

# An internet-based intervention with brief nurse support to manage obesity in primary care (POWeR+): a pragmatic, parallel-group, randomised controlled trial



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## Summary

**Background** The obesity epidemic has major public health consequences. Expert dietetic and behavioural counselling with intensive follow-up is effective, but resource requirements severely restrict widespread implementation in primary care, where most patients are managed. We aimed to estimate the effectiveness and cost-effectiveness of an internet-based behavioural intervention (POWeR+) combined with brief practice nurse support in primary care.

**Methods** We did this pragmatic, parallel-group, randomised controlled trial at 56 primary care practices in central and south England. Eligible adults aged 18 years or older with a BMI of 30 kg/m<sup>2</sup> or more (or  $\geq 28$  kg/m<sup>2</sup> with hypertension, hypercholesterolaemia, or diabetes) registered online with POWeR+—a 24 session, web-based, weight management intervention lasting 6 months. After registration, the website automatically randomly assigned patients (1:1:1), via computer-generated random numbers, to receive evidence-based dietetic advice to swap foods for similar, but healthier, choices and increase fruit and vegetable intake, in addition to 6 monthly nurse follow-up (control group); web-based intervention and face-to-face nurse support (POWeR+Face-to-face [POWeR+F]; up to seven nurse contacts over 6 months); or web-based intervention and remote nurse support (POWeR+Remote [POWeR+R]; up to five emails or brief phone calls over 6 months). Participants and investigators were masked to group allocation at the point of randomisation; masking of participants was not possible after randomisation. The primary outcome was weight loss averaged over 12 months. We did a secondary analysis of weight to measure maintenance of 5% weight loss at months 6 and 12. We modelled the cost-effectiveness of each intervention. We did analysis by intention to treat, with multiple imputation for missing data. This trial is registered as an International Standard Randomised Controlled Trial, number ISRCTN21244703.

**Findings** Between Jan 30, 2013, and March 20, 2014, 818 participants were randomly assigned to the control group (n=279), the POWeR+F group (n=269), or the POWeR+R group (n=270). Weight loss averaged over 12 months was recorded in 666 (81%) participants. The control group lost almost 3 kg over 12 months (crude mean weight: baseline 104.38 kg [SD 21.11; n=279], 6 months 101.91 kg [19.35; n=136], 12 months 101.74 kg [19.57; n=227]). The primary imputed analysis showed that compared with the control group, patients in the POWeR+F group achieved an additional weight reduction of 1.5 kg (95% CI 0.6–2.4; p=0.001) averaged over 12 months, and patients in the POWeR+R group achieved an additional 1.3 kg (0.34–2.2; p=0.007). 21% of patients in the control group had maintained a clinically important 5% weight reduction at month 12, compared with 29% of patients in the POWeR+F group (risk ratio 1.56, 0.96–2.51; p=0.070) and 32% of patients in the POWeR+R group (1.82, 1.31–2.74; p=0.004). The incremental overall cost to the health service per kg weight lost with the POWeR+ interventions versus the control strategy was £18 (95% CI –129 to 195) for POWeR+F and –£25 (–268 to 157) for POWeR+R; the probability of being cost-effective at a threshold of £100 per kg lost was 88% and 98%, respectively. No adverse events were reported.

**Interpretation** Weight loss can be maintained in some individuals by use of novel written material with occasional brief nurse follow-up. However, more people can maintain clinically important weight reductions with a web-based behavioural program and brief remote follow-up, with no increase in health service costs. Future research should assess the extent to which clinically important weight loss can be maintained beyond 1 year.

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## Introduction

Obesity is a major threat to public health,<sup>1,2</sup> the prevalence has risen sharply since the early 1990s,<sup>3</sup> and most patients are managed in primary care.<sup>4</sup> Systematic reviews,<sup>5</sup>

including that from the National Institute for Health and Care Excellence (NICE),<sup>4</sup> advocate dietary and physical activity intervention supported by intensive behavioural techniques. The low availability of high-level dietetic and

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### Research in context

#### Evidence before this study

We did not repeat the most recent systematic review, done by Hutchesson and colleagues, which included studies of adults aged 18 years or older that assessed weight loss or weight maintenance interventions with an e-Health component. Between 1995, and Sept 17, 2014, Hutchesson and colleagues searched the Cochrane Library, MEDLINE and PreMEDLINE, Embase, CINAHL, Web of Science, Scopus, PubMed, and PsycINFO. Search terms were obesity/ or obesity, abdominal/ or obesity, orbid/Overweight/Adiposity/ obese.mp.ehealth.mp. or telemedicine/ telehealth.mp.Text Messaging/mhealth.mp. Computers, Handheld/(tablet\* and (mac or ipad or android\* or microsoft or windows)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]exp Internet/world wide web.mp.web based.mp.((web\* or remote or online) adj3 deliver\*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]website\*.mp.online.ab.ti.smart phone\*.mp.digital game\*.mp.smartphone\*.mp.Computer Simulation/ or virtual reality.mp. exp diet/healthy eating.tw. nutrition.tw.physical activity.tw.exp exercise/\*motor activity/\*Physical Fitness. 23 (27.4%) studies were classified as higher quality (quality and risk of bias), 57 (67.9%) studies were classified as moderate quality, and nine (10.7%) studies were lower quality. Meta-analysis showed significantly greater weight loss (kg) with e-Health interventions than with minimal interventions (mean difference -1.40, 95% CI -1.98 to -0.82;

$p < 0.001$ ). However, two studies had unusual populations (university staff; lactating women), and the only study to report fewer than ten contacts by behavioural counsellors documented less than 1.5 kg weight loss and high attrition at 12 months, with only 49% of individuals followed up. Thus, evidence for the effectiveness of internet interventions using brief behavioural support in a primary care setting is poor.

