Health Technology Assessment Programme

NHS
National Institute for Health Research

NIHR HTA Programme

23 August 2012

POWER Positive Online WEight management in Routine care

Sponsor: University of Southampton

Chief Investigator:
Prof Paul Little
Prof of Primary Care Research
Community Clinical Sciences Division
University of Southampton
Aldermoor Health Centre
Aldermoor Close
Southampton
Hants
SO16 5ST

p.little@soton.ac.uk
02380241050

Research Objectives:

To estimate the effectiveness and cost-effectiveness of a) an internet based behavioural intervention with face to face support as needed and b) an internet behavioural intervention with minimal face to face support among obese patients in primary care.

Design Summary.
This study is in two phases:
1) Phase I (12 months): research governance arrangements will be finalised, practices recruited and trained in study procedures and intervention, the development of the website will be extended to address maintenance issues, and testing will take place to ensure the full trial protocol works seamlessly.
2) Phase II. A randomised trial will compare management using a) web intervention with nurse support; b) web intervention with minimal nurse support; c) brief structured advice and follow up for weighing.

Methods:
Phase 1 (0-12 months): further development of the website for maintenance and relapse.

Development of support for weight maintenance. Regular self-monitoring of weight and rapid action to correct relapse is crucial to weight maintenance, and so we will create a series of 24 brief (2 page) maintenance-oriented web-based sessions with novel and interesting content and links to encourage patients to continue to use the website to track their weight at least bi-weekly (preferably weekly); similar content has recently been successful in achieving 65% adherence at 28 months without face-to-face support [12]. After mandatory weight entry patients will receive tailored feedback giving encouragement and virtual rewards if maintaining weight loss (e.g. reminders of health benefits accrued; 'achiever class' awards, with emails notifying nominated support people of achievements, including nurse). Weight gain will trigger initial referral to an automated 'recovery package' including reminders, personalised messages preset by the patient and new advice concerning appropriate goal-setting, boosting motivation, planning for and recovering from difficult times (e.g. holidays), overcoming difficulties etc. Weight gain on two consecutive logins will trigger nurse input (if randomised to receive this). Failure to login for more than 2 weeks will trigger automated reminders and motivating messages.

Patient Interviews

Intensive qualitative piloting will be carried out to ensure that these new web-based sessions are accessible and engaging, and to inform modification of them as necessary. For this purpose we will use a panel of over 30 people recruited for piloting the weight loss intervention; these will be participants who indicated on their consent form that they would be prepared to be approached. Face-to-face 'think-aloud' sessions[13,] **and telephone interviews** will be used to elicit and observe immediate responses to every aspect of each session. Users will be invited to use the website for consecutive weeks and months while keeping a semi-structured diary recording their reactions and experiences; diary data will be analysed and participants interviewed retrospectively about their experiences over this period. Thematic analysis [14] will be employed to identify common reactions to the website and experiences of the intervention and inform iterative modification. This process will be continued until no significant modifications to the website appear to be required.

Healthcare professional process interviews

Following the completion of all nurse support appointments, practice staff with experience of recruiting and/or supporting patients recruited to the study will be invited to take part in an interview in order to understand their experiences of delivering the study and working with patients in the study. Views about the website and the study procedures will be sought in order to improve our understanding of the deployment of the programme within primary care and inform future programme development.

Phase 2. RCT

Inclusion criteria. Adult patients with BMI >=30 (or 28 with hypertension or hypercholesterolaemia) documented in the GP case records[12] will be eligible.

Exclusions: Current major mental problems e.g. psychosis (difficulty completing outcomes); very ill or unable to change diet (e.g. severe LVF); pregnancy, or breast feeding; perceived inability to walk 100 metres (physical activity difficult).

Invitation of patients/recruitment. Up to 100 patients in each practice will be randomly chosen from GP electronic records, and invited by letter to a screening appointment to confirm eligibility; with 15-20 patients per practice being recruited to the trial. Patients can also be referred opportunistically when seen in practice nurse or GP clinics. Recruitment will take place over 6 months in up to 44 practices from the South West and South East Hubs of the PCRN.

Randomisation and informed consent. At the screening appointment the practice nurse will take written, informed consent and the patients' details in each practice will be sent to an external randomisation line to allow stratification of randomisation - gender; waist (>102 cm men; >88cm women); BMI >=35; Index of material deprivation score (>median); partner in the household; source of patients (invited by mailing or opportunistically invited). Practice staff will inform patients of their group indicating the nature and timing of contacts (and with the personalised website password as appropriate in the web group).

Planned interventions

1) Control: Very brief advice and follow-up. The practice nurse will provide brief structured advice (less then 5 minutes) about a healthy diet (healthy food swaps) and physical activity (advice to take 30 minutes of moderate intensity exercise per day) using brief written materials. For follow-up, nurses will arrange very brief follow-up (5 minute appointment) with sufficient time for measurement of weight only at 6 months and 12 months. Nurses will not have time to perform counselling, and will also actively be instructed to provide supportive comments only - and not to engage in active behavioural intervention over and above the brief structured advice.

