

## **The Person-Based Approach in Practice: Methods for Intervention Development**

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### *Abstract*

The “Person-based Approach” to intervention development uses qualitative and mixed methods to ensure that the process of intervention development takes into account the beliefs, attitudes, needs and context of the particular user group the intervention is designed to target. Qualitative research is used in several ways: in the form of a background literature search, in collecting qualitative data from target users to assess their specific needs, and in “think-aloud” interviews that gather detailed feedback on each aspect of the intervention from target users. This allows iterative development of the intervention to be based directly on the input of the target users. We provide an overview of best practices when using the Person-based Approach, together with examples of aspects of intervention development from previously-developed interventions. Including feedback from target users from the beginning of intervention development results in interventions that are more likely to make a difference in practice.

Intervention development is a complex process. It is important to get right, as the design of an intervention can make or break the intervention's success. Developing interventions for specific groups, including patient groups, can be particularly challenging – it can be difficult to know what key behavioural issues, needs and challenges will affect how a particular group (the “target users”) will engage with the intervention.

One traditional way to manage this is to use patient and public involvement (PPI) (Brett et al., 2014). Often this involves the intervention being developed by the research team, with PPI representatives giving feedback on draft intervention materials. Occasionally, PPI representatives may co-design the intervention with the research team to ensure that the patient perspective is incorporated throughout the intervention's development. The inclusion of more patient and public involvement is extremely valuable and can only benefit the final intervention. However, traditional PPI may include only a small number of patients, these patients may be particularly motivated to take part and/or educated about the topic of research. Therefore, it may additionally be beneficial to include more extensive patient or target user feedback during an intervention's development process that take into account the views of a larger and potentially more diverse group of users. This is particularly important for behavioural interventions, such as websites that prompt users to set fitness goals or booklets that support self-management of a chronic condition, because they rely on the user to engage with the intervention (e.g., set the goals or read the booklet). Target users are more likely to use an intervention that makes sense to them and that they find to be engaging.

The Person-Based Approach (PBA) to intervention development (Yardley, Morrison, Bradbury, & Muller, 2015) involves the intervention's target users right from the beginning of development using in-depth qualitative research to inform decisions about the design and content of the intervention. This is to ensure that the final intervention is acceptable to patients and feasible to use, and to enhance its effectiveness (Yardley, Ainsworth, Arden-Close, & Muller, 2015). The PBA differs from other qualitative approaches to intervention development in that it focusses on engaging a wide

range of target users in an iterative manner at every stage of intervention development. It includes the use of guiding principles (described below) to ensure the final intervention has a coherent focus. Although usability of the intervention is a concern, the PBA goes beyond traditional usability testing to explore target users' engagement with the behavioural goals of the intervention to ensure it works to change behaviour.

#### *Using the Person-based Approach*

The PBA relies heavily on qualitative research (Yardley, Ainsworth, et al., 2015) to gain an in-depth understanding of the behavioural issues, needs, and challenges of the target users. The PBA can be used at all stages of intervention development, including planning, development, and evaluation of the intervention. It uses a systematic approach to intervention development, which is in line with guidance on developing complex interventions (e.g., from the Medical Research Council)(Craig P, 2006). Here we focus on ways in which the PBA uses qualitative research to inform intervention planning and development.

#### *Intervention planning using qualitative data*

Intervention planning involves two iterative phases: collating and analysing evidence, and creating an intervention plan. Evidence concerning the behavioural issues, needs, and challenges of the target users is first collated and analysed. This will often consist largely of qualitative literature; however, other studies (such as data from surveys) may be included. Where the intervention development process has strict time constraints, this may take the form of a rapid scoping review in order to quickly incorporate existing evidence into the intervention plan. A full qualitative synthesis of the literature may also be planned. In each case, the literature is searched for previous qualitative studies that may be relevant, which may include studies that focused on user experiences with similar interventions. However, qualitative work that includes the target group but does not focus on interventions may also provide information about the perspective of members of this group - for example, information about their attitudes and needs which may influence acceptance of the

eventual intervention. Useful insights should be extracted from this literature and used as part of the intervention planning process - for example, using thematic analysis of the qualitative data.

Additional qualitative or mixed-methods research may also be carried out. This can help to determine what components of the eventual intervention target users would find necessary or helpful, as well as key behavioural issues, needs and challenges the intervention should address (Yardley, Ainsworth, et al., 2015). This could include interviews, questionnaires, focus groups, or any other methods of exploring the perspectives of the intervention's target user group. If there are specific gaps in the published literature or clear open questions, the interview questions might be purposively targeted to address these. However, sometimes it is helpful for this research to be exploratory and address many topics related to the focus of the intervention.

The collation of primary and secondary qualitative data is essential for identifying needs and issues related to the feasibility and acceptability of the eventual intervention. It provides the basis for deciding on the overall look and feel of the intervention (design, content, language) and for selecting theory- and evidence-based techniques for behaviour change that will be acceptable to the target users.

#### *Developing guiding principles*

Intervention planning is informed by the qualitative data collected. A key feature of the PBA is the identification of "guiding principles", designed to ensure a coherent focus underpins the intervention. The first step involves specifying the intervention objective in terms of the outcome that the intervention is trying to achieve (e.g. improved patient symptoms) and the behaviours that the intervention will target to try to achieve this (e.g. improved treatment adherence). The guiding principles consist of intervention **design objectives** and the **key features** of the intervention design that will achieve these objectives. The intervention design objectives are based on key issues that have been identified based on the previous literature review and qualitative or mixed-methods research. This provides a way to quickly remind members of the project team of the design

objectives of the intervention and serve as a sort of beacon to keep the intervention development moving in the right direction. Key features of the intervention might include the “tone” or “feel” of the intervention - its design, the formality of the language used, elements of technology (app vs. website vs. paper booklet) or implementation setting (primary care vs hospital context). For an example of the development of guiding principles for the REDUCE maintenance intervention, see Box 1.

**Box 1: Using Qualitative Research to Develop Guiding Principles for the REDUCE Maintenance Intervention**

We used the Person-based Approach to develop a plan for the REDUCE maintenance intervention (Greenwell, 2018). This intervention will support people with a history of diabetic foot ulcers (DFUs) to maintain four behaviours hypothesised to reduce re-ulceration risk: regular foot checking, rapid self-referral in the event of changes in foot health, regular and graded physical activity, and emotional management.

We carried out a rapid scoping review of the qualitative and quantitative literature to examine the behavioural and psychosocial needs, issues, and challenges of people with a history of DFUs. Literature was identified through searching Web of Science and reference lists, and expert consultation. Key findings were organised into themes using thematic analysis.

We also used primary qualitative research with members of target user group (i.e. people who had a history of DFUs) to explore the acceptability and feasibility of initial ideas regarding the content and delivery of the maintenance intervention and to identify potential barriers and facilitators to the target behaviours. Semi-structured interviews were carried out with a purposive sample of 20 participants and the data were analysed using thematic analysis.

Here are some examples of the issues we identified through this work:

1. The scoping review highlighted that people who have had DFUs may feel a lack of control over preventing DFUs, making them feel hopeless or frustrated. Some people reported feeling guilt or self-blame for not engaging in foot care behaviours, particularly if they got another DFU.
2. Although the scoping review suggested that some people experience difficult emotions after a DFU, some qualitative participants did not experience such emotions and, therefore, did not perceive emotional management as relevant to them.
3. While many qualitative participants reacted positively to the idea of a web-based intervention, both the scoping review and the qualitative research highlighted that this target group may have concerns about their computer literacy.

We created the guiding principles to address these key issues. Examples of our final guiding principles (taken from Greenwell, Sivyer et al., 2018) are outlined below:

| Intervention design objectives                   | Key features  |
|--|---|
| To reduce feelings of hopelessness, frustration, | <ul style="list-style-type: none"> <li>• Emphasise behaviours that patients can do to reduce their chances of getting another DFU, while acknowledging that there are precipitating factors that are out of their control.</li> </ul> |

**Commented [GK1]:** Reviewer comment: Box 1 provides an interesting example. I think it would be useful to include some detail of the process of the rapid scoping review (how data was analysed etc). More detail on the 'primary qualitative research' that was completed would also be useful here. What methods did you use to collect data, how many participants took part and why were they chosen, how was the data analysed?

KG: Added sources searched for scoping review and how data was analysed. Added in data collection methods, sample size, and data analysis method. I have clarified in the first sentence that the pts were chosen because they were from our target user group.

Reviewer comment: The information in Box 2 could also be enhanced by including some detail about the qualitative interviews that were conducted. Were these individual interviews? How was the data analysed?

KG: most info in now Box 1 so didn't repeat. Have added "see Box 1 for more detail" in Box 2.

|   |  |
|---|--|
| self-blame, and guilt following a DFU   | <ul style="list-style-type: none"> <li>• Enhance patients' confidence in the target behaviours (e.g. providing a rationale for the behaviours and patient stories).</li> <li>• Validate patients' feelings of frustration and hopelessness if a DFU does reoccur and avoid arguments that may be viewed as blaming patients for this re-occurrence.</li> </ul> |
| To acknowledge that emotional management may not be relevant for all patients | <ul style="list-style-type: none"> <li>• Make intervention content on emotional management optional.</li> <li>• Emphasise that some people, but not everyone, might experience difficult emotions following a DFU to avoid excluding those who may not relate to this content.</li> </ul>  |
| To ensure patients feel confident in using the maintenance intervention       | <ul style="list-style-type: none"> <li>• Health professionals at the prior initiation phase will provide technical support, address self-doubts, and speak favourably of the digital intervention to encourage use.</li> <li>• Provide a booklet for quick reference and for those who do not have access to the internet.</li> </ul>                          |

The qualitative data is also used to identify potential barriers and facilitators to the intervention's target behaviours, in order to inform the selection of intervention components and techniques. See Box 2 for an example of this.

**Box 2: Using Qualitative Research to Identify Barriers and Facilitators to the REDUCE Maintenance Intervention's Target Behaviours and Select Appropriate Behaviour Change Techniques**

In REDUCE, we used our scoping review and primary qualitative research to help us identify barriers and facilitators to the target behaviours in order to select appropriate behaviour change techniques (see Box 1 for more detail). In our semi-structured interviews with 20 people with a history of diabetic foot ulcers, we also explored participants' views of an initial plan of the intervention, including ideas for potential content, design features (e.g. foot checking reminders), and modes of delivery (e.g. booklet, website). Ideas were presented to participants using prompt cards. We explored participants' views on each of the target behaviours and explicitly asked about things that might make it difficult for them to do these behaviours, as well as any concerns they might have.

Here are some examples of what we found and how this guided decision-making for two of our target behaviours: regular foot checking, and regular and graded physical activity.

The scoping review highlighted that some patients were unsure how to identify a potential DFU or how to check their feet. These barriers also emerged in the qualitative interviews. This suggested that there was a need to provide information and pictures to explain what a DFU looked like and to provide instructions on how to perform foot checking if you had such limitations.

In our qualitative interviews, people expressed positive views of physical activity and believed it had benefits for their diabetes and general health. However, many participants found physical activity difficult due to physical limitations, such as pain, fatigue, and residual damage to their feet caused by previous ulcers. Some patients also worried that physical activity would make them get another ulcer. In response to these findings, we decided to provide a variety of examples of safe low-to-moderate activity and to include information that addressed any concerns users may have about the safety of physical activity.

In the interviews, we asked participants for their views on receiving regular email or text message reminders to check their feet. We found that there were mixed views about this technique. Some people believed it would be useful to set up regular foot checking reminders because it is easy to forget. Others felt reminders could be irritating or were unnecessary, as they, or their podiatrist, already regularly checked their feet. Likewise, participants expressed mixed views on the use of pedometers to encourage physical activity. Generally, participants thought that pedometers would be helpful for maintaining motivation. However, others disliked the idea of being 'spied on' or told what to do, expressed doubts about the accuracy of pedometers, or were unsure whether they would use them. We therefore decided to include these techniques, but make them optional, allowing users to set up their own reminders or request a pedometer if they wanted to.

#### *Developing the intervention and think-aloud interviews*

The intervention development stage can then take into account all of this preliminary information that has been collected, together with the guiding principles that have been drafted based on input from the target user group. Research team members should now have a very good idea of what sort of intervention would be useful and acceptable to the target group, and a "first-draft" intervention can be developed. This preliminary intervention can then be modified in an iterative manner based on feedback from users. This is generally done in the form of a "think-aloud interview" (Charters, 2003), in which members of the target group go through the intervention with a researcher, verbalising their thoughts about different parts of the intervention. This could include areas where instructions are unclear, information is too wordy, or participants are confused for any other reason. For some examples of user feedback and the changes that were made to the "Breaks from Sitting" section of the RECON intervention, see Box 3.

The results of these think-aloud interviews can then be used to improve the intervention. One way to do this is to tabulate all the feedback from each interview, determining changes which seem important in line with the Guiding Principles and areas which many participants mentioned as being problematic, as well as easy fixes that might clarify the intervention for participants. Each comment from a think-aloud participant can then be assigned a priority, possibly in discussion with the rest of the research team. One way to prioritise changes is to use the MoSCoW technique (Bradbury, Watts,

Arden-Close, Yardley, & Lewith, 2014): changes that the intervention Must have, Should have, Could have, or Won't have. This therefore provides a clear template for the order of priority when making changes to the intervention.

The think-aloud interview process is generally iterative. Thus, the "first-draft" intervention is shown to a set of target users and their feedback is collected. Changes are made based on this initial feedback, and a second-draft intervention version is produced. This is shown in turn to a different set of target users, and think-aloud interview data is collected in the same manner. Again, comments are addressed in order of priority and another version of the intervention is produced. This process can continue until few new important changes to the intervention are being suggested and most interviewees agree that the intervention would be useful to them. The number of rounds of think-aloud interviews needed for a particular intervention component can vary, and is up to the discretion of the researcher. However, in general the aim is data saturation – the point at which no new information, problems or concerns are emerging from the think-aloud data. Think-aloud interviews can safely be ended when the only additional suggestions emerging are quite minor ones or matters of preference (logos, wording, layouts)(Bradbury et al., 2018).

*Box 3: Iterative updating of the "Breaks from Sitting" component of the RECON intervention*

The RECON intervention (REducing and preventing Cognitive impairment iN older age groups) is a website designed to encourage older adults with and without cognitive impairment to increase behaviours that have been shown to prevent cognitive decline. These include physical activity, healthy eating, cognitive exercises and avoiding sedentary behaviour. The "Breaks from Sitting" section of the intervention focusses on the latter topic.

Initial draft content for this section was developed based on preliminary reviews on the literature around the benefits of avoiding sedentary behaviour in older age, in the form of a website module encouraging older adults to "take breaks from sitting or lying down" by standing and moving more. This content was then the subject of think-aloud interviews with adults in the target user group. Target users clicked through the "Breaks from Sitting" module exactly as if they were exploring it as a user and reported their thoughts and opinions on the content and layout. This was audio-recorded and transcribed. Specific pieces of data (thoughts, opinions or suggested changes) were extracted to a Table of Changes and prioritised using MoSCoW. Changes deemed important or which were suggested by multiple interviewees were made to the website in an iterative manner, with additional think-aloud interviews being conducted with the updated content until no more important changes were suggested.