#### Added value of this study

Our results show that clinically important weight reduction is possible with a web-based behavioural program lasting 6 months combined with brief remote follow-up. Patients assigned to the web-based intervention and either face-to-face nurse support (POWeR+Face-to-face) or remote nurse support (POWeR+Remote) achieved roughly 1.5 kg more weight loss than those assigned to the control group (evidence-based dietetic advice and 6 monthly nurse follow-up). Furthermore, 30% of patients in the POWeR+ groups maintained 5% weight loss by 12 months, with less recourse to other weight loss activities and with no increase in health service costs.

#### Implications of all the available evidence

The weight loss achieved with POWeR+ was similar to that achieved with the best performing interventions evaluated in a primary care setting over a 12 month period, including those produced by face-to-face commercial programmes. When combined with very brief staff support, the POWeR+ program could be feasibly used in most practices and could make a clinically important contribution to the management of obesity. Future research should assess the extent to which clinically important weight loss can be maintained beyond 1 year.

behaviour-change expertise, and the little time available for counselling and follow-up, makes this approach challenging in the progressively resource-constrained primary care environment. A review<sup>6</sup> of randomised controlled trials in primary care (excluding trials with more than 30% attrition at 12 months, which is common in studies of obesity) showed little evidence of appropriately intensive behavioural counselling and suggested trained interventionists.

One alternative to a cadre of highly trained interventionists is to harness the capacity of the internet to help support behaviour change. Reviews suggest that automated interactive web-based interventions without human input can achieve greater weight loss than does no treatment or minimal interventions, but the evidence base included too many small, short-term trials in volunteer samples, arguing the need for large, pragmatic trials with at least 1 year of follow-up and including assessments of cost-effectiveness.<sup>7,8</sup> The trials identified by NICE mostly had expert lifestyle and behavioural input, and followed up patients intensively—on average 13 times per year during the first 12 months.<sup>4</sup> NICE also estimated that any intervention costing £100 per kg lost was likely to be

cost-effective if a 1 kg difference in weight was maintained for life. Automated interventions could be enhanced by human support, but although intensive support improves web-based weight management,<sup>9</sup> we are aware of no studies examining the effectiveness of brief support by primary care staff that is likely to be both more feasible and cost-effective. A 2015 review<sup>10</sup> identified nine studies comparing internet support with minimal intervention, but two studies had unusual populations (university staff; lactating women), and the only study to report fewer than ten contacts by behavioural counsellors documented less than 1.5 kg of weight loss and high attrition at 12 months, with only 49% of individuals followed up.

We did the POWeR+ trial to estimate the effectiveness and cost-effectiveness of a web-based behavioural weight management intervention (POWeR+) with either brief face-to-face nurse support or brief remote nurse support for obese patients managed in primary care.

## Methods

### Study design and patients

We did this pragmatic, parallel-group, randomised controlled trial at 56 primary care practices in central and

south England (around Southampton and Oxford). Up to 100 patients from each practice were randomly chosen, by use of computer-generated numbers, and invited to a screening appointment. Patients could also be referred opportunistically from routine practice appointments.

We enrolled individuals aged 18 years or older with a BMI of 30 kg/m<sup>2</sup> or more (or  $\geq 28$  kg/m<sup>2</sup> with hypertension, hypercholesterolaemia, or diabetes) as identified from general practitioner (GP) routine electronic health records. We excluded patients with severe mental health problems (eg, psychosis; difficulty completing outcomes), patients who were too ill to take part in a study such as this one or who were unable to change their diet (eg, individuals with severe heart, lung, kidney, bowel, or liver diseases), patients who were pregnant or breastfeeding, patients with a perceived inability to walk 100 m (physical activity difficult), and patients with another member of the household taking part or no regular access to the internet. The study was approved by the National Research Ethics Service Committee South Central—Southampton B (reference 11/SC/0455). All participants provided written informed consent.

### Randomisation and masking

Patients were given details of how to log in and register to the POWeR+ intervention, whereupon individuals were presented with baseline questionnaires. Upon completion of the questionnaires, the website automatically randomly assigned patients (1:1:1), via computer-generated random numbers, to one of three intervention groups: evidence-based dietetic advice and 6 monthly nurse follow-up (control group); web-based intervention and face-to-face nurse support (POWeR+Face-to-face [POWeR+F] group); or web-based intervention and remote support (POWeR+Remote [POWeR+R group]). Participants and investigators were masked to group allocation at the point of randomisation; masking of participants was not possible after randomisation. The 12 month weight measurement was masked whenever possible.

### Procedures

POWeR+ is a theory and evidence-based intervention to teach patients self-regulation and cognitive-behavioural techniques to form sustainable eating and physical activity habits for long-term weight management in a series of 24 web-based sessions designed to be used over 6 months, with novel content, links to external content, and email reminders. Patients initially chose either a low-calorie or a low-carbohydrate eating plan, but could change plans at any stage if they wished (appendix pp 1–4).

Participants assigned to the control group were directed to a set of two printable web-based pages with brief structured advice. This intervention was active, since it was intended to aid weight loss. The materials were developed by the Institute of Food Research to provide appealing strategies to minimise the pressure to cut down favourite foods, and to instead swap less healthy foods for healthier

choices (healthy foods swap sheet), or to increase fruit and vegetable intake (we used the National Health Service [NHS] five-a-day sheet). Our previous trial<sup>11</sup> documented 1.2 kg weight loss at 6 months when patients with hypertension received prompt sheets promoting healthy eating compared with a generic advice booklet. To enhance retention, participants were informed that this intervention had been shown to support weight loss. Nurses arranged brief follow-up (5–10 min appointments) with sufficient time to measure weight at 6 months and 12 months, but not to provide explicit counselling.

The aim of the POWeR+F intervention was to provide automated behavioural counselling, with just three scheduled (and four optional) face-to-face nurse support sessions, thus requiring substantially less health professional skill and time than the evidence-based lifestyle interventions documented in the NICE review,<sup>4</sup> and hence being much easier to implement in the NHS. In addition to weight recording every 6 months, as in the control group, participants had three scheduled face-to-face appointments in the first 3 months, and then up to four more appointments during a further 3 months if needed (ie, 6 months in total). Weight gain on two consecutive logins triggered an automated email to the nurse advising that the patient needed further support, or patients could request additional support.

The aim of the POWeR+R intervention was to assess whether even briefer professional support for the web intervention could be effective. Patients could access the same web-based intervention as in the POWeR+F group. In addition to weight recording every 6 months, as in the control group, participants had three scheduled phone or email contacts and up to two optional phone or email contacts in the first 6 months (triggered by weight gain or patient request, as in the POWeR+F group).

### Outcomes

The primary outcome was weight loss averaged over 12 months. Weight loss was measured with participants lightly clothed without shoes, at the same time every day when possible, with automated digital scales (Tanita Europe BV, Amsterdam, the Netherlands). Piloting suggested that intensive follow-up for anything but the primary outcome would increase dropout, we therefore focused on weight. As such, the final analysis plan (July 1, 2015), matching the clinical rationale for our original sample size, included a secondary analysis of weight—maintenance of 5% weight loss. This outcome is very important clinically,<sup>12,13</sup> and facilitated direct comparison with a previous UK primary care trial<sup>14</sup> published after our study commenced. Although there was no explicit measurement of the work of participants (ie, how much time was spent doing the intervention activities), other secondary outcomes included health service resource use, use of the website (pages accessed and time taken, recorded automatically by the website), how enabled patients felt (measured with the modified Patient Enablement Instrument<sup>15</sup>), and any

See Online for appendix

additional activities participants used to help lose weight. We also documented various other secondary outcomes (waist measurement, blood pressure, HbA<sub>1c</sub>, liver function tests, self-reported measures of physical activity, and diet; appendix p 11). We planned to use Actiheart monitors in a randomised subset of individuals, but organising this method at a time of intensive final follow-up became too difficult.

Participants had appointments for weight measurement with the practice nurse at baseline and 6 months, and an appointment or home visit by a nurse researcher masked to group allocation at 12 months. When a blinded weight measurement could not be obtained, we used practice nurses' recorded weights, and when that was not possible, we used participants' reported weights. Participants received a £10 gift voucher with the 12 month appointment notification letter as a thank you for participation, irrespective of whether an appointment was made. For self-reported measures, participants received three emails prompting online completion followed by a postal version of the questionnaire.

### Statistical analysis

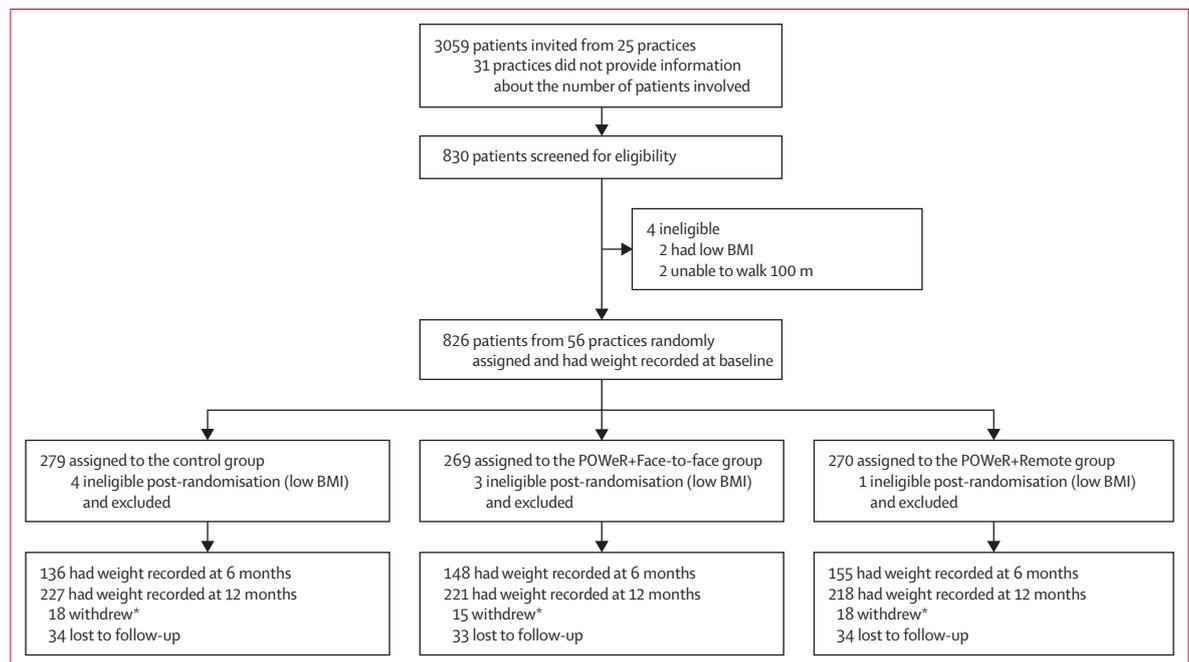
On Sept 25, 2013, the Trial Steering Committee advised an increase to the sample size to allow for clustering; this amendment required an extension to the planned recruitment period.

We allowed all groups to be compared with each other ( $\alpha 0.05/3=0.017$ ), but for the primary analysis compared each intervention group with the control group. For the primary outcome, we estimated that a standardised

effect size of 0.33 (equivalent to 2–3 kg difference assuming a standard deviation of change of 6.5–7.5 kg<sup>16,17</sup>), and 80% power, required 174 patients per group with complete data or 654 patients in total, allowing for a 20% loss to follow-up. After liaison with both the funder of the study and the Trial Steering Committee, the power calculation was revised on Sept 25, 2013, to allow for modest clustering at practice level if significant clustering was recorded. We assumed recruitment of 18 patients per practice to achieve 15 patients at follow-up, of whom roughly five to six patients would be in each of the two intervention groups at follow-up. Assuming five patients per group in each practice for an intracluster correlation of 0.05—ie, a design effect of 1.2 ( $1+[(5-1)\times 0.05]$ )—resulted in a minimum of  $654\times 1.2=785$  patients.

To avoid loss of data, on July 1, 2015, repeated measures ANOVA for the principal continuous outcome (ie, weight) was changed to mixed multivariate regression models to enable data to be used from any participant who had 6 months' or 12 months' data. We modelled the risk ratios compared with the control group for the number of patients achieving 5% weight loss. All regression models controlled for weight at baseline, sex, age, smoking, diabetes, medications (including orlistat used at baseline), any comorbidities, deprivation (Index of Material Deprivation 2010), and any clustering by practice. No interim analyses were undertaken.

Intention-to-treat analysis used both measured and reported weights in a multiply imputed dataset (based on



**Figure: Trial profile**

\*Reasons for withdrawal: the patient's situation changed (eg, pregnancy, moved house; n=18), the patient disliked their group (n=8), the patient had no time to participate or changed their mind (n=4), or no reasons were given (n=21).

50 replications). Secondary analyses used both complete cases and measured weights.

We explored whether there was significant effect modification in subgroups using interaction terms in the models. Key pre-identified subgroups were baseline waist measurement (high or very high waist *vs* low waist; men: high 94 cm, very high 102 cm; women: high 80 cm, very high 88 cm), and presence of metabolic syndrome (syndrome *vs* no syndrome). Metabolic syndrome<sup>18</sup> was defined as the presence of three out of five conditions: elevated waist circumference (>94 cm for men, 80 cm for women), triglyceride concentrations of 1.7 mmol/L or more, reduced HDL-cholesterol (<1.00 mmol/L in men, <1.3 mmol/L in women), raised blood pressure (systolic >130 mm Hg or diastolic >85 mm Hg, or treatment of high blood pressure), and elevated fasting glucose ( $\geq 5.6$  mmol/L).<sup>18</sup> We also explored outcomes according to the type of diet chosen by patients.

We obtained data for health service resource use from case-note review of medication, primary care visits, outpatient consultant, obesity-related admissions to accident and emergency and hospital (eg, for management of obesity and disorders affected by obesity, such as cardiovascular disease, control of asthma, and musculoskeletal problems [hip, back, and knee]; appendix pp 5–8). For the cost-effectiveness analysis, we measured outcomes as incremental costs per kg weight loss; we imputed missing data and used bootstrapping methods to produce confidence intervals. We did analysis with Stata (version 14).

### Role of the funding source

The funder of the study had no role in study design, data collection, data interpretation, data analysis, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

### Results

Figure 1 shows the trial profile. Between Jan 30, 2013, and March 20, 2014, 826 patients underwent randomisation. After exclusion of eight participants identified as ineligible post-randomisation, 818 individuals were randomly assigned to the control group (n=279), the POWeR+F group (n=269), or the POWeR+R (n=270). 439 (54%) patients had a weight recorded at 6 months' follow-up and 666 (81%) patients had a weight recorded at 12 months. 510 (77%) of the 666 recordings were blinded, 28 (4%) were unblinded, and 128 (19%) were self-reported. The number of self-reported measurements was similar between groups (control n=40, POWeR+F n=48, POWeR+R n=40). Baseline characteristics were generally well balanced (table 1). The practice intracluster correlation for weight in the repeated measures analysis was 0.01 (95% CI 0.003–0.09) when controlling for baseline weight.