2) Web intervention with nurse support. The aim in this group is to provide a more intensive evidence-based intervention, but which should require less than half the time of traditional face to face evidence-based lifestyle interventions. The intervention components are as follows:

- **Physical activity.** Diet and physical activity targets supported by drug treatment as necessary are based on NICE guidance. Participants will be given targets of at least 2.5 hours of moderate intensity physical activity per week (brisk walking), and, where walking is the preferred physical activity, will be encouraged, where possible, to aim for at least 10,000 steps per day supported by pedometers[40]. Observational studies suggesting 1500-2000 Kcal per week may be required to maintain weight loss - and thus a flexible approach will be used to increase the target amount of physical activity if necessary[7].

- **Diet.** Participants will be given the choice of either low calorie or low carbohydrate approaches (based on a strong preference expressed in the pilot phase by patients for a choice of dietary approaches). These eating plans are intended to achieve a sustainable rate of weight loss of 0.5-1Kg a week [17]; a graded approach to negotiating more demanding dietary targets will be used if no weight loss is occurring. Patients who have succeeded in losing 5% of body weight will be given the choice of continuing to pursue gradual weight loss or attempting to maintain this weight loss.
  Low Calorie eating plan: the website provides a choice of dietary behavioural components (e.g. portion size, food swaps, calorie counting, meal spacing etc) to achieve a 600Kcal deficit diet[18]; *Low carbohydrate eating plan*: this will consist of an induction phase (<50g carbohydrate) for 2 weeks, followed by targets intended to produce ongoing weight loss (50-80g carbohydrate). This low carbohydrate eating plan differs from current commercial diets (e.g. Atkins) in ensuring at least 5 fruit and vegetable portions after the first 2 weeks.

- **Web-based self management.** Key principles adopted for development of our intervention were that it should a) be theory- and evidence-based[4], b) be accessible and engaging, c) should offer users who have become sceptical about the efficacy of diets a novel, empowering self-management approach [9;19], d) have a positive, sustainable focus on forming flexible healthy eating and physical activity habits rather than prescribing restrictive, complex, or intrusive regimes[9;10;17;18] e) be fully integrated with the nurse support (for those receiving it), f) take a graded approach to target-setting, ensuring the patient experiences early success in achieving goals [17;21] . Using the MRC-recommended approach to developing complex interventions [22], key evidence-based elements and behaviour change techniques[23] we have identified for inclusion are: goal-setting, planning and self-monitoring[23;24], techniques to enhance motivation and self-confidence[1;21] , change self-defeating cognitions[25] and create an environment that reduces cues to unhealthy eating and prompts and rewards healthy eating and physical activity [26;27], 'success stories' and evidence summaries that demonstrate how these techniques have been used by others to overcome barriers to weight loss[21]; a discussion board with expert feedback from the nurse [3;28], and email and text reminders [22;28].
  In the introductory orientation session the patient chooses their eating plan and initial personal goals and logs their weight. The first and all subsequent sessions conclude with an index of recommended, trustworthy links to relevant further web resources (e.g. on NHS Choices), including meal swap plans, calorie counters, motivating videos of success stories etc. All subsequent sessions commence with asking the patient their weight and whether they achieved the goals set the previous week, and then give feedback tailored to their progress (e.g. achieved goals but did not lose weight triggers pages on setting more demanding goals; did not achieve goals or lose weight triggers pages on increasing motivation, overcoming barriers or choosing different goals). The second session, after providing feedback relevant to progress during the first week, focuses on obtaining support from family and friends, the website (including setting personalised email and text message reminders) and the nurse. The third session offers a choice between a web-based adaptation of a well-validated primary care intervention to promote regular walking[1]

reinforced by pedometer use[8] , or setting personal physical activity goals. The patient can select all subsequent weight loss sessions from a menu which includes coverage of healthy drinking patterns, relapse prevention, and coping with cravings, stress-induced eating, busy times and social pressures.

- **Nurse support.** Very brief appointments for weight measurement at 6 months and 12 months (final follow-up) will occur as in the control group. In addition all patients will be offered brief face to face behavioural assessments at 2 weeks, 6 weeks, and 3 months. If a rate of weight loss equivalent to 5% weight loss over 6 months is not being achieved or maintained - which we anticipate could be up to half the cohort - face to face appointments will be made, up to a maximum of 4 more appointments in total in the first year (which is half the number of the average face to face appointments for dietary and behavioural counselling from trials documented in the NICE review[5]). In line with NICE guidance[5] if 5% weight loss in not achieved Orlistat will be offered; it will be stopped according to standard stopping rules [5]. Orlistat can also be used for weight maintenance[5]. The purpose of the nurse contacts is to provide reinforcement, and also to be able to help patients address ongoing or new issues where the web has provided limited support. Where issues arise the approach will be to encourage patients to find their own solutions to the problems raised.
- **Other features.** Based on previous evidence from systematic review of particular strategies to encourage maintenance of weight loss[11], patients will asked to participate in web based peer interaction, and to involve the family or spouse to help limit weight regain.

3) Web intervention with minimal face to face support. This group aims to provide a very brief intervention with minimal face to face contact time which therefore could be applied more rapidly and extensively in the NHS. Patients will work through the website, will be prompted to use it regularly by email, and brief face to face contact for weighing only at 6 and 12 months as in the control group. In addition this group will have a brief (10 min) face to face consultation at 2 weeks to confirm the physical activity and dietary targets, 3 brief online contacts at 1, 2, and 3 months and up to 2 further telephone contacts (i.e. 3 brief additional personal contacts compared with the control group until final follow-up) for patients not losing 5% of weight.

Support and training for Nurses. We have shown in piloting that nurses can learn to use the structured intervention materials both easily (i.e. requiring relatively little training) and effectively. The web pages for nurses a) provide a brief overview of the rationale, philosophy and structure of the intervention, b) provide a structured guide to the content of each patient support session c) give nurses access to an overview of their patients' progress and the content of each session, and d) send email reminders and notifications to nurses when patient support sessions are required (at timed intervals and if patient not using website or not losing weight), and include a tick-box record for nurses to complete logging what support has been provided.

Proposed time period for retention of relevant trial documentation
Trial documentation will be kept for 15 years.

Proposed outcomes/data collection (at baseline and unless specified at 6 and 12 months).
Primary outcome measure:
Weight (primary outcome): lightly clothed, without shoes, at the same time each day, and using automated Tanita digital scales (which will also allow measurement of body composition).
Secondary outcome measures:
Food and drink consumption and physical activity (at baseline and final follow-up): These behavioural measures (and intentions/attitudes to behaviour – see below) will be made in the intervention group at baseline and follow-up but in the control group only at final follow-up to avoid

such measurement being a prompt for behaviour change in the control group.

Physical activity: Using the validated Godin leisure time physical activity questionnaire and physical activity monitors[29,30]. Activity monitors have well documented limitations in validity, although may provide an adequate proxy to estimate between group differences. One third of the sample will in addition be randomised to wear the Actiheart monitors which will allow much more precise estimation of physical activity.

Food and drink consumption: Using validated brief FFQs for major food groups and also alcohol developed by our group for use in primary care.[31,32]

Indices of the metabolic syndrome (waist,BP,glucose,TG,HDL)[33-36]. Individuals with the metabolic syndrome are at particular risk. We will report the number (%) in each group using a definition of 3 out of 5 of high measurements[37], and a continuous outcome based on the mean z score for each individual (or mean rank as appropriate) - supported by empirical evidence of a close factor structure among the variables[38];

Waist: nurses will measure waist midway between the lower ribs and the iliac crests[39]also height, hip, skin fold thickness – to allow estimation of BMI, waist hip ratio, and fat mass [40; 41]

Blood pressure (BP) [42]: Measured 3 times (after 5 min) using a validated OMRON[43;44];

Serum measures: Liver function tests (particularly to monitor non alcoholic fatty liver disease), fasting serum cholesterol/HDL/LDL/triglyceride (TG) [41,45,46 47] glucose, HbA1c and insulin[48,49] (which would be expected to be modified by weight reduction); also ferritin (important to measure due to reducing cereals (a key source of iron) in the low carbohydrate diet)

Patient satisfaction and understanding. Simple Likert scale responses are reliable and valid.[59];

SF36[50]: The eight scales have been shown to be valid in a wide range of conditions in primary care;

EuroQol[51;52] (EQ-5D): the EuroQol provides a measure of quality of life for economic analysis;

Psychological status: Using the Hospital Anxiety and Depression scale[50] and brief state anxiety.[53] Obesity is associated with psychological morbidity,[54] and distress, anxiety and depression may be changed by physical activity[55];

Adherence and predictors of adherence. We will measure intention to change behaviour for each specific behaviour, and other items based on components of the TPB[56] (attitudes, social norms, perceived behavioural control) [2;15;16 56]. We will measure behavioural adherence through self report which is likely to strongly predict weight loss[35]. All website usage is automatically recorded, including frequency and duration of logins, options selected and all data inputted (e.g. weekly goal achievement).

Outcome measurement: At the appointments with the practice nurse (baseline, 6 months, 12 months), the physiological measurements will be performed, and patients weighed; research staff blind to group will also perform a final weight measurement at 12 months. For the few patients who do not provide questionnaire answers we will perform up to 2 emails/mailings, and telephone follow-up of those still not responding.