Example feedback from users and the changes made to the intervention:

| User feedback  | Changes made   |
|--|--|
| More information should be added for the physically less able who are not able to stand at all   | Links added to information on chair-based exercises  |
| Participants were asked to choose when they sit or lie down and to link this activity to a goal related to sitting less. However, goal suggestions were a long drop-down list, not all relevant to each activity | Initial choice of activities done while sitting linked to only a subset of goals that applied to that activity (e.g., sitting down to sew linked to leaving snacks or drinks in another room, while watching television was linked to moving around during television adverts) |
| Activity suggestion of "leaving a bedtime book on the kitchen table" disliked by users because it seemed silly or unreasonable   | Activity suggestion removed  |
| Activity suggestion of "stand while you brush your teeth" thought by users to be unhelpful because none of them had ever brushed their teeth while seated  | Activity suggestion replaced by "Stretch or move around while you wait for food to heat"   |
| In the "Concerns" section, a section labelled "I have too much pain" bothered participants because they thought it would put people off  | Section name changed to "I have pain when I move around" to clarify that pain is not a barrier to reducing sedentary time  |

#### *Success with the PBA*

One of the strengths of the PBA is the amount and quality of input from the target users, both in terms of knowledge harvested from the existing literature, and of information provided directly from focus groups, diaries, think-aloud interviews etc. The intervention is updated iteratively, making it very responsive to feedback from the target user group.

However, because the process is so rigorous, several key aspects need to be in place for the PBA to be used successfully. It is important to think about these aspects very early in the planning process. For example, there are additional expenses related to think-aloud interviews that must be costed in, and the time each step takes must be considered carefully.

Below are some prerequisites for successfully developing an intervention using the PBA. Thinking about these issues in advance will assist with intervention planning and help to ensure the eventual development process runs smoothly, without too many unforeseen problems.

**Flexibility of intervention format and ability to iterate** – for the PBA to work well, researchers must be able to iterate the intervention based on participant feedback. A format that can be updated by the researchers themselves may be ideal, as this will allow the quickest iteration process. However, other methods may be appropriate as long as the process is considered early in planning the project. For example, does the ability to update a website multiple times based on feedback from Think-Aloud interviews need to be built in to a contract with a web developer? For a printed booklet, does the ability to provide multiple drafts need to be agreed with a graphic designer?

**Resources to obtain feedback built into project** – funding, resources and time must be built in for think-aloud interviews. This may include: recording equipment, travel costs, laptop to show intervention version, transcribing of interviews, staff time to undertake interviews, telephone costs. All of these may not be necessary for every project, but the think-aloud process should be laid out from the beginning, including estimated numbers of think-aloud interviews needed. A general guideline of 15-20 think-aloud interviews per intervention component is common, but this will depend on the particular intervention.

**Ability to recruit think-aloud participants** – members of the target group must be available and willing to be interviewed and give their opinions on the intervention. During project planning, this means thinking about advertising or other methods of obtaining interest in participating, travel costs (for researcher or participant), reimbursement for participants' time and timing of think-aloud interviews (e.g. to fit around school hours or work time). Because of the iterative nature of the PBA, small groups of think-aloud participants (usually 5-6) can be recruited at a time, allowing their feedback to be collated and intervention materials updated before the next set of think-aloud interviews.

### *Use of Qualitative Data in the Person-based Approach*

Collecting and using qualitative data is a key component of the PBA. The only way to be sure you have taken into account the attitudes and preferences of a particular target user group is to ask them what they think. The PBA makes use of qualitative data at multiple stages of intervention development:

1). **Use of previously published qualitative studies.** An initial literature search can provide useful information and prevent “reinventing the wheel” if additional qualitative data is collected. This literature search may provide insight into the kinds of questions which might be asked by researchers during their own qualitative interviews as well as highlighting gaps in the published literature on the topic.

2. **Primary qualitative interviews with target users.** The aim of these interviews is to learn as much as possible about the topic from the perspective of the target users, particularly in terms of issues that are important to this group and of what type of intervention components would be useful for them. This can provide crucial feedback about the eventual form the intervention might take. For example, the team that developed the Renewed intervention (Corbett, Cheetham, et al., 2018) realised that their participants worried about feeling blamed for their cancer and did not want to feel pressured to make changes. The intervention was therefore developed to provide information on the possible benefits of making positive changes, rather than suggesting changes in a more prescriptive manner (see Box 4 for more information on using qualitative data to iterate the intervention).

3. **Qualitative feedback on the intervention.** The think-aloud interviews use qualitative data to provide crucial feedback about which sections of the intervention require further development. Participants might comment on aspects of the intervention content as well as on the format,

wording or ease of use of the intervention. All of this feedback is taken into account and carefully tabulated, then used to make the intervention more useful and acceptable to the target users.

*Box 4: Using Qualitative Data to Iterate the Renewed Intervention*

In the development of the Renewed intervention (Corbett, Singh, et al., 2018), we used the Person-based Approach to elicit participants' perceptions of the intervention, as well as their thoughts about implementing behaviour changes after cancer (Corbett, Cheetham, et al., 2018). We found that many varied and complex factors were implicated in motivation for engaging with diet and physical activity changes. In particular, the findings highlighted that health-related concerns can pose genuine barriers to behaviour change after cancer. Overcoming cancer-specific barriers to behaviour change was therefore a key challenge for the developers of the intervention.

Some participants suggested that they would feel blamed or responsible for their cancer if it was linked to their past behaviour. Others felt pressurised into making changes after cancer. Therefore in designing the intervention, we avoided discourses which could be perceived as blaming the individual for their cancer. Instead, the tone of the intervention focused on positively framing messages that emphasized wellbeing. We discussed the wider benefits of making behavioural changes (such as increased energy, improved mood or memory), rather than illness management or risk of disease. The website highlighted that health behaviour changes may also benefit overlapping symptoms and facilitate self-management of ongoing side effects and pre-existing comorbidities. The website aimed not to promote unrealistic messages about cancer survivorship. Instead, the intervention endorsed achievable changes that people could build on to accomplish their goals. We used patient stories that acknowledged difficulties with change and provided realistic examples of how people can overcome barriers.

In recognition that some individuals may choose not to make changes, or may only want to make changes in a specific area, we facilitated autonomy and choice of different behaviour changes on the website (i.e. diet, physical activity, weight loss or mood). Some individuals suggested that changing behaviour might be in conflict with other priorities after cancer. We suggested a range of ways in which people could implement changes to incorporate the priorities and values of participants as much as possible. While pointing to the health benefits that could be gained, we also emphasised the social or enjoyment benefits that could be achieved. For example, we suggested family-based and social activities and recipes to promote enjoyable participation.

Participants described a perceived absence of support after cancer ends. This sometimes led to uncertainty about how to adopt lifestyle changes. The website therefore incorporated links to existing digital resources which provide advice and support for making healthy behaviour changes. The Renewed website also addressed common concerns that patients have about changing routines after cancer and engaging in healthy behaviours (e.g. concerns about safety of engaging in physical activity with side effects such as pain or fatigue). Individuals were encouraged to discuss any continued concerns about their health and lifestyle changes with a health care professional.

In the interviews, some participants expressed confusion due to conflicting advice or information that is difficult to understand. The website was designed to provide clear guidance from credible and reputable sources in an easily accessible format. Renewed was iteratively refined and tested to ensure that the website was perceived as easy to navigate and that the content was easy to understand.

## Conclusion

When designing a complex intervention, the patient or target user should be at the centre of the process. The Person-Based Approach allows an intervention development team to design an intervention around a user, taking into account their preferences, needs and challenges during the intervention development. This results in more useful interventions: they are more acceptable to target users and more likely to make a difference in practice.

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