**Using mixed methods to develop and evaluate an online weight management intervention**

**Abstract**

Purpose: This article illustrates the use of mixed methods in the development and evaluation of the Positive Online Weight Reduction (POWeR) programme, an e-health intervention designed to support sustainable weight loss. The studies outlined also explore how human support might enhance intervention usage and weight loss.

Methods: Mixed methods were used to develop and evaluate POWeR. In the development phase, we drew on both quantitative and qualitative findings to plan and gain feedback on the intervention. Next, a feasibility trial, with nested qualitative study, explored what level of human support might lead to the most sustainable weight loss. Finally, a large community based trial of POWeR, with nested qualitative study, explored whether the addition of brief telephone coaching enhances usage.

Results: Findings suggest that POWeR is acceptable and potentially effective. Providing human support enhanced usage in our trials, but was not unproblematic. Interestingly, there were some indications that more basic (brief) human support may produce more sustainable weight loss outcomes than more regular support. Qualitative interviews suggested that more regular support might foster reliance, meaning patients cannot sustain their weight losses when support ends. Qualitative findings in the community trial also suggested explanations for why many people may not take up the opportunity for human support.

Conclusions: Integrating findings from both our qualitative and quantitative studies provided far richer insights than would have been gained using only a single method of inquiry. Further research should investigate the optimum delivery of human support needed to maximise sustainable weight loss in online interventions.

**Introduction**

Positive Online Weight Reduction (POWeR) is an e-health intervention designed to produce sustainable weight management. POWeR consists of 12 sessions which teach users self-regulation skills in order for them to become their own personal health trainer (for further details about the content of POWeR see Yardley et al., 2012). The current article illustrates how we combined inductive qualitative and deductive quantitative methods in the development and evaluation of this new intervention. We predominantly draw on our research which has already been published, but also present some new, as yet unpublished, qualitative findings.

The overall aim of this body of work was to create a weight management intervention suitable for primary care, which would produce sustainable weight loss (i.e. weight loss which can be maintained and is not regained once support ceases). An online intervention offered several key advantages over a purely face to face intervention; it might be more feasible for primary care to deliver, since it requires less of practitioners’ time, it would likely be cheaper to roll out at scale and would increase access to patient care, since patients can log on twenty-four hours a day to get support with their weight loss (see Yardley et al, 2014 for further detailed discussion of the rationale for an online weight management intervention). We also chose to provide a small amount of human support to accompany our online intervention, since this can improve outcomes in e-health interventions (Kodama et al., 2012; Neve, Morgan, Jones & Collins, 2011), whilst remaining cheaper than a purely face to face intervention.

To achieve our aim of developing an online intervention which would produce sustainable weight loss we needed to answer a variety of research questions, which required a mixed methods approach. Firstly, we needed to explore whether the intervention was acceptable to patients; their feedback enabled us to make improvements to the website before testing its effectiveness. Qualitative methods were best suited to exploring acceptability, since they allowed identification of novel, unanticipated perceptions, which might not have been captured using pre-determined questionnaire items. We also wanted to test whether the online intervention was effective, and what impact different levels of human support would have on weight loss. Quantitative methods, using randomised clinical trials, were best suited to answer these questions, since such methods allow great precision and control, maximising a study’s internal validity, thereby allowing causal inferences to be drawn. Finally we also wanted to explore participants’ perceptions of the online intervention and human support within our trials, to help generate potential explanations for our quantitative findings. Table 1 provides an overview of the research questions and methods used at each different stage of this programme of research. Many of our research questions were known at the beginning, others developed over time based on the findings from earlier studies. For example, our qualitative process studies were used to explore interesting quantitative findings from our trials which were not anticipated at the outset.

**Insert TABLE 1 here**

We took a pragmatic approach to combining our qualitative and quantitative studies within this programme of research. Pragmatism proposes that the methods most useful to address a research question, or most feasible for explaining a particular phenomenon, should be adopted (Creswell, 2003; Morgan, 2007; Yardley & Bishop, 2007). Under this paradigm neither qualitative or quantitative research are viewed as inherently superior, instead the methods which best suit the research aims are adopted (Creswell, 2003).

We triangulated the findings from each study using a composite analysis technique (Yardley & Bishop, 2007). This meant that data were collected and analysed using either qualitative or quantitative methods, to preserve the integrity and unique contribution of each methodological approach. The findings of these studies were then integrated to inform the overall aims of the research programme.