Socio-Demographic data. Age, gender, education, internet experience, social deprivation indices based on post code will be recorded.

Notes review. All patient's notes will be reviewed to document consultations, returns, time to return, reasons for returns, complications, economic data and any subsequent referrals. [57]

Sample size. We wish to compare each of the intervention groups primarily with control but also with each other so for our primary outcome (weight) we allow for alpha=0.017 (i.e. 0.05/3) to minimise type I error. For a standardised effect size of 0.33 (i.e. a small effect size, equivalent to 2-3 Kg difference assuming an SD of change of 6.5-7.5 Kg[6;48]) and 80% power this requires 174 patients per group with complete data, or 654 patients in total allowing for 20% loss to follow-up (hence we will aim to recruit a minimum of 660 patients).

Analyses

Primary analysis: Repeated measures ANOVA for the principal continuous outcomes (i.e. weight) between groups and for the secondary outcomes, controlling for stratification variables.

Subgroup analyses: Estimates of effect in subgroups according to baseline waist measurement (high vs low waist), and the presence of the metabolic syndrome (syndrome vs no syndrome) will be explored. Assessments will be made of outcomes (weight, reported behaviour change, measured behaviour change) according to website usage and changes in psychological variables (e.g. change in components of the TPB) and according to the type of diet chosen by patients.
Other analyses: Weight changes will be plotted against changes in metabolic variables to compare slopes between groups.

The most conservative intention to treat analysis will assume that those patients lost to follow-up have regained their initial weight, with an adjustment to allow for the variance (if exactly the same measurements were used there would be no variance of change for the missing data, and so would underestimate the overall variance of change). The study will be reported in accordance with the CONSORT (Consolidated Standards of Reporting Trials) statement.

Economic analysis. The cost of intervention and follow-up related service use, including the time taken to train staff, surgery attendance, admissions and referrals, will be collected in the trial. Resource use data will be collected by notes review, GP and nurse documentation (e.g. of consultation time) and patient self-report.

Qualitative process analysis: During months 18 to 24 of the study we will interview 12-16 patients from both the intervention groups immediately after the 12 month appointment, purposively sampling for diversity in baseline characteristics (age, gender, internet experience), adherence levels and outcomes. Interviews will be tape-recorded, fully transcribed and analysed by thematic analysis [14] with constant comparison[58] of emerging themes based on intervention group and all the factors used for purposive sampling. The aim will be to identify processes that may have influenced intervention acceptability and effectiveness for different patients.

Risk and benefits for trial participants
Since the study will use recommended strategies there should be no risk to participants. Major complications are unlikely in this sample. Given the structured advice to patients – probably better information than is normally available in routine care - the standard of care in the control group is likely to be higher than routine practice since most patients with obesity currently get little or no help either in weight loss or weight maintenance.

Project timetable.
0-12 months secure local approvals; approach recruit and train practices; prepare practices for recruitment including preparing list of patient and letters; perform ongoing qualitative work with existing pilot sample; pilot the website to address maintenance.
12 months - 18 months recruit patients for main trial
18 to 30 months follow-up patients from main trial
30 to 36 months complete data collection, cleaning, analysis and report writing

Reference List
  (1) French D, Stevenson A, Michie S. An Intervention to Increase Walking Requires Both Motivational and Volitional Components: A Replication and Extension. International Journal of Behavioral Medicine 2010; 17:71.

  (2) Yardley L, Donovan-Hall M, Smith H, Walsh B, Mullee M, Bronstein A. Effectiveness of Primary Care Vestibular Rehabilitation for Vestibular Dizziness. Ann Int Med 2004; 141:598-605.

  (3) 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 reviews 2010; 11:306-321.

(4) Webb T, Joseph J, Yardley L, Michie S. Using the Internet to promote health behavior change: A meta-analytic review. Journal of Medical Internet Research 2010; 12:e4.

(5) Obesity guideline development group. National Institute for Health and Clinical Excellence: Obesity full guideline. Nice org 2006; http://guidance.nice.org.uk/CG43/guidance.

(6) Rothert K, Strecher V, Doyle L, Caplan W, Joyce J, Jimison H et al. Web-based Weight Management Programs in an Integrated Health Care Setting: A Randomized, Controlled Trial. Obesity 2006; 14:266-272.

(7) Fogelholm M, Kukkonen-Harjula K. Does physical activity prevent weight gain - a systematic review. obesity reviews 2000; 1:95-111.

(8) Bravata D, Smith-Spangler C, Sundaram V, Gienger A, Lin N, Lewis R et al. Using Pedometers to Increase Physical Activity and Improve Health: A Systematic Review. JAMA 2007; 298:2296-2304.

(9) Anhoj J, Jensen A. Using the Internet for life style changes in diet and physical activity: A feasibility study. Journal of Medical Internet Research 2004; 6:47-55.

