.

What are the risks or disadvantages of taking part?
Taking part and completing the study questionnaires and sessions will involve thinking about your life and some of the challenges of being on dialysis, including difficulties or frustrations you might experience managing fluids. Some people may find thinking about these topics upsetting. You will only ever be asked to share as much as feels comfortable to you, and you do not have to answer any questions you do not wish to, so we do not anticipate that taking part will cause more discomfort than you might encounter in daily life when thinking about these topics. However, it is important to consider whether you would feel comfortable speaking about these issues with a psychologist before deciding to take part.

What are the possible benefits of taking part?
As this is a new intervention, we cannot guarantee that you will experience any direct benefit from taking part. We hope that the sessions we are offering will provide a useful opportunity for people to reflect on things that are important to them and explore alternative ways of thinking about the challenges of managing dialysis. Participants will also be helping to further research into support for those on dialysis and some find this an interesting thing to be involved in.

Will my General Practitioner/family doctor (GP) be informed of my participation?
We will inform your family doctor about your participation in the study and will also inform the Renal Medicine Team that you are taking part in the study.

Will my participation be kept confidential?
Your participation and the research data you provide will be kept strictly confidential. Only members of the research team undertaking the study and those providing your medical care will be aware that you are taking part, and only the research team will have access to your study data. We will send a brief letter and a copy of the information sheet and your consent form to your GP and the renal medical team who care for you, but none of the questionnaire data you provide will be shared with your medical team. The only exception to these conditions is that we have an ethical duty to share clinically relevant information with those who provide your medical carewhen we become aware of it. In this situation, wherever possible, we would discuss this with you first. Likewise, we are obliged to monitor the occurrence of any serious and medically significant events experienced by research participants, whether or not they are related to study procedures. We will ask your medical team to let us know if you experience such an event, in order to ensure that the research is safe. The only other exception is that individuals from regulatory authorities, who monitor and audit research to ensure that it is being carried out correctly, may request access to your data. These people would also have a duty to keep your information strictly confidential.

Do I have to take part?
No, as discussed above, there is no obligation to take part. If you decide that you would like to take part you will be asked to complete a consent form, putting your initials in the box beside each statement to indicate that you agree, and then signing and dating the sheet. The researcher completing the consent process with you will also sign and date the form. You will be provided with a copy of the consent form, one copy will be placed in your medical records, and one copy will be retained by the research team.

What if I change my mind?

You can stop being part of a research study at any time, without giving a reason, but the research team will keep the research data about you that they already have. You can find out what would happen with your data before you agree to take part in a study. Once the study is complete (i.e. the date of the end point of the study has passed) we will anonymise study data and remove the participant ID codes.

How will we use information about you?
We will need to use information from you and from your medical records for this research project.

This information will include:

- your name
- your contact details
- your gender and ethnicity

- some details of previous medical treatment you have received.

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. Although we may use direct quotes in study publications we will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to catherine.crane@hmc.ox.ac.uk
- by ringing us on (01865) 902401

General Data Protection Regulations

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the sponsor for this study, based in the United Kingdom, is the data controller and is responsible for looking after your information and using it properly.

With your consent, we will be using information from your medical records, in order to undertake this study and will use the minimum personally-identifiable information possible. We will keep identifiable information about you for

no more than six months after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for ten years after the end of the study.

In the event that this study is conducted digitally due to the ongoing COVID-19 pandemic some data may be collected through Qualtrics, an online questionnaire platform. The University of Oxford Information Security Team has approved the use of Qualtrics for the collection of all types of personal data including confidential data.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting Catherine.crane@hmc.ox.ac.uk

Video and Audio Recording

Video or audio recordings of intervention sessions will be taken, with consent, for the purposes of clinical supervision and to rate the delivery of the sessions to assess their quality. Clinical supervision is part of routine practice for psychologists and is conducted to ensure that psychological interventions are being delivered safely. Dr Louise Hankinson, investigator, will provide clinical supervision for Dr Catherine Crane. Recordings of sessions will be stored securely on an encrypted device. Recordings may also be formally rated for fidelity (how closely the intervention delivered by a psychologist in a session matches what was intended). Fidelity ratings may be included on reports on the study. Recordings will only be viewed by the study researchers: Dr Catherine Crane, Dr Louise Hankinson and Dr Louise Johns and once ratings of intervention quality have been made these recordings will be destroyed (e.g., before the study end).

Who is conducting the research?

The research is being undertaken as part of a doctoral qualification in clinical psychology, being completed by the lead researcher, Dr Catherine Crane, who is a postgraduate student at the University of Oxford. The research is supervised by Dr Louise Hankinson, Clinical Psychologist in Renal and Transplant Medicine, Oxford University Hospitals NHS Trust, and Dr Louise Johns, Senior Research Tutor, Oxford Institute of Clinical Psychology Training.

What will happen at the end of the study?

The results of this study will be written up as part of the doctoral thesis of Dr Catherine Crane. The results may also be presented at academic conferences or meetings, or written up for publication in a peer-reviewed academic journal. We will provide a summary of the project findings to participants who wish to receive it. Participants will not be identified in any reports or publications arising from this project.

What if something goes wrong?
If you have any concerns about any aspect of this study, you should speak to the researchers who will do their best to answer your questions. They can be contacted at the following addresses: Catherine.crane@hmc.ox.ac.uk; Louise.Hankinson@ouh.nhs.uk and Louise.johns@hmc.ox.ac.uk.

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. You can find your nearest PALS office on the NHS Choices website (https://www.nhs.uk/Service-Search/Patient-advice-and-liaison-services- (PALS)/LocationSearch/363). You can also ask your GP surgery, hospital or phone NHS 11 for details of your nearest PALS. The PALS team covering Oxfordshire, Buckinghamshire, Swindon, Wilshire, Bath and North East Somerset can be contacted on 0800 3287971 or via email to PALS@oxfordheath.nhs.uk.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Catherine Crane (Catherine.crane@hmc.ox.ac.uk) or Louise Johns (tel: 07880 458628) or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, email ctrg@admin.ox.ac.uk.

How have patients and the public been involved in this study?
We have consulted with people who have been treated with dialysis about the design of this study as well as clinicians who provide treatment and support. We have obtained feedback on study documents and we have taken into account service users' views about how and where we should collect information as part of this study.

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by Leicester South Research Ethics Committee

I am interested in taking part!

Thank you for taking the time to read this information sheet. If you would like further information or are interested in taking part, please tell the researcher, **Catherine Crane**:

Email: Catherine.crane@hmc.ox.ac.uk or Call us on: **07880 458628**

Patient Information Leaflet

Study Title: Exploring the effect of a brief values-based intervention on adherence to fluid restriction and quality of life in haemodialysis.

Chief Investigator: Catherine Crane
IRAS Project number: 290048
REC Reference number: 21/EM/0025
Version/Date: v2.2. 21.09.21

Appendix O2. Study Consent Form

Oxford University Hospitals
NHS Foundation Trust

UNIVERSITY OF OXFORD

Oxford Institute of Clinical Psychology Training
Isis Education Centre, Warneford Hospital
Oxford, OX3 7JX

Supporting Fluid Restriction and Quality of Life on Dialysis **Please initial box**

1. I confirm that I have read the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from regulatory authorities or from the Sponsor and from the NHS Trust where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
4. I understand that the information I provide as part of this study will be kept confidential with the exception that the researchers will pass on clinically relevant information to my medical team to keep me safe. ☐
5. I agree that my involvement in the study can be recorded in my hospital records and that, if necessary, information about me can be exchanged between my renal medical team and the research team. This includes the research team gathering data about inter-dialytic weight gain for the purposes of the research study from my medical records and the renal clinical team informing the research team if I experience a medically serious event. ☐
6. I agree to the study sessions being audio / video recorded for clinical supervision and quality rating ☐
7. I understand that the research team will hold my personal details (e.g. name, contact details) for the duration of the study, in order to contact me for research purposes, and that following completion of the study, this information will be destroyed. ☐

Consent Form

Study Title: Exploring the effect of a brief values-based intervention on adherence to fluid restriction and quality of life in haemodialysis.

Chief Investigator: Catherine Crane
IRAS Project number: 290048
REC Reference number: 21/EM/0025
Version/Date: v2.2. 21.09.21

8. I agree to take part in the above study. ☐

9. I understand that my research data are going to be shared in an anonymised form with other researchers in the future. ☐

Name of Participant	Date	Signature

Name of Person taking consent	Date	Signature

Consent Form

Study Title: Exploring the effect of a brief values-based intervention on adherence to fluid restriction and quality of life in haemodialysis.