In the following sections we illustrate how we used a combination of qualitative and quantitative methods in our intervention planning and development, in a feasibility trial based in primary care and finally in a community based trial.

**Intervention planning and development**

Our intervention planning commenced with a scoping review of the quantitative evidence for which weight management interventions (especially internet-delivered) were most effective. To plan the philosophy and key ingredients needed in POWeR, we identified the behaviour change techniques used in successful interventions, and also drew on psychological theory. Our intervention planning was also informed by a qualitative synthesis (Garip & Yardley, 2011) and a qualitative interview study, which both explored experiences of weight management (Yardley et al., 2012). During this phase both the quantitative and qualitative evidence were considered equally important and complementary. For instance, quantitative evidence from clinical trials suggested factors which are effective in producing weight loss (such as calorie counting), but the qualitative evidence suggested that this might be difficult for people to adhere to and not sustainable long term. The interview study gave us further insight into peoples’ experiences of trying to lose weight. Participants in this study attributed previous diet failures to their restrictive and intrusive nature. It was clear that POWeR would need to appear novel, since participants would likely have previously failed at many diets, and incorporate more flexibility than traditional weight loss approaches. POWeR was therefore designed to include flexible principles which participants could use to self-regulate, rather than prescriptive diets. For instance, weekly weighing (which is associated with greater weight loss than less frequent weighing; VanWormer et al, 2008) was promoted as a way of measuring whether a person was eating too much or the right amount, instead of complicated calorie counting; if a person had not lost weight then this was a sign that they should reduce portion sizes.

Once the first version of POWeR was completed, we used qualitative think-aloud interviews to help us further develop and refine the website to enhance its acceptability (Yardley et al., 2012). This was an iterative process, moving between collecting participants’ views, making changes to the website and then collecting further views to confirm that our changes were adequate. We interviewed 16 participants, many of whom took part in multiple interviews viewing all 12 of the POWeR sessions we had created. Participants were generally very positive about the intervention, valuing its choice and flexibility, but demonstrated problems with creating if-then plans (Adriaanse, de Ridder, & de Wit, 2009), which previous quantitative studies and theory had suggested would be an important ingredient. These plans involve identifying positive behaviours to implement in relevant contexts which are written in the format of “If cue X occurs, then I will perform behaviour Y”, but we observed that many participants simply restated goals or made imprecise or irrelevant plans which were unlikely to lead to weight loss when asked to create their own if-then plans. We consequently re-designed these plans, making the format simpler for people to understand and provided concrete examples which would be sufficient to produce weight loss. However, we still had concerns that some users might struggle to implement self-regulation skills alone because of the degree of difficulty that people had encountered with setting adequate plans, and therefore believed that human support might support self-regulation and enhance motivation in some users.

**Feasibility study POWeR1**

Next we conducted a feasibility trial of POWeR (Yardley et al., 2014), to determine the level of nurse support needed to maximise sustainable weight loss in obese patients in a primary care setting. This study aimed to inform our later planned fully powered trial which would test the cost effectiveness of POWeR and its accompanying nurse support.

Patients were randomised to either usual care (n=43), the POWeR website (n=45), POWeR accompanied by basic nurse support (3 sessions in 3 months, n= 44), or POWeR with regular nurse support (7 sessions in 6 months, n=47). The nurse support was mainly delivered face to face, although telephone and email support could also be provided if the patient was unable to attend a face to face session (though were seldom used). The support was designed to provide encouragement and reassurance, rather than to give advice or provide sophisticated behaviour change counselling.

Nurse logs revealed that two practices did not adhere to the protocol for usual care (of minimal support), instead providing intense face-to-face support which they introduced especially for this study. It is therefore more straightforward to interpret the findings of the per protocol practices (although results were in the same direction in both analyses). Figure 1 provides an overview of the weight loss in each group at 6 and 12 months. Both nurse support groups lost more weight than the web only and usual care groups at 6 months, with the largest weight loss in the regular support group. Interestingly, by 12 months those receiving only POWeR or POWeR plus regular nurse support did not sustain their weight loss, whereas those receiving the basic nurse support continued to lose weight, with a final mean weight loss of 4.64kg. Weight loss in the basic support group was therefore comparable to that of one of the most effective face-to-face weight management interventions in the UK (Jolly et al, 2011).