(10) Mann T, Tomiyama A, Westling E, Lew A-M, Samuels B, Chatman J. Medicare's Search for Effective Obesity Treatments: Diets Are Not the Answer. American Psychologist 2007; 62:220-233.

(11) Thorogood M, Hillsdon M, Summerbell C. Lifestyle interventions for maintaining weight loss. Clinical Evidence 2006.

(12) Funk K, Stevens V, Appel L, Bauck A, Brantley P, Champagne Cea. Associations of Internet website use with weight change in a long-term weight loss maintenance program. Journal of Medical Internet Research 2010; 12:e39.

(13) Cotton D, Gresty K. Reflecting on the think-aloud method for evaluating e-learning. British Journal of Educational Technology 2006; 37:45-54.

(14) Joffe H, Yardley L. Content and thematic analysis. In: Marks D, Yardley L, editors. *Research Methods for Clinical and Health Psychology* (pp. 56-68). London: Sage. London: Sage; 2004. 56-68.

(15) Little P, Dorward M, Gralton S, Hammerton L, Pillinger J, White P et al. A Randomised Controlled trial of three pragmatic approaches to initiate increased physical activity in sedentary patients with risk factors for cardiovascular disease. BJGP 2004; 54:189-195.

(16) Yardley L, Beech S, Zander L, Evans T, Weinman J. A randomized controlled trial of exercise therapy for dizziness and vertigo in primary care. B J G P 1998; 48:1434-1435.

(17) Goldberg J, King A. Physical activity and weight management across the lifespan. Annu Rev Pub Health 2007; 28:145-170.

(18) Frost G, Masters K, King C, Kelly M, Hasan U, Heavens P et al. A new method of energy prescription to improve weight loss. J Hum Nutr Dietetics 1991; 4:369-373.

(19) Stevens V, Funk K, Brantley P, Erlinger T, Myers V, Champagne C. Design and implementation of an interactive website to support long-term maintenance of weight loss.   Journal of Medical Internet Research, 2008; 10: e1 doi:10.2196/jmir.931.

(20) Toubro S, Astrup A. Randomised comparison of diets for maintaining obese subjects weight after major weight loss: as lib low fat high carbohydrate diet v fixed energy intake. B M J 1997; 314:29-34.

(21) Bandura A. Self-efficacy: the exercise of control. 1 ed. New York: W.H.Freeman; 1997.

(22) Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: new guidance. MRC; 2008.

(23) Abraham C, Michie S. A taxonomy of behavior change techniques used in interventions. Health Psychology 2009; in press.

(24) Luszczynska A, Sobczyk A, Abraham C. Planning to lose weight: Randomized controlled trial of an implementation intention prompt to enhance weight reduction among overweight and obese women. Health Psychology 2007; 26(4):507-512.

(25) Beck J. The Diet Solution. 1 ed. Birmingham: Oxmoor House; 2008.

(26) Gollwitzer P, Sheeran P. Implementation intentions and goal achievement: a meta-analysis of effects and processes. Advances in Experimental Social Psychology 2006; 38:69-119.

(27) Shaw K, O'Rourke P, Del Mar C, Kenardy J. Psychological interventions for overweight or obesity. Cochrane Database Syst Rev 2005; 2:CD003818. DOI: 10.1002/14651858.CD003818.pub2.

(28) Lustria MLA, Cortese J, Noar SM, Glueckaluf RL. Computer-tailored health interventions delivered over the web: Review and analysis of key components. Patient Education and Counseling 2009; 74(2):156-173.

(29) Jacobs D, Ainsworth B, Hartman T, Leon A. A simultaneous evaluation of 10 commonly used physical activity questionnaires. Med Sci Sports Exercise 1993; 25:81-91.

(30) Riddoch C, Aznar S, Batty G. Measurement of physical activity of children in free living environments. Proc.of the Paediatric Work Physiology Group September 1995, Odense, Denmark. 1995.
Ref Type: Abstract

(31) Little P, Barnett J, Kinmonth AL, Margetts B, Gabbay J, Thompson R et al. Can dietary assessment in general practice target patients with unhealthy diets. B J G P 2000; 50:43-45.

(32) Little P, Barnett J, Margetts B, Kinmonth AL, Gabbay J, Thompson R et al. Validity of dietary assessment in general practice. J Epidemiol Community Health 1999; 53:165-172.

(33) Executive Summary of The Third Report of The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, And Treatment of High Blood Cholesterol In Adults (Adult Treatment Panel III). J A M A 2001; 285:2486-2497.

(34) Balkau B, Charles M, Drivsholm T, Borsch-Johnsen K, Wareham N, Yudkin J et al. Frequency of the WHO metabolic syndrome in European cohorts, and an alternative definition of an insulin resistance syndrome (European Group For The Study Of Insulin Resistance (EGIR)). Diabetes Metab 2002 Nov;28(5):364-76 2002; 28:364-376.

(35) Meigs J. Epidemiology of the insulin resistance syndrome. Curr Diab Rep 2003; 3:73-79.

(36) Executive Summary of The Third Report of The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, And Treatment of High Blood Cholesterol In Adults (Adult Treatment Panel III). J A M A 2001; 285:2486-2497.

(37) Consensus statement International Diabetes Federation (IDF), the National Heart, Lung, and Blood Institute (NHLBI), the World Heart Federation, the International Atherosclerosis Society, and the American Heart Association (AHA). Circulation 2009; 120:1640-1645.

(38) Shen B, Todaro J, Niaura R, McCaffery J, Zhang J, Spiro A. Are metabolic risk factors one unified syndrome? Modeling the structure of the metabolic syndrome X. Am J Epidem 2003; 157:701-711.

(39) Han T, Lean M. Self-reported waist circumference compared with the 'Waist Watcher' tape-measure to identify individuals at increased health risk through intra-abdominal fat accumulation. B J Nutr 1998; 80(1):81-88.

(40) Lean M, Han T, Morrison C. Waist circumference as a measure for indicating need for weight management. BMJ 1995; 311:158-161.

(41) Despres J-P, Lemieux I, Prud'Homme D. Treatment of obesity: need to focus on high risk abdominally obese patients. BMJ 2001; 322:687-689.

(42) MacMahon S, Cutler J, Brittain E, Higgins M. Obesity and hypertension: epidemiological and clinical issues. Eur Heart J 1987; 8(suppl b):57-70.

(43) Assad M, Topouchian J, Asmar R. Evaluation of two devices for self-measurement of blood pressure according to the international protocol: the Omron M5-I and the Omron 705IT. Blood Pressure Monitoring 2003; 8:127-133.

(44) Little P, Barnett J, Barnsley L, Marjoram J, Fitzgerald-Barron A, Mant D. Comparison of agreement between different measures of blood pressure in primary care and daytime ambulatory blood pressure . BMJ 2002; 325:254.

(45) Dattilo AM, Kris-Etherton PM. Effects of weight reduction on blood lipids and lipo-proteins: a meta-analysis. Am J Clin Nutr 1992; 56 (2):320-328.

(46) Hegsted DM, Augman LM, Johnson JA, Dallal GE. Dietary fat and serum lipids: an evaluation of the experimental data. Am J Clin Nutr 1993; 57:875-883.

(47) Mensink RP, Katan MB. Effect of dietary fatty acids on serum lipids and lipoproteins. A meta-analysis of 27 trials. Arterioscler Thromb 1992; 12(8):911-919.

(48) Sjostrom L, Rissanen A, Andersen T, Boldrin M, Golay A, Koppeschaar HP 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; 352:167-172.

(49) Lillioja S, Mott DM, Spraul M, Ferraro R, Foley JE, Ravussin E et al. Insulin resistance and insulin secretory dysfunction as precursors of non-insulin-dependent diabetes mellitus. Prospective studies of Pima Indians. N Eng J Med 1993; 329:1988-1992.

(50) Wilkin D, Hallam L, Doggett AM. Measures of need and outcome for primary health care. Oxford: O.U.P.; 1992.

(51) Kind P, Hardman G, Macran S. UK population norms for EQ-5D. Discussion paper 172. York: Centre for Health Economics, University of York; 1999.

(52) Brooks R. The EuroQol Group. EuroQol: the current state of play. Health Policy 1996; 37:53-72.

(53) Marteau TM, Bekker H. The development of the short form of the state scale of the speilberger State/Trait Anxiety Inventory. Br J Clin Psychol 1992; 31(3):301-306.

(54) Garrow JS. Obesity and related diseases. 1 ed. London: Churchill Livingstone; 1988.

(55) Petruzzello SJ, Landers DM, Hatfield BD, Kubitz KA, Salazar W. A meta-analysis on the anxiety-reducing effects of acute and chronic exercise. Outcomes and mechanisms. Sports Med 1991; 11(3):143-182.

(56) Johnston M. Models of Health-Related Behaviour Change. King's Fund Centre Conference, November 7th 1994. The way forward following the publication of the OXCHECK and FHS studies. Conference Proceedings 1994.

(57   Little PS, Gould C, Williamson.I., Warner G, Gantley M, Kinmonth AL. Reattendance and complications in a randomised trial of prescribing strategies for sore throat: the medicalising effect of prescribing antibiotics. B M J 1997; 315:350-352.

(58)   Strauss A, Corbin J. Grounded theory methodology: An Overview. In: Denzin N, Lincoln Y, editors. Strategies of Qualitative Inquiry. 1 ed. London: Sage; 1998. 158-183.