Chief Investigator: Catherine Crane
IRAS Project number: 290048
REC Reference number: 21/EM/0025
Version/Date: v2.2. 21.09.21

Appendix O3 NRES Approval Letter

Health Research Authority

East Midlands - Leicester South Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Telephone: 0207 1048310

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

23 February 2021

Dr Catherine Crane
Trainee Clinical Psychologist
Oxford Health NHS Foundation Trust
Isis Education Centre
Warneford Hospital
ox3 7jx

Dear Dr Crane

Study title:	**Exploring the Effects of a Brief Values-Based Intervention on Adherence to Fluid Restriction Recommendations and Quality of Life in Haemodialysis Patients**
REC reference:	**21/EM/0025**
Protocol number:	**as above**
IRAS project ID:	**290048**

Thank you for your letter of 13February submitted on 22 February 2021, responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above

research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral:
https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

If you have not already included registration details in your IRAS application form, you should notify the REC of the registration details as soon as possible.

Further guidance on registration is available at:
https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit:
https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at:
https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at
https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites listed in the application subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of materials calling attention of potential participants to the research [Introductory flyer]	1.0	21 November 1920
GP/consultant information sheets or letters [Clinician letter]	1	21 November 1920
Interview schedules or topic guides for participants [Summary of Intervention]		12 January 2021
IRAS Application Form [IRAS_Form_09012021]		09 January 2021
IRAS Application Form XML file [IRAS_Form_09012021]		09 January 2021
IRAS Checklist XML [Checklist_22022021]		22 February 2021
Letter from sponsor [Sponsorship letter]		04 January 2021
Letters of invitation to participant [Letter of invitation to participants]	1.1 (changes tracked)	13 February 2021
Letters of invitation to participant [Letter of invitation to participants]	1.1 (changes accepted)	13 February 2021
Non-validated questionnaire [Sociodemographic Questionnaire]		12 January 2021
Non-validated questionnaire [Credibility and Expectancy Questionnaire]		12 January 2021
Other [Responses to Review]	1	13 February 2021
Participant consent form [Consent Form (changes tracked)]	1.1 (changes tracked)	13 February 2021
Participant consent form [Consent Form (changes accepted)]	1.1 (changes accepted)	13 February 2021
Participant information sheet (PIS) [Patient information sheet]	1.1 (changes tracked)	13 February 2021
Participant information sheet (PIS) [Patient Information Sheet Changes Accepted]	1.1 (changes accepted)	13 February 2021
Research protocol or project proposal [Study Protocol]	1	28 December 2020
Summary CV for Chief Investigator (CI) [Chief investigator CV]		21 November 1920
Summary CV for supervisor (student research) [Supervisor CV - Louise Johns] Summary CV for supervisor (student research) [Supervisor CV -		21 November 1920 05 January 2021

Louise Hankinson]		
Validated questionnaire [CompACT]		
Validated questionnaire [CORE-10]		
Validated questionnaire [Dialysis Symptom Index]		
Validated questionnaire [Diet and fluid intake non-adherence questionnaire]		
Validated questionnaire [End Stage Renal Disease Questionnaire]		
Validated questionnaire [EQ5D5L]		
Validated questionnaire [Valuing Questionnaire]		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:
https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 290048 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

Mrs Jeanne-Anna Charly
Chair

Email:leicestersouth.rec@hra.nhs.uk

Enclosures: "After ethical review – guidance for researchers" *[SL-AR2]*

Copy to: Ms Brandy Coote, Oxford Health NHS Foundation Trust

Appendix O4. HRA Approval Letter

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Dr Catherine Crane
Trainee Clinical Psychologist
Oxford Health NHS Foundation Trust
Isis Education Centre
Warneford Hospital
ox3 7jx

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

23 February 2021

Dear Dr Crane

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Exploring the Effects of a Brief Values-Based Intervention on Adherence to Fluid Restriction Recommendations and Quality of Life in Haemodialysis Patients**
IRAS project ID:	**290048**
Protocol number:	**as above**
REC reference:	**21/EM/0025**
Sponsor	**Oxford Health NHS Foundation Trust**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report

(including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **290048**. Please quote this on all correspondence.

Yours sincerely,



Helen Poole
Approvals Specialist
Email:approvals@hra.nhs.uk

Copy to: *Ms Brandy Coote, Oxford Health NHS Foundation Trust*

Appendix O5. Sponsorship Transfer Confirmation Letter

RESEARCH SERVICES
Clinical Trials and Research Governance
Joint Research Office
Boundary Brook House
Churchill Drive
Headington, Oxford
OXON
OX3 7GB

To whom it may concern

Date: 19/05/2021

Dear Sir/Madam,

Title: Supporting fluid restriction and quality of life on dialysis

PID: 15290

Protocol Date/Version: 6/05/21, Version 2.1

The above study has been designed by Catherine Crane and colleagues previously at Oxford Health NHS Foundation Trust and funded by departmental funds. I confirm that the University will accept transfer of the role of Research Sponsor of this Study from the date of this letter and will comply with the requirements of the UK Policy Framework for Health and Social Care Research 2017.

Insurance-provided indemnity arrangements are in place for the project:

Newline Underwriting Management Ltd., at Lloyd's of London.

Sponsorship is confirmed subject to the condition that the following are sent to Clinical Trials and Research Governance for review prior to submission to the Research Ethics Committee. Failure to do so may compromise insurance cover for the project.

- Any minor or substantial amendments
- Any extension to the study end date
- Addition of any new research site or patient identification centre

In addition, annual progress reports, the end of study notification and final report must be copied to Clinical Trials and Research Governance.

Lastly, where they exist, University Core SOPs must be followed by default for all clinical research sponsored by the University. Further information can be found here: https://researchsupport.admin.ox.ac.uk/ctrg/resources

Any communications relating to Research Sponsorship should be directed to the undersigned.

Yours faithfully

Nigel Wellman
Clinical Trials and Research Governance

Tel: +44 (0)1865 616480 :Email: https://researchsupport.admin.ox.ac.uk/contacts/ctrg

Appendix O6. Oxford University Hospitals Management Approval

SOP GE-04

Oxford University Hospitals
NHS Foundation Trust

Assignee:DF/RP/LoA Ref: 2012

Catherine Crane
Oxford Health NHS Foundation Trust,
The White
Building, Littlemore MHC,
Sandford Road,
Oxford OX4 4XN

OUH Research & Development
Joint Research Office
Second Floor, OUH Cowley
Unipart House Business Centre
Garsington Road
Oxford
OX4 2PG
Jo.Franklin@ouh.nhs.uk
Tel: 01865 572231

Date: 15/02/2022

Dear Ms Crane

Letter of access for research:
Study Title: Supporting fluid restriction and quality of life on dialysis
PID: 15290

As an existing NHS employee you do not require an additional honorary research contract with this NHS organisation. We are satisfied that the research activities that you will undertake in this NHS organisation are commensurate with the activities you undertake for your employer. Your employer is fully responsible for ensuring such checks as are necessary have been carried out. Your employer has confirmed in writing to this NHS organisation that the necessary pre-engagement check are in place in accordance with the role you plan to carry out in this organisation. This letter confirms your right of access to conduct research through **Oxford University Hospitals NHS Foundation Trust** for the purpose and on the terms and conditions set out below. This right of access commences on **15.02.2022** and ends on **31.03.2023** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

You are considered to be a legal visitor to **Oxford University Hospitals NHS Foundation Trust** premises. You are not entitled to any form of payment or access to other benefits provided by this organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through **Oxford University Hospitals NHS Foundation Trust** you will remain accountable to your employer **Oxford Health** but you are required to follow the reasonable instructions of your nominated manager **Louise Hankinson** in this NHS organisation or those given on her/his behalf in relation to the terms of this right of access.

Oxford University Hospitals
NHS Foundation Trust

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with **Oxford University Hospitals NHS Foundation Trust** policies and procedures, which are available to you upon request, and the UK Policy Framework for Health and Social Care Research (Nov 2017)
You are required to co-operate with **Oxford University Hospitals NHS Foundation Trust** in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on **Oxford University Hospitals NHS Foundation Trust** premises. Although you are not a contract holder, you must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of a contract holder and you must act appropriately, responsibly and professionally at all times.

If you have a physical or mental health condition or disability which may affect your research role and which might require special adjustments to your role, if you have not already done so, you must notify your employer and the Trust (OUHTMA@ouh.nhs.uk) prior to commencing your research role at the Trust.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

Oxford University Hospitals NHS Foundation Trust will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. You must not undertake regulated activity if you are barred from such work. If you are barred from working with adults or children this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity and you MUST stop undertaking any regulated activity immediately.