**INSERT FIGURE 1 HERE**

It appeared that POWeR accompanied by basic nurse support may potentially provide a sustainable and feasible approach to weight loss in primary care, although of course this result requires replication in our fully powered trial (in progress, ISRCTN21244703). Our qualitative process study (Renouf, Bradbury, Little & Yardley, Submitted) was useful to suggest potential reasons why the regular nurse support group regained weight between six and twelve months (after the nurse support had finished), whereas the basic nurse support group continued to lose weight during this time. Twenty-three patients from our feasibility trial were interviewed at six months to explore perceptions of nurse support. The data were analysed using thematic analysis.

Some participants, particularly those in the basic support group, emphasised autonomous motivation, whereby the nurse support was seen as valuable, but not relied upon.

*I’ve managed to keep you know get the best out of this that I can. So I haven’t had to rely on support (P12 Basic Support)*

In contrast, several participants from the regular nurse support group viewed the nurse as an external motivator, someone to check up on them that they were accountable to, which they described as motivating.

*I thought that if I was being monitored it would make me enthusiastic, and stick with it. (P16 Regular Support)*

*Oh God I haven’t done what I should of done and I promised to do it and I know that isn’t what’s supposed to spur you on but it I think it does. (P22 Regular Support)*

These participants were also concerned about the nurse support ending and wanted more support.

*Bit apprehensive actually (about support ending) because it’s, I’ve found it a really helpful experience...I shall miss it actually very much (14)*

*I was devastated when I realised it was the last one, I don’t think I realised it was just for six months (P16, Regular Support)*

 It seemed possible that over-reliance on support might have meant that some patients who received regular nurse support lost motivation when the nurse support ended. This might explain why the regular support group regained weight after nurse support ended, whereas the basic nurse support group were able to continue losing weight. It might be that a smaller amount of support can foster motivation for weight loss without creating over-reliance on that support. We will be exploring this issue further in our fully powered trial.

**A community trial of POWeR**

In a subsequent community trial of POWeR (Dennison et al., 2014) we got the opportunity to explore the issue of human support further. NHS public health teams in the North East of the UK helped us to disseminate the POWeR intervention via mail-outs, posters, press releases and social media. All registration and quantitative data collection procedures were online and fully automated. This sample and setting differed considerably from our primary care trial, since the community rollout was not restricted to people who were obese (participants had a BMI ≥23), while the primary care patients met their nurse at baseline and follow-up to complete assessments and trial procedures.

We wanted to explore intervention usage in this context and, in keeping with most published e-health research in community contexts, expected light usage and early discontinuation from a large proportion of users (Kohl, Crutzen & de Vriesl, 2013). We were interested in whether users could be kept engaged with the intervention for longer by supplementing the web intervention with a brief and low-cost form of human contact. We were also interested in whether this sort of support would also boost weight loss outcomes, but were aware that in this particular research context we were unlikely to get high follow-up rates and would not be able to collect objective data on pre and post intervention weight. We randomised participants to either use the POWeR programme independently (n=264) or with brief support (n=247) . Our human support consisted of two brief (10 minute) telephone calls from ‘POWeR coaches’, who were psychology research fellows/assistants. The coaching content was highly influenced by the Supportive Accountability model (Mohr, Cuijpers & Lehman, 2011) and aimed to encourage ongoing use of POWeR.

The majority of participants were obese (44.9%) or overweight (34%), smaller numbers were morbidly obese (15%) or were in the upper part of the normal weight range (6.1%). In line with our hypotheses, we observed significant differences in usage between the web and coach arms; coach participants were 1.6 times more likely to complete at least the core 3 sessions of POWeR, although usage was low across both arms, with only a minority (25.9% of coach, 17.8% of web only) continuing to use POWeR until the end of the core sessions. However, since we also conducted a qualitative process study (unpublished elsewhere) we were also able to explore helpful (and unhelpful) aspects of coaching. LD conducted telephone interviews which explored experiences of POWeR and the accompanying coaching, including what aspects people found most helpful, unhelpful, appealing or unappealing and what factors seemed to influence whether participants continued to follow POWeR. Interviews lasted between 20 mins-1 hour. Participants were sampledfrom both the coaching arm (10 women, 4 men) and web only arm (4 women, 1 man) and varied in their usage of POWeR, from quitting after part of the first session, to using regularly and intending to continue after the trial had finished. Participants were aged between 34-68 (median= 56). An inductive thematic analysis was conducted by LD to explore participants’ experiences of POWeR and the coaching support. Line by line coding was employed and a coding manual was created and updated as codes were organised into themes. Here we present the findings relating to the ‘Experiences of coaching’ theme and also briefly touch on ‘Comparisons between POWeR and alternative weight loss methods’ and ‘Experiences of using POWeR’. Two other themes (‘Barriers and facilitators to continued use of POWeR’ and ‘Perceived effects of POWeR’) were identified in the analysis but are not presented here.

Participants who received coaching viewed it positively and coaches were perceived as very supportive. Some participants appreciated the chance to ask questions about eating or exercise plans or to be reassured that they were ‘doing it right’. Many participants described appreciating simply knowing that a real human was interested in them and cared about their progress:

*It makes you feel quite good when somebody else actually takes the time to um look it up and get in touch and um you feel good afterwards. [P18, coach]*

Several highlighted the praise and encouragement they gained from the conversations as being beneficial.

*I like to have someone say well done when I have done well. [P5, coach]*

*I kind of used the coach as a…you know, as a boost. [P9, coach]*

Some participants’ accounts of coaching suggested that they experienced accountability to the coach which made them more committed and motivated.

*If you have somebody who...pays an interest in how things are going for you, then that sort of, that must kind of motivates you and also seeks a commitment as well. You know, because you want to, you want to take advantage of it, you want to take on board what they're saying and that motivates you to keep doing what you are doing [P9, coach]*

Others described working harder on the programme because of having a coach. For example, the knowledge of an upcoming coach phone call could motivate users to ensure that they had completed the most recent website session and made good progress towards their goals

One participant described how the second coaching call had come at a time when she was struggling to stick to her eating and physical activity plans and was at the point of giving up but that the coaching had pushed her to continue.

*After talking to her I did sort of reign in some of what I was eating and thought about it a bit more rather than just thinking oh blow it all… … and it gave me a bit more incentive to try and do some exer… more exercise… [P1, coach]*

This suggests that the timing of coaching may be critical for its impact and acceptability, an issue that several other users picked up on. Generally, participants wanted more coaching calls, but also more flexibility about when the calls took place. A system of contact based on the user’s needs and experiences was preferred, rather than a schedule set in advance.

Despite participants describing the benefits of coaching in the qualitative interviews, quantitative data showed that a) uptake of coaching was actually very low (only 18.6% of coach arm participants received the full ‘dose’ i.e. both sessions, 23.5% had one session, 57.9% had none), b) drop-out from the intervention was higher in participants allocated to coaching compared to web only, and c) drop-out seemed to occur at points in the intervention where participants were expecting a coaching call. These quantitative observations suggested that there was likely to be something unfeasible or unappealing about the coaching for a considerable proportion of participants. Again, our qualitative data allowed us some insights into possible explanations. A major recurring theme was how POWeR compared positively to their negative previous experiences of weight loss programmes, much of which was from slimming clubs. Many had previously experienced feeling shamed, excluded or embarrassed in these group situations, especially with regard public weigh-ins.

*If you go to a slimming and class you feel that you’ve made a fool of yourself or you get weighed and you’ve put on half a pound or a pound, and then you don’t want to go back the next week so you don’t go back (P14, coach)*

*[POWeR] was lovely, cause I was never embarrassed, sometimes, one week I actually put on two pounds but nobody went “tut tut tut”, nobody looked at me oddly, so that was good. (p3, web)*

Although interview participants described how their experience of coaching in POWeR did *not* have these negative elements (it was considered friendly and non-judgemental) we might speculate that some of those coaching arm participants who withdrew completely from the trial, or who did not answer calls from coaches, may have been put off because their previous experiences led them to expect coaching to be negative, pushy or embarrassing.

 *I wasn’t quite sure if he was going to tell me off (P11, coach)*

In addition, some qualitative findings tentatively suggested that having input from another person, however approachable and supportive, might run counter to one or more of the features of POWeR that users perceive as attractive. Firstly, one theme centred around the convenience of POWeR as an attractive feature; they could use it when and where they wanted. Coaching, however, appeared less conducive to busy lifestyles and some had apparently missed phone calls because of their busy schedules. This triangulates with our quantitative finding that uptake of coaching was highest in older compared to younger participants; perhaps coaching telephone calls were less suitable for younger participants who potentially had more work and family commitments and less predictable routines. Another perceived attractive feature of POWeR emerging from the qualitative analysis was that it allowed users to tackle weight loss privately and independently, focusing on their own goals and plans and being accountable only to themselves for their progress, rather than having to think about and please others. The provision of coaching may not have complemented these website features.