(59)   Little PS, Williamson I, Warner G, Gould C, Kinmonth AL, Gantley M. An open randomised trial of prescribing strategies for sore throat. B M J 1997; 314:722-727.
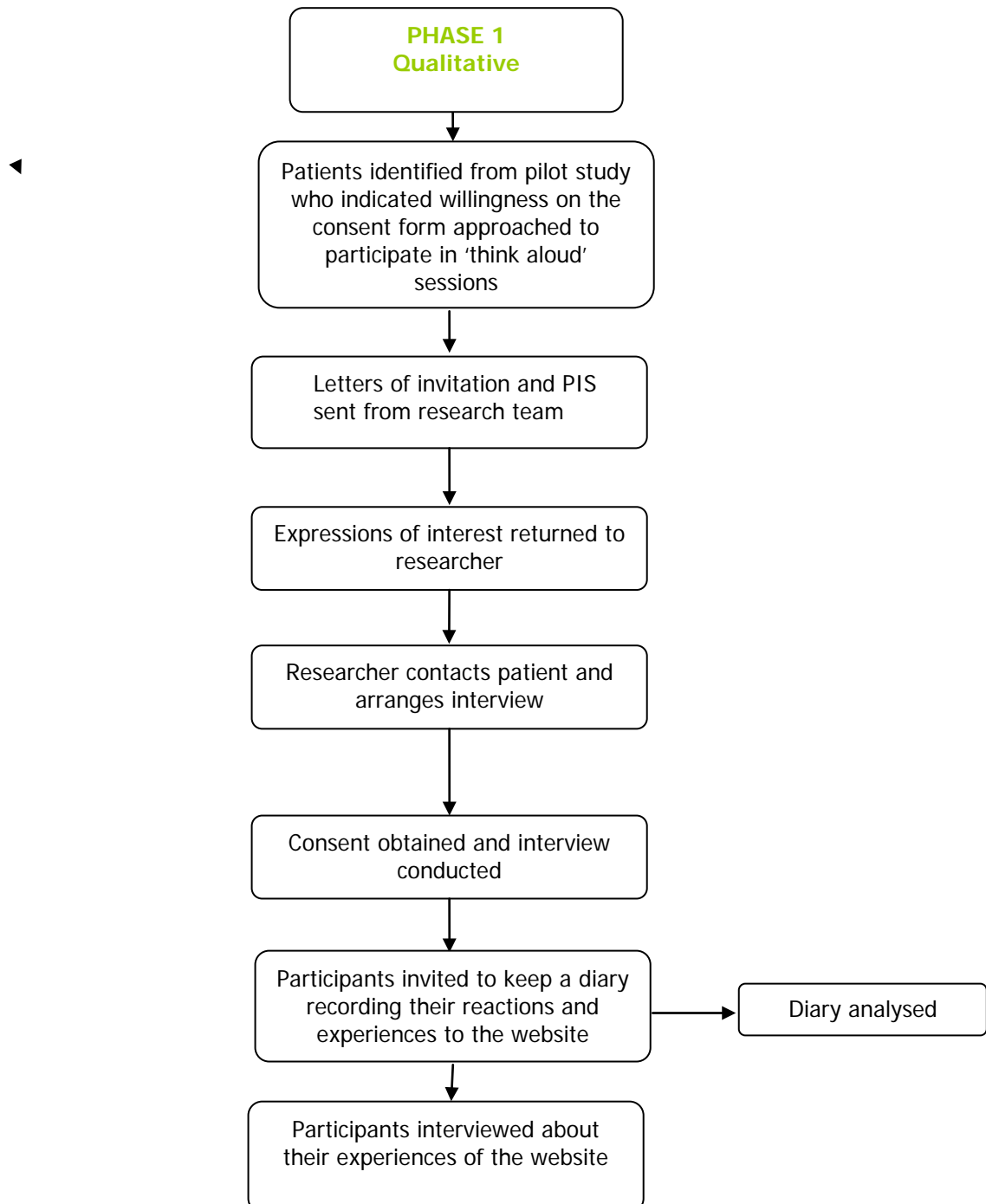
Table 1 Outcome Measures by Group