Oxford University Hospitals
NHS Foundation Trust

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

If your circumstances change in relation to your health, criminal record, professional registration or suitability to work with adults or children, or any other aspect that may impact on your suitability to conduct research, or your role in research changes, you must inform the NHS organisation that employs you through its normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely

J Franklin

Mrs Jo Franklin
Senior Research Support Manger

cc: Sandra.smith@oxfordhealth.nhs.uk

PID15290 Amendment Capacity and Capability

FD

Franklin, Debbie (RTH) OUH <Debbie.Franklin@ouh.nhs.uk>
To Hankinson, Louise (RTH) OUH
Cc 'oxfordjro@mail.studyline.uk.com'; Catherine Crane

Reply | Reply All | Forward

Tue 22/02/2022 11:24

Our reference: PID15290-A003-SI001

Dear Louise Hankinson,

Re: Supporting fluid restriction and quality of life on dialysis

IRAS No: 290048
Amendment Ref: PID15290-A003
Title: 21.02.2022 Minor Amendment 1
Site Summary: The study protocol section detailing method of randomisation has been updated. The randomisation software named in the previous version of the protocol cannot be used due to unanticipated costs associated with its use. As a result, an alternative randomisation procedure will be employed. This is described in the protocol v2.2.1 20.02.21 (changes tracked). Additionally, the administration of the Dialysis Diet and Fluid Intake Non-Adherence Questionnaire (a brief 4-item measure) has been moved from odd study weeks to even study weeks during the baseline and intervention phases of the study (also shown in Table 1 of Protocol V2.2.1 (changes tracked). This questionnaire asks participants about adherence retrospectively so moving its administration from odd to even weeks improves its ability to capture in-study adherence behaviour. However this will not increase participant burden, and in fact will minimally reduce burden for participants with longer baseline periods.

Amendment Capacity and Capability

Thank you for submitting your amendment to Oxford University Hospitals NHS Foundation Trust Research and Development department.

This amendment has been given the appropriate level of consideration by the R&D team, and on behalf of the Head of Research Governance I can confirm continued capacity & capability for the study.

As part of this amendment, we note the documents approved as listed:

Trust Management Approval and Indemnity is dependent upon completion of satisfactory compliance with Trust policies and all regulatory requirements for the conduct of clinical research.

Recruitment of participants to this study needs to be reported via the Siteline system. Contact your department Siteline administrator to request a userid. If you are unsure of your local administrator and for any queries, email support@siteline.uk.com or call 01865 221916.

Further recruitment updates will automatically be uploaded to Studyline (the R&D database) from Siteline. If you find that you are struggling to meet your targets, or become aware that you definitely won't achieve them, please also contact ResearchRecruitment@ouh.nhs.uk and we will provide support where we can.

Yours sincerely,

Debbie Franklin.

On behalf of the Head of Research Governance

The R&D teams are currently working from home until further notice.
Therefore, please contact the R&D teams by email in the first instance (rather than by phone).
Many thanks for your understanding at this time.

Appendix P

Table 5. Tau-U Analysis of Phase A (Baseline) and Phase B (Intervention) Trend and Phase A and Phase B Contrast

ID	Contrast	Tau U Phase A (SD, Z)	*P*	Tau U Phase B (SD, Z)	*P*	Tau U Phase A vs Phase B (SD, Z)	*p*
105	**Days non-adherent**	1 (1.9, 1.97)	0.11	-0.33 (1.91, -0.55)	0.60	-.056 (4.58,-1.09)	0.28
	Degree of Deviation	-.067 (-1.91, -1.0)	0.30	-.067 (-1.91, -1.0)	0.30	-.033 (4.58, -0.65)	0.51
	IDWG	0.12 (24.40, 0.72)	0.47	0.36 (8.08, 1.24)	0.22	0.39 (36.00, 1.56)	0.12
	Progress	0.4 (5.32, 1.13)	0.26	0.3 (4.08, 0.73)	0.46	0.133 (10.95, 0.37)	0.72
	Obstacles	-.267 (5.33, -0.75)	0.45	0.3 (4.08, 0.73)	0.46	-0.33 (10.95, -.91)	0.36
107	**Days non-adherent**	0 (4.08, 0)	1.0	-1 (1, -1)	0.32	0.8 (5.16, 1.55)	0.12