Of the 539 participants randomised to the POWeR+ intervention groups, 524 (97%) participants started the first

session and 404 (75%) participants completed all three core sessions (n=208 in the POWeR+F group and n=196 in the POWeR+R group). Participants completed a mean of 10.97 (SD 12.65) weight and goal reviews (range zero to 52), with a mean of 10.16 (11.92) completed reviews in the POWeR+F group and 11.85 (13.38) in the POWeR+R group. The median number of nurse contacts was four (range zero to seven) in both intervention groups, with a median of two (IQR one to three) face-to-face contacts, one (zero to two) phone contact, and one (zero to two) email contact in the POWeR+F group, and a median of one (zero to two) phone contact and three (two to four) email contacts in the POWeR+R group. We recorded a 2–2.5 kg difference in weight reduction for participants who completed more than the first basic stage of the program.

Patients in the control group maintained a weight loss of almost 3 kg in total over 12 months (table 2). The primary imputed analysis showed that compared with the control group, patients in the POWeR+F group achieved an estimated additional 1.5 kg reduction averaged over 12 months and patients in the POWeR+R group achieved an additional 1.3 kg reduction (table 3). A secondary analysis of only the complete cases showed a greater weight reduction at 12 months in the intervention groups than in the control group (POWeR+F: –1.78 kg, 95% CI –2.81 to –0.76; p=0.001; POWeR+R: –1.6 kg, –2.6 to –0.6; p=0.002; appendix pp 9, 10).

By month 12, with data for complete cases, the proportion of patients maintaining a 5% reduction in weight or more

	Control group (n=279)	POWeR + Face-to- face group (n=269)	POWeR + Remote group (n=270)
Age (years)	52.69 (13.25)	53.70 (13.21)	54.74 (12.95)
Sex			
Female	185 (66%)	175 (65%)	160/269 (60%)
Male	94 (34%)	94 (36%)	109/269 (40%)
Smoker	24 (9%)	21 (8%)	25/269 (9%)
Diabetes	48 (17%)	46/268 (17%)	42 (16%)
Orlistat use	3/270 (1%)	5/262 (2%)	5/266 (2%)
Comorbidity	48 (17%)	55 (20%)	55 (20%)
Deprivation score (IMD 2010)	14.32 (10.45)	13.73 (10.28)	13.29 (10.17)
Weight (kg)	104.38 (21.11)	102.40 (16.87)	102.93 (18.26)
BMI (kg/m <sup>2</sup> )	37.10 (5.97)	36.66 (5.36)	36.28 (5.65)

Data are mean (SD), n (%), or n/N (%), unless otherwise specified. Data were missing for some individuals. IMD=Index of Material Deprivation.

**Table 1: Baseline characteristics**

	Baseline	6 months	12 months
Control group	104.38 (21.11); n=279	101.91 (19.35); n=136	101.73 (19.57); n=227
POWeR+Face-to-face group	102.40 (16.87); n=269	97.55 (15.99); n=148	98.56 (15.95); n=221
POWeR+Remote group	102.93 (18.26); n=270	98.30 (18.34); n=155	99.72 (18.88); n=218

Data in parentheses are SDs.

**Table 2: Crude mean weights for complete cases at baseline, 6 and 12 months**

was 19% in the control group, 28% in the POWeR+F group, and 32% in the POWeR+R group; the imputed estimates were 21%, 29%, and 32%, respectively (table 4).

We reviewed 753 case notes from the GP electronic health records for 12 months after recruitment. Mean intervention costs were low both per person using the services (£22 [95% CI 21–23] for POWeR+F and £12 [11–13] for POWeR+R) and for all participants in each group (£17 [15–18] and £9 [8–10], respectively). Addition of the estimated cost of the website raised the overall costs for all participants to £18 [95% CI 16–19] in the POWeR+F group and £10 [9–11] in the POWeR+R group. We recorded greater differences in overall costs for estimated overall NHS resource use related to obesity in the intervention versus the control groups (appendix pp 7, 8). Bootstrapping analysis showed that differences in costs compared with the control group were £23 for POWeR+F and -£36 for POWeR+R; neither of these differences was statistically significant (table 5). The estimated incremental overall NHS cost per kg weight loss was £18 for POWeR+F and -£25 for POWeR+R (table 5)—ie, POWeR+R was more effective and cost less than the control strategy. The probability of cost-effectiveness was more than 80% in cost-effectiveness acceptability curves for both POWeR+F and POWeR+R versus control (88% and 98%, respectively; appendix pp 8, 9).

For patients returning the final questionnaire, almost half the people in the control group were doing additional activities, compared with almost two-fifths in the POWeR+F group and only a quarter in the POWeR+R group (table 6). Participants in the intervention groups also felt more enabled to manage their weight problem than did those in the control group (table 6).

Due to the priority to obtain follow-up data for weight, and the clear feedback from piloting suggesting that

pressurising participants to have blood taken was off-putting, achievement of high follow-up for blood samples was necessarily a secondary priority; therefore, only a small number of participants had follow-up blood measurements. The available results suggest generally positive directions of outcomes in the POWeR+ groups versus the control group, although changes were mostly non-significant (raised HDL cholesterol, lower aspartate transaminase and alanine transaminase, lower HbA<sub>1c</sub>; appendix pp 12–14). The low completion rate of the EuroQol-5D (EQ-5D) questionnaire reduces the reliability of these data; as such, the direction of change in EQ-5D scores is difficult to interpret, particularly because the estimate of direction of change varies dependent on whether we controlled for baseline values (appendix p 18).

Body fat percentage and blood pressure were recorded in most participants at follow-up (n=454 and n=494, respectively), and although there were no consistent changes in blood pressure in any of the three groups, fat mass was slightly reduced at 12 months in both POWeR+ groups (appendix p 15).

In subgroup analysis, we recorded some evidence of a reduced effect of the POWeR+F group at 6 months in patients with metabolic syndrome, but no significant effect of type of diet chosen (appendix p 9). No harms were reported during the study

### Discussion

This study is one of few to compare simple weight management interventions using primary care staff for support to manage obesity. Clinically important weight loss (5% reduction) was achieved by some participants in the control group, and the crude mean weight reduction by 12 months was not significantly lower in the POWeR+ behavioural web-based intervention groups. However, in the POWeR+ groups, significantly more weight loss occurred over 12 months, and more participants maintained clinically important weight reduction and felt enabled to manage their weight. This outcome was achieved with no increase in health service costs despite brief nurse remote support.

Individuals who take part in trials are likely to be fairly well motivated, but participants are also the intended target group in whom intervention is likely to be most helpful. The present study was large and pragmatic,

	6 months	12 months	Overall*
POWeR+Face-to-face group	-2.54 (-3.66 to -1.42; p<0.001)	-0.37 (-1.66 to 0.92; p=0.566)	-1.49 (-2.41 to -0.58; p=0.001)
POWeR+Remote group	-1.97 (-3.18 to -0.76; p=0.002)	-0.58 (-1.88 to 0.72; p=0.375)	-1.27 (-2.19 to -0.34; p=0.007)

Data in parentheses show 95% CI; p value. Analysis based on 50 imputations. \*Repeated measures.

**Table 3: Difference in weight loss (kg) for POWeR+ versus control, with imputed data**

	Complete cases				Imputed data			
	≥5% reduction in weight		Risk ratio versus control		≥5% reduction in weight		Risk ratio versus control	
	6 months	12 months	6 months	12 months	6 months	12 months	6 months	12 months
Control	16/136 (12%)	42/227 (19%)	1.00	1.00	15.9%	20.8%	1.00	1.00
POWeR+ Face-to-face	59/148 (40%)	62/221 (28%)	3.42 (2.10–5.56; p<0.001)	1.46 (1.02–2.08; p=0.036)	36.8%	29.2%	3.10 (1.85–5.18; p<0.001)	1.56 (0.96–2.51; p=0.070)
POWeR+Remote	55/155 (35%)	69/218 (32%)	3.02 (1.89–4.83; p<0.001)	1.67 (1.17–2.37; p=0.004)	33.7%	32.4%	2.64 (1.60–4.36; p<0.001)	1.82 (1.21–2.74; p=0.004)

Data are n/N (%) or risk ratio (95% CI; p value), unless otherwise specified.

**Table 4: Patients maintaining at least 5% weight loss from baseline to months 6 and 12**

mimicking the everyday conditions in primary care settings; therefore, patients in the control group were not closely regulated and so undertook other activities to lose weight. However, this factor is also a strength because resulting estimates are more reflective of real-world practice. Participants with obesity in primary care settings are notoriously difficult to follow up, but we achieved follow-up of more than 80% of individuals at 12 months. Loss to follow-up was similar between groups, which reduces the effect of missing data. Furthermore, we imputed data for the primary analysis, thus providing more conservative estimates of effectiveness than complete cases. However, in practice, multiple imputation modified the estimates only slightly, which suggests that attrition bias was not a major issue. On the basis of the experience of piloting, whereby pressure to achieve follow-up of both primary and secondary outcomes resulted in participants dropping out, our efforts were concentrated on maximising the primary outcome, which resulted in fewer secondary outcomes being available. As a result, even though estimates used multiple imputation, the results for blood samples should be interpreted cautiously. Nevertheless, we recorded significant weight loss irrespective of the method of specifying the weight outcome (average reduction over 12 months as specified in the funding application, or clinically important [5%] weight loss at 6 months or 12 months), and most secondary outcomes also changed in positive directions, albeit mostly not significantly, suggesting that selective reporting and type I error are less likely.

In the control group, we observed 3% loss in weight, and 12% and 19% of participants in this group maintained a clinically important weight loss (5%) at 6 and 12 months, respectively. These results are consistent with our previous findings,<sup>11</sup> showing that a brief intervention promoting the use of simple sheets for food swaps and five-a-day fruit and vegetable consumption aids weight control. Some of the effective weight management in this group might also be due to the motivational effects of regular follow-up weighing by the nurse, and to the undertaking of additional activities to help themselves (which about half of participants did). By contrast, fewer individuals offered the POWeR+ interventions undertook other activities, and they felt significantly more enabled to manage their weight.