Group	Baseline	6 months	12 months
Web + Nurse support	weight, waist, height, bodyfat, blood pressure, Liver function test; fasting serum cholesterol / HDL / LDL/triglyceride(TG), glucose, Hb1Ac and insulin; ferritin	weight, waist, height, bodyfat, blood pressure, Liver function test; fasting serum cholesterol / HDL / LDL/triglyceride(TG), glucose, Hb1Ac and insulin; ferritin	weight, waist, height, bodyfat, blood pressure, Liver function test; fasting serum cholesterol / HDL / LDL/triglyceride(TG), glucose, Hb1Ac and insulin; ferritin
	EQ-5D, FFQ, Godin, SF36, sociodemographic Q, patient satisfaction and understanding Q, HAD	EQ-5D, Godin, SF36, patient satisfaction and understanding Q, HAD	EQ-5D, FFQ, Godin, SF36, patient satisfaction and understanding Q, HAD
	Attitudes & Intentions baseline	Attitudes & Intentions mid-trial	Attitudes & Intentions post trial
	Motivation to take part Q	PETS adherence mid-trial	PETS Adherence
Web + minimal support	weight, waist, height, bodyfat, blood pressure, Liver function test; fasting serum cholesterol / HDL / LDL/triglyceride(TG), glucose, Hb1Ac and insulin; ferritin	weight, waist, height, bodyfat, blood pressure, Liver function test; fasting serum cholesterol / HDL / LDL/triglyceride(TG), glucose, Hb1Ac and insulin; ferritin	weight, waist, height, bodyfat, blood pressure, Liver function test; fasting serum cholesterol / HDL / LDL/triglyceride(TG), glucose, Hb1Ac and insulin; ferritin
	EQ-5D, FFQ, Godin, SF36, sociodemographic Q, patient satisfaction and understanding Q, HAD	EQ-5D, FFQ, Godin, SF36, patient satisfaction and understanding Q, HAD	EQ-5D, FFQ, Godin, SF36, patient satisfaction and understanding Q, HAD
	Attitudes & Intentions baseline	Attitudes & Intentions mid-trial	Attitudes & Intentions post trial
	Motivation to take part Q	PETS adherence mid-trial	PETS Adherence
Normal Care	weight, waist, height, bodyfat, blood pressure, Liver function test; fasting serum cholesterol / HDL / LDL/triglyceride(TG), glucose, Hb1Ac and insulin; ferritin	weight, waist, height, bodyfat, blood pressure, Liver function test; fasting serum cholesterol / HDL / LDL/triglyceride(TG), glucose, Hb1Ac and insulin; ferritin	weight, waist, height, bodyfat, blood pressure, Liver function test; fasting serum cholesterol / HDL / LDL/triglyceride(TG), glucose, Hb1Ac and insulin; ferritin

	EQ-5D, sociodemographic Q,	EQ-5D,	EQ-5D, FFQ, Godin, SF36, patient satisfaction and understanding Q, HAD
			Attitudes & Intentions post trial
			PETS Adherence

POWER Phase 1:
Web development
0-12 months
RECRUITMENT FLOWCHART

Web site developed, building on previous websites and materials used in Counterweight programme

PHASE 1
Qualitative

Patients identified from pilot study who indicated willingness on the consent form approached to participate in 'think aloud' sessions

Letters of invitation and PIS sent from research team

Expressions of interest returned to researcher

Researcher contacts patient and arranges interview

Consent obtained and interview conducted

Participants invited to keep a diary recording their reactions and experiences to the website → Diary analysed

Participants interviewed about their experiences of the website

Phase 2:
RCT *12-24 months*
RECRUITMENT FLOWCHART AND OVERVIEW

Phase 2 - Randomised controlled Trial

Up to 44 Practices identified

Patients identified from practice database

- Letters of invitation and PIS sent from practice
- Patients recruited opportunistically in consultation

Signed consent by GP/nurse in practice

RANDOMISED within practice

Minimal face-to-face support
1 f/up after 2 wks + 3 online contacts (1m,2m&3m) and up to 2 further phone contacts + baseline, 6m and 12m follow up
(n=220)

Nurse support
face to face visits at 2wks, 6wks & 3m, then up to 4 extra face to face contacts + baseline, 6m and 12m follow up
(n=220)

Normal care
+ baseline, 6m and 12m follow up
(n=220)

Baseline — Outcome measures as detailed in Table 1

6 months — Outcome measures as detailed in Table 1

12 months — Outcome measures as detailed in Table 1

Notes review of all patients

Phase 2 (RCT) - DETAILED OUTLINE OF RECRUITMENT AND PARTICIPATION

Identification of participants	Letters sent by practice to potential participants with PIS

Interested participants	Interested participant asks to see Practice Nurse about study Interested participant discusses study details with GP or nurse Interested participant can contact study team to discuss study

Consent	GP or nurse answers any queries the potential participant may have and takes informed consent
	Nurse answers any queries the potential participant may have and takes informed consent

Baseline measures	Practice nurse completes baseline assessment

Baseline questionnaires	Patient completes baseline questionnaires on-line

Randomisation	Research team contacts external randomisation service

Notify participant of random allocation	Research team contacts participant and practice to inform them of allocation

Randomisation options	A	Minimal face-to-face support (1 follow up after 2 wks + 3 online contacts (1m,2m&3m) and up to 2 further phone
	B	Intensive (face to face visits at 2wks, 6wks & 3m, then up to 4 extra face to face contacts)
	C	Normal care

6 month follow up data collection	A, B, C	Appointment made with practice nurse

12 month follow up data collection	A,B, C	Appointment made with practice nurse, validation of final weight by research nurse

Notes review	A B, C	Completed by practice or research team