	Degree of Deviation	0 (4.08, 0)	1.0	-1 (1, 0)	1	0 (5.16, 0)	1
	IDWG	*0.36* *(35.46, -2.20)*	*0.03*	*-0.33* *(2.94, -0.68)*	*0.50*	*0.64* *28.14, 1.99)*	***0.047***
	Progress	-0.24 (11.18, -0.98)	0.33	0 (2.94, 0)	1.0	0.025 (14.14, -0.64)	0.52
	Obstacles	0.42 (11.18, 1.70)	0.09	-0.83 (2.94, -1.70)	0.09	0.175 (14.14, 0.49)	0.62
109	***IDWG***	*-0.06* *(30.82, -0.39)*	*0.70*	*0.81* *(6.66, 2.55)*	*0.01*	*-0.67* *(36.15, -2.60)*	***0.009***
111	**Progress**	0.2 (11.18, 0.81)	0.4	0.5 (2.94, 1.02)	0.31	-0.45 (14.14, -1.27)	0.2
	Obstacles	*-.036* *(11.18, -1.43)*	*0.15*	*-0.17* *(2.94, -0.34)*	*0.73*	*-1* *(14.14, -2.82)*	***0.005[a]***
	Days non-adherent	*0.9* *(4.08, 2.20)*	*0.03**	*1* *(1, 1.00)*	*0.32*	*-1.4* *(5.16, -2.71)*	***0.007 [a] ****
	Degree of Deviation	-0.6 (4.08, -1.47)	0.14	0 (1, 0)	1.0	-1 (5.16, -1.94)	**0.052**
	IDWG	*-0.14* *(33.11, -0.91)*	*0.37*	*0.5* *(8.08, 1.73)*	*0.08*	*-0.67* *(40.98, -2.73)*	***0.006***

201	***Progress***	*-0.79 (8.08, -2.72)*	*0.007*	*0.1 (4.08, 0.24)*	*0.8*	*0.73 (13.66, 2.12)*	***0.03****
	Obstacles	0.39 (8.08, 1.36)	0.17	-0.4 (-0.44, 0.98)	0.3	0.125 (13.66, 0.37)	0.71
	Days non-adherent	-0.17 (2.94, -0.34)	0.73	0 (1.91, 0)	1.0	0.25 (5.66, 0.53)	0.60
	Degree of Deviation	0 (2.94, 0)	1	0 (1.91, 0)	1.0	0 (5.65, 0)	1.0
	IDWG	0.01 (30.82, 0.03)	0.97	0.38 (6.66, 1.20)	0.23	0.34 (36.15, 1.33)	0.18
203	**Progress**	-0.13 (SD = 5.32, Z = -0.38)	0.7	0 (SD = 1.91, Z = 0)	1.0	-0.06 (SD = 7.75, Z = -0.13)	0.90
	Obstacles	-0.67 (SD = 5.32, Z = -1.88)	0.06	0.67 (SD = 1.91, Z = 1.04)	0.30	-0.78 (SD = 7.75, Z = -1.80)	0.07
	Days Non-adherence	-0.33 (SD = 1.91, Z = -0.52)	0.60	Only one intervention measurement point			
	Deviation	0 (SD = 1.91, Z = 0)	1.0	Only one intervention measurement point			
	IDWG	-0.36 (SD = 35.46, Z = -2.37)	0.02	0.32 (SD = 8.08, Z = 1.11)	0.27	-0.36 (SD = 35.46, Z = -2.37)	**0.02***

209	**Progress**	0.4 (SD = 5.32, Z = 1.13)	0.26	0.6 (SD = 4.08, Z 1.47)	0.14	0.77 (SD = 10.95, Z = 2.10)	**0.04**
	Obstacles	0.2 (5.32, Z = 1.47)	0.14	-0.5 (4.08, Z =-1.22)	0.22	-0.13 (SD = 10.95, Z = -0.37)	0.72
	Days non-adherent	0 (SD = 1.91, Z = 0)	1.0	-0.67 (SD = 1,91, Z = -1.04)	0.29	-0.67 (SD = 4.58, Z =-1.31)	0.19
	Degree of Deviation	1 (SD = 1.91, Z = 1.57)	0.11	0.67 (SD = 1.91, Z = 1.04)	0.30	-0.22 (SD = 4.58, Z = -0.44)	0.66
	IDWG	-0.10 (SD = 26.40, Z = -0.57)	0.57	-0.18 (SD = 8.08, Z = -0.62)	0.54	-0.38 (SD = 36, Z = 1.33)	0.18

* Controlling for baseline trend; [a] Based on only two intervention measurement points

Appendix Q

Author Guidelines for proposed Journals - Redacted due to Copyright