Systematic reviews<sup>4,6,19</sup> of interventions in other settings and primary care suggest that both intensive dietetic behavioural counselling and intensive follow-up are usually necessary to achieve effective weight reduction. However, we found that a behavioural web-based intervention such as POWeR+ was effective with just a few brief phone calls and emails, plus weight monitoring every 6 months. The weight loss achieved with POWeR+ compares favourably with other internet-based interventions, which, on average (albeit with high heterogeneity), have led to only short-term weight loss, of less than 1 kg weight loss compared with no treatment, or less than 2 kg when combined with face-to-face support,

	Mean difference in overall costs (£)	Mean difference in weight lost (kg)	Incremental cost (£) per kg of weight lost
POWeR+ Face-to-face versus control	23 (-105 to 152)	1.49 (0.58 to 2.41)	18 (-129 to 195)
POWeR+Remote versus control	-36 (-154 to 81)	1.27 (0.34 to 2.19)	-25 (-268 to 157)

Based on imputed data with repeated measures. Data in parentheses are 95% CIs.

**Table 5: Incremental overall National Health Service cost per kg of weight lost in the POWeR+ groups versus the control group**

	Control group	POWeR+Face-to-face group	POWeR+Remote group
<b>Additional activities</b>			
Took part in regular activity for long enough to produce sweat			
Rarely	50/135 (37%)	38/134 (28%)	39/146 (27%)
Sometimes	57/135 (42%)	69/134 (51%)	77/146 (53%)
Often	28/135 (21%)	27/134 (20%)	30/146 (21%)
Took part in another weight loss			
WeightWatchers or Slimming World (or similar) meetings	23/136 (17%)	22/137 (16%)	14/150 (9%)
Another weight management website	0/135	4/136 (3%)	4/150 (3%)
Mobile phone application	13/136 (10%)	8/136 (6%)	10/149 (7%)
Weight loss pills	5/136 (4%)	4/137 (3%)	2/150 (1%)
Health trainer programme	4/136 (3%)	2/136 (1%)	3/148 (2%)
Exercise referral scheme	4/136 (3%)	7/137 (5%)	4/148 (3%)
Another weight loss scheme	8/136 (6%)	13/136 (10%)	8/149 (5%)
Any other weight management method	22/97 (23%)	13/87 (15%)	8/103 (8%)
<b>Patient enablement</b>			
Item score at baseline	3.19 (1.27)	3.42 (1.19)	3.31 (1.26)
Item score at 12 months	3.23 (1.57)	4.10 (1.28)	3.85 (1.35)
Difference in enablement score versus control group	..	0.70 (0.39-1.01; p<0.0001)	0.54 (0.24-0.85; p<0.0001)

Data are n/N (%), mean (SD), or difference (95% CI; p value).

**Table 6: Additional activities undertaken over 12 months, and patients' enablement in managing their weight**

based on a review of predominantly motivated volunteer samples.<sup>20</sup> Improved weight loss (around 5 kg) with an internet-based program has only been achieved with much more intensive human support (eg, weekly 20 min contact for 12 weeks, and then monthly up to 24 month follow-up<sup>9</sup>). Encouragingly, the weight loss achieved with POWeR+ was similar to that achieved with the best-performing interventions<sup>21</sup> evaluated over 12 months in a primary care setting, including those produced by face-to-face commercial programmes.

The estimates of resource use suggest that neither intervention was resource intensive. Considering overall NHS costs, fewer NHS resources were used in the POWeR+R group, mainly due to reduced primary care costs. In view of the variability of cost estimates, these results should be treated with some caution, but health service costs are unlikely to be significantly increased with the remote POWeR+ intervention. We also recorded that POWeR+ users felt significantly more enabled to manage their condition, so if individuals can be enabled to manage

their own condition without needing significant face-to-face contact, this could empower self-management more generally. Previous modelling by NICE showed that at least a 1 kg per head weight loss among overweight or obese adults is likely to be cost-effective, provided that the cost per person of intervening is less than £100 and the weight difference is maintained for life. The present results suggests that irrespective of whether intervention costs or overall costs are used, both POWeR+ interventions achieve weight losses at a cost per kg that is less than required by NICE.<sup>4</sup> The POWeR+ intervention was for 6 months, but the number of patients maintaining clinically important weight loss remained steady up to 1 year, which suggests that long-term benefit could be achieved. However, future research should assess the extent to which clinically important weight loss can be maintained beyond 1 year.

#### Contributors

PL devised the protocol, led protocol development and the funding application, supervised the running of the lead study centre and coordination of centres, contributed to the analysis, and led the drafting of the report. FDRH developed the protocol for funding, contributed to management of the study, supervised the Oxford study centre, and contributed to drafting of the report. JK and ERS (senior trial managers) developed the protocol, provided day-to-day overall management of the study, coordinated recruitment in the lead study centre and coordination of other centres, and commented on drafts of the report. MD coordinated the Oxford study centre. JH provided coordination and data management for the Southampton study centre. GY, SZ, and JR (health economists) developed the protocol for analysis of data from the medical notes reviews and contributed to the drafting of the paper. JR contributed to the management of the study and supervised the analysis of data for resource use. KJB and SH (health psychologists) contributed to protocol development, were responsible for the day-to-day development and piloting of the intervention, and commented on drafts of the report. MVM developed the protocol for funding, contributed to management of the study, and contributed to the analysis and drafting of the report. BS (study statistician) and PWFS developed the analysis protocol, did the quantitative analysis, and contributed to drafting of the report. LY developed the protocol and funding application with PL, led the development of the intervention, contributed to daily supervision of website issues, contributed to broader study management, and contributed to drafting of the report. MEJL, BMM, and CDB developed the protocol for funding, contributed to management of the study, and contributed to drafting of the report.