*I could write down what I thought was right for me, and not just put down maybe what somebody else wanted to read if you get what I mean, I could actually do something that mattered to me, so it was very, very personal. (P10, web)*

Overall our qualitative data suggested that coaching was highly valued by some users and the quantitative trial results suggest that coaching does improve use of the intervention somewhat. The qualitative data also suggests ways in which the coaching might be tailored, either to be provided when users most need it, or perhaps to be provided only to those who want or need it.

**Conclusion**

In this paper we have demonstrated how we used mixed methods in the development of POWeR. Being able to integrate the findings from both our qualitative and quantitative studies gave us far greater insight than would have been gained if using only one method of inquiry.

Across all of our studies, human support appeared to be important to users’ successful engagement with the website and (where assessed) with their weight loss. Our qualitative development study suggested that whilst POWeR appeared acceptable to many users, some might struggle to implement self-regulation skills alone and might benefit from some human support. Findings from the feasibility and community trials suggested that brief support does indeed appear to promote better outcomes. Triangulation of the qualitative and quantitative findings from our feasibility trial helped us to propose tentative explanations for why basic nurse support appeared to promote more sustained weight loss than more regular support; the basic support group appeared more autonomously motivated, whereas those who had received regular support appeared more externally motivated and had perhaps become overly reliant on nurse support, which may have been responsible for their relapses once nurse support ended. Triangulation of the qualitative and quantitative findings from our community trial suggested potential explanations for why uptake of the coaching support was lower than expected. These included participants’ negative previous experiences with weight loss services, a desire for greater flexibility in when coaching calls took place and the potential that some users may value POWeR because it enables autonomy and privacy, which might run counter to desiring human support. Triangulating these findings across the whole programme of research provides some indications of how support might be provided most cost-effectively, by tailoring it to best meet users’ needs (through flexibility in availability) and perhaps limiting provision to occasional support targeted at those who desire it.

The use of qualitative research is sometimes overlooked in the development and evaluation of online interventions, but we have found it as valuable as our quantitative studies. In these contexts, qualitative studies allowed us to develop a more acceptable, feasible intervention and to learn more about the mechanisms that might influence the effectiveness of website and nurse support. Qualitative development and process studies can therefore also make an important contribution to the literature, providing crucial complementary evidence to clinical trials to guide the development of other interventions.

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**Table 1:** Research questions and methods used in the development and evaluation of POWeR

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| Phase of research | Research questions | Research methods |
| Development of the POWeR intervention | 1. What features will make an effective web-based weight management intervention?
 | Review of quantitative literature on weight management interventions, examining predictors of weight loss and which behaviour change techniques were used by successful interventions. |
| 1. What features appear to be important for patient acceptability, i.e. make the intervention credible, comprehensible, usable, and engaging?
 | Qualitative synthesis of studies exploring weight loss experiences (Garip & Yardley, 2011)New primary research - qualitative interview study exploring previous weight loss experiences (Yardley et al., 2012)New primary research - think aloud qualitative interview study with obese adults (Yardley et al., 2012) |
| Evaluation of the POWeR intervention in primary care | 1. Is POWeR feasible for supporting weight loss in primary care?
2. What level of support leads to the most sustainable weight loss outcomes?
 | New primary research - POWeR Feasibility RCT (Yardley et al., Submitted) |
| 1. How do primary care patients experience POWeR and its accompanying nurse support?
2. What might explain difference in weight losses between intervention groups?
 | New primary research - qualitative process interviews with participants from the POWeR Feasibility RCT (Renouf et al., Submitted) |
| 1. Is POWeR effective in primary care? Which level of support is most effective/cost effective?
 | New primary research in progress – POWeR2, a large fully powered RCT (ISRCTN21244703) 1 |
| 1. How do primary care patients experience POWeR?
2. What might explain differences in weight loss/maintenance?
 | New primary research in progress - process interviews with participants from the POWeR2 RCT (ISRCTN21244703)1 |
| Evaluation of the POWeR intervention in community sample | 1. How is POWeR used when disseminated in the community?
2. Does adding coaching to POWeR in the community boost usage of the intervention?
 | New primary research - Community POWeR RCT(Dennison et al., 2014) |
| 1. What aspects of POWeR do community users like /dislike and find helpful/unhelpful?
2. How do community participants experience coaching support? What aspects of coaching do users like /dislike and find helpful/unhelpful?
 | New primary research (unpublished elsewhere) - qualitative process interviews with participants from the community POWeR RCT |

1 Final results not yet available for inclusion in this analysis.



**Figure 1:** Weight Loss at 6 and 12 months in the POWeR feasibility study