# Randomised controlled trial and economic analysis of an internet-based weight management programme: POWeR+ (Positive Online Weight Reduction)

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**Declared competing interests of authors:** Paul Little is Editor-in-Chief of the Programme Grants for Applied Research journal and a member of the National Institute for Health Research (NIHR) Journals Library Board. James Raftery is a member of the Health Technology Assessment (HTA) and Efficacy and Mechanism Evaluation editorial boards and a member of the NIHR Journals Library Editorial Group and was previously Director of the Wessex Institute and Head of NETSCC. Barrie Margetts states that since retiring from the University of Southampton (in September 2014) he has undertaken paid consultancies for the World Bank, UNICEF and the World Health Organization. Up until December 2015 he was an unpaid trustee of the international charity 'Riders for Health' and up until May 2015 he was unpaid president of the World Public Health Nutrition Association. Lucy Yardley is a member of the NIHR Public Health Research Funding Board and the HTA Efficient Study Designs Board.

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# **Scientific summary**

# POWeR+ (Positive Online Weight Reduction)

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# **Scientific summary**

#### **Background**

Obesity is an epidemic with major downstream consequences for a range of health issues from musculoskeletal pain, diabetes mellitus, cardiovascular and cerebrovascular disease to cancer. The National Institute for Health and Care Excellence (NICE) has supported intensive expert dietetic counselling and intensive follow-up, which is effective, but the resource requirements are a major barrier to widespread implementation in resource-constrained primary care settings where most obesity is managed. An alternative to a cadre of highly trained interventionists is to harness the capacity of the internet to help support behaviour change. A systematic review of internet-based behavioural health-related interventions concluded that web-based interventions are effective for supporting behaviour change, although with considerable heterogeneity, and that interventions employing multiple theory-based techniques achieve the best results. However, major heterogeneity was documented in the effectiveness of internet interventions, with a trend towards better outcomes in interventions with additional personal support, so it remains very unclear how much facilitation is needed for effective weight reduction, whether face-to-face support is necessary and/or whether briefer remote support could suffice. Using the person-based approach, we previously developed an augmented web-based intervention for weight management in primary care, the Positive Online Weight Reduction (POWeR+) programme, a prototype version of which (POWeR) helped to support weight loss in a feasibility study.

## **Objectives**

Among obese patients or overweight patients with significant comorbidities in primary care, we wanted to compare the effect of three brief approaches with an intervention that could feasibly be applied. We chose to use for a control group brief advice sheets for food swaps and increasing fruit and vegetable consumption, which we had previously shown to help with weight control without expert dietetic input. Compared with this group we wanted to estimate the incremental clinical effectiveness and cost-effectiveness of (1) the internet-based behavioural intervention with face-to-face support as needed (POWeR+F) and (2) the internet behavioural intervention with remote support (POWeR+R).

#### **Methods**

This was an individually randomised, three-arm parallel trial. Participants with a body mass index of  $\geq 30 \text{ kg/m}^2$  (or  $\geq 28 \text{ kg/m}^2$  with additional risk factors of hypercholesterolaemia, hypertension or diabetes mellitus) were identified from general practice electronic records. They were then recruited by postal invitation.

The POWeR+ intervention was developed previously: this is a 24-session web-based weight management intervention consisting of a series of 24 brief (two-page) maintenance-oriented sessions for up to 6 months and links to encourage patients to continue to use the website to track their weight at least fortnightly (preferably weekly) until they have formed healthy eating habits that sustain weight management without the need to access the website. Tailored feedback was provided, giving encouragement if participants maintained weight loss (e.g. reminders of health benefits accrued); if weight increased, this triggered new reminders, personalised messages, appropriate goal-setting, boosting motivation, and planning for and overcoming difficulties.

Following consent and online registration with the POWeR+ website, patients were randomly allocated using computer-generated random numbers (in a 1 : 1 : 1 ratio) by the automated intervention website to either:

- 1. control group receiving only brief web-based information about healthy food swaps and eating five fruits and vegetables a day
- 2. POWeR+F access to POWeR+ and subsequent face-to-face nurse support (up to seven contacts)
- 3. POWeR+R access to POWeR+ and remote nurse support of up to five brief e-mail/telephone contacts.

All participants were given appointments to be followed up at 6 and 12 months. The primary outcome was the estimated average weight reduction from available data over 12 months. An important secondary weight outcome was the proportion achieving a clinically important 5% reduction in weight at 12 months. A range of other secondary outcomes was also measured [liver function tests, indices of metabolic syndrome (waist circumference, high-density lipoprotein, triglycerides, blood pressure, fasting glucose), reported fruit and vegetable consumption and reported physical activity]. Resource use was estimated from the medical records and health-related quality of life measured using the EuroQol-5 Dimensions (EQ-5D) instrument. Cost-effectiveness (cost per kilogram lost) and cost-utility (cost per quality-adjusted life-year) analyses were performed. However, completion of the EQ-5D was limited and so the cost per kilogram analysis was our primary economic analysis. We were also able to use previous modelling by NICE, which had demonstrated that at least 1 kg per-person weight loss among overweight or obese adults, if maintained for life, is likely to be cost-effective, provided that the cost per person of intervening is < £100. Thirty-one patients and 19 health professionals who took part in POWeR+ agreed to participate in an interview to discuss their perceptions about using POWeR+. Interviews were transcribed and thematically analysed.

#### Results

Fifty-six general practices agreed to participate in the study and 818 eligible individuals from these practices were randomised from January 2013 to March 2014. Of these, 439 had a weight recorded at the 6-month follow-up and 666 had a weight recorded at the 12-month follow-up. Of the 666, 510 (76.6%) were blinded weights, 28 (4.2%) were unblinded weights and 128 (19.2%) were reported weights. The groups were well balanced at baseline.

The control group achieved a reduction in weight of nearly 3 kg (baseline weight 104.4 kg, 6-month weight 101.9 kg and 12-month weight 101.7 kg). Compared with the control group, POWeR+F participants achieved an estimated additional weight reduction of 1.5 kg averaged over 12 months [95% confidence interval (CI) 0.6 to 2.4 kg; p = 0.001] and POWeR+R participants achieved a 1.3 kg weight reduction (95% CI 0.34 to 2.2 kg; p = 0.007). At 12 months, although there were no statistically significant differences in mean weight loss between groups, 20.8% of the control group, 29.2% of the POWeR+F group (risk ratio 1.56, 95% CI 0.96 to 2.51; p = 0.070) and 32.4% of the POWeR+R group (risk ratio 1.82, 95% CI 1.31 to 2.74; p = 0.004) had maintained a clinically important 5% weight reduction. The POWeR+R group included fewer individuals who reported doing another activity to help lose weight [control: 47.1% (64/136); POWeR+F: 37.2% (51/137); POWeR+R: 26.7% (40/150)]. The estimated incremental overall cost to the health service per kilogram weight lost compared with the control group was £18 (95% CI -£129 to £195) for POWeR+F and -£25 (95% CI -£268 to £157) for POWeR+R. The probability of being cost-effective at a threshold of £100 per kilogram lost was 88% and 98%, respectively. POWeR+R was dominant compared with the control. This makes it very likely that both interventions are cost-effective at current willingness-to-pay thresholds, with the most cost-effective intervention being POWeR+R.

The qualitative study with health-care professionals (HCPs) found that they generally enjoyed supporting patients using POWeR+ and often perceived POWeR+ as superior to the weight-loss services that were

available in their practices. HCPs also highlighted a number of challenges that they faced in providing support for POWeR+, which can be addressed in revised versions of the website. The qualitative study with patients found that POWeR+ was viewed positively, as was nurse support for POWeR+, and that if POWeR+ is used remotely the option of contacting the nurses if necessary was important.

# Implications for health care

Weight loss is maintained for some individuals by promoting novel written materials with occasional brief nurse follow-up in primary care. However, more people can achieve clinically important weight reduction with a web-based behavioural programme and brief remote follow-up, individuals feel more enabled to manage their weight and undertake fewer other weight-loss activities, and it is likely to be cost-effective.

## **Future research implications**

- 1. Many individuals did not continue to use the POWeR+ website and, given the evidence that those who did lost more weight, a key research priority is to identify the most clinically effective and cost-effective ways of continuing to engage more individuals.
- 2. Given the utility of POWeR+ with brief support in primary care, the question then arises of what public health benefit might accrue from using POWeR+ in community settings, and what magnitude and nature of support is necessary, such as a central facilitator or pharmacy support, in order to achieve effective weight control.
- 3. Very few participants were engaged in using drug management of their weight problems, despite this being intended as part of the package, and few individuals increased physical activity; an implementation study to develop and trial a complex intervention to address both these issues is warranted.
- 4. Future research to test the clinical effectiveness, acceptability and feasibility of similar methods for providing human support for digital interventions in a range of health conditions is needed.

#### **Trial registration**

This trial is registered as ISRCTN21244703.

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