#### Declaration of interests

We declare no competing interests. The views expressed in this publication are those of the authors and not necessarily those of the Health Technology Assessment Programme (HTA), the National Health Service, the National Institute for Health Research (NIHR), or the Department of Health.

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#### References

- 1 Troiano RP, Frongillo EA Jr, Dohal J, Levitsky DA. The relationship between body weight and mortality: a quantitative analysis of combined information from existing studies. *Int J Obes Rel Metabol Dis* 1996; **20**: 63–75.
- 2 National Institutes of Health (NIH), National Heart Lung and Blood Institute. Clinical guidelines on the identification and treatment of overweight and obesity in adults. Bethesda, MD: NIH, 1998.
- 3 Department of Health; Joint Surveys Unit of Social and Community Planning Research; Department of Epidemiology and Public Health, University College London. Health Survey for England 1996. London: HMSO, 1998.
- 4 Obesity guideline development group, National Institute for Health and Care Excellence. Obesity full guideline. 2006. <http://guidance.nice.org.uk/CG43/guidance> (May 15, 2016).
- 5 Avenell A, Broom J, Brown T, et al. Systematic review of the long term effects and economic consequences of treatment for obesity and the implications for health improvement. *Health Technol Assess* 2004; **8**: iii–iv, 1–182.
- 6 Wadden T, Butryn M, Hong P, Tsai A. Behavioral treatment of obesity in patients encountered in primary care settings: a systematic review. *JAMA* 2014; **312**: 1779–91.
- 7 Wieland LS, Falzon L, Sciamanna CN, et al. Interactive computer-based interventions for weight loss or weight maintenance in overweight or obese people. *Cochrane Database Syst Rev* 2012; **8**: CD007675.
- 8 Tang J, Abraham C, Greaves C, Yates T. Self-directed interventions to promote weight loss: a systematic review of reviews. *J Med Internet Res* 2014; **16**: e58.
- 9 Appel LJ, Clark JM, Yeh H-C, et al. Comparative effectiveness of weight-loss interventions in clinical practice. *N Engl J Med* 2011; **365**: 1959–68.
- 10 Hutchesson MJ, Rollo ME, Krukowski R, et al. eHealth interventions for the prevention and treatment of overweight and obesity in adults: a systematic review with meta-analysis. *Obes Rev* 2015; **16**: 376–92.
- 11 Little P, Kelly J, Barnett J, Dorward M, Warm D, Margetts B. Randomised controlled factorial trial of dietary advice for patients with a single high blood pressure reading in primary care. *BMJ* 2004; **328**: 1054–60.
- 12 Tuomilehto J, Lindstrom J, Eriksson J, et al. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *N Engl J Med* 2001; **344**: 1343–50.
- 13 Knowler W, Barrett-Connor E, Fowler S, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med* 2002; **346**: 393–403.
- 14 Jolly K, Lewis A, Beach J, et al. Comparison of range of commercial or primary care led weight reduction programmes with minimal intervention control for weight loss in obesity: Lighten Up randomised controlled trial. *BMJ* 2011; **343**: d6500.
- 15 Little P, Lewith G, Webley F, et al. Randomised controlled trial of Alexander technique lessons, exercise, and massage (ATEAM) for chronic and recurrent back pain. *BMJ* 2008; **337**: a884.
- 16 Sjostrom L, Rissanen A, Andersen T, et al. Randomised placebo-controlled trial of orlistat for weight loss and prevention of weight regain in obese patients. European Multicentre Orlistat Study Group. *Lancet* 1998; **352**: 167–72.
- 17 Rothert K, Strecher V, Doyle L, et al. Web-based weight management programs in an integrated health care setting: a randomized, controlled trial. *Obesity* 2006; **14**: 266–72.
- 18 Alberti K, Eckel R, Grundy S, et al. Harmonizing the metabolic syndrome: a joint interim statement of the International Diabetes Federation Task Force on Epidemiology and Prevention; National Heart, Lung, and Blood Institute; American Heart Association; World Heart Federation; International Atherosclerosis Society; and International Association for the Study of Obesity. *Circulation* 2009; **120**: 1640–45.
- 19 Neve M, Morgan P, Jones P, Collins C. Effectiveness of web-based interventions in achieving weight loss and weight loss maintenance in overweight and obese adults: a systematic review with meta-analysis. *Obesity Rev* 2010; **11**: 306–21.
- 20 Kodama S, Saito K, Tanaka S, et al. Effect of Web-based lifestyle modification on weight control: a meta-analysis. *Int J Obes* 2012; **36**: 675–85.
- 21 Hartmann-Boyce J, Johns D, Jebb S, Summerbell C, Aveyard P. Behavioural weight management programmes for adults assessed by trials conducted in everyday contexts: systematic review and meta-analysis. *Obes Rev* 2014; **15**: 920–32.