POWER STUDY

Positive Online Weight Reduction

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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 remote 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/exclusion criteria

Inclusion criteria

- Adult patients with BMI >=30 (or 28 with diabetes, 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/ breast feeding
- perceived inability to walk 100 metres (physical activity difficult)
- another member of the household taking part
- no regular access to the internet

Patients/recruitment

1. Patients in each practice will be randomly chosen from GP electronic records, and invited by letter to a screening appointment to confirm eligibility; with typically 15-20 patients per practice being recruited to the trial.
2. Patients can also be referred opportunistically during GP or nurse consultations.
3. Recruitment will take place over 6 months in around 44 practices from the South West and South East Hubs of the PCRN.

Informed consent

Invitation to participate and the patient information sheet will come from the practice (either by post or given out by the GP or nurse opportunistically). Then, following a consultation with the nurse, the patient can either consent at the time or can take more time and return the consent forms by post.

Randomisation

Patients' will register on the POWeR website and enter their details and measurements taken during the baseline appointment. The website will automatically randomise participants, stratified by:

- gender
- waist (>102 cm men; >88cm women)
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Patients will be notified by the POWeR website as to which of the three groups they have been randomised to. They will receive further information on the nature and timing of contacts with their practice. Practice staff will also be notified of patients study group by email.

Only one patient per household will be randomised

Planned interventions

1) Control: Monitoring + Waiting List group)**.** Upon randomisation to this group, participants will be provided with brief information about a healthy diet. (healthy food swaps) and physical activity (advice to take 30 minutes of moderate intensity exercise per day). 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 will also be actively instructed not to engage in any active behavioural intervention.

2) Website + Face-to-Face Support group. 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).Where walking is the preferred physical activity, they will be encouraged to aim for at least 10,000 steps per day supported by pedometers[40]. Observational studies suggest 1500-2000 Kcal per week may be required to maintain weight loss - 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 on-going 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) 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 12 weeks. If a rate of weight loss equivalent is not being achieved or maintained - which we anticipate could be up to half the cohort - additional 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]If 2.5kg weight loss is not achieved after 3 months, a six month trial of Orlistat will be recommended; it will be stopped according to standard stopping rules[5]. Orlistat can also be used for weight maintenance if the patient requests it[5]. The purpose of the nurse contacts is to provide reinforcement, and also to be able to help patients address on-going 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) Website + Remote Support group)**.** This group aims to provide a very brief intervention using only remote (email and phone) methods of contact 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 have 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) telephone consultation at 2 weeks to confirm the physical activity and dietary targets, 2 brief online contacts at 6 weeks, and 12 weeks, , and up to 2 further telephone contacts (i.e. 4 brief additional personal remote 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
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.
Training will also provide instruction and advice on how to manage those participants in the control group (Monitoring + Waiting List group), making sure there is a clear understanding that this group should receive no additional support sessions for weight loss. Discussions around what constitutes 'normal-care' and what goes beyond 'normal-care' practices will be prominent to avoid contamination of results.

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

Outcomes
Outcomes will be collected at (unless otherwise stated):

- Baseline
- 6 months
- 12 months

Primary outcome:

- **Weight:** 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, [29,30].
- **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, , waist hip ratio. Percentage body fat will be measure using the Tanita scales (using bio impedence) [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 with the website**. Will be measured using a previously validated 3-item measure [60,61]and a modified version of the Patient Enablement Instrument will be administered[59]; At 12 months we will also use validated measures to evaluate perceptions of nurse support[62]
- **Habits**. A modified version of the Self-Reported Habit Index will be used to measure physical activity and dietary habits[63].
- **EuroQol**[51;52] (EQ-5D): the EuroQol provides a measure of quality of life for economic analysis;
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- **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), the physiological measurements will be performed, and patients weighed; a research nurse blind to group will perform final physiological measurements 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.

A paper-based questionnaire will also be posted with a stamped addressed envelope to participants, giving them the choice of completing the measures online or by post.

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. Allowing for an ICC of 0.05 and 5 patients per group at each practice gives a design effect of 1.2, giving a total sample size of 654*1.2 = 785.

Procedure for follow-up at 12 months

High rates of attrition are frequently observed in behavioural weight loss interventions (60). In order to improve the rate of attendance the patients will be visited at home by an independent nurse for the 12 month follow up. The process outlined below will be used for all patients (unless withdrawn from the trial) at 12 months:

1.-Three weeks before the appointment is due, the patient will be sent a letter (Follow up letter 1) encouraging them to contact the trial co-ordinator (Southampton or Oxford) to arrange an appointment at home with the research nurse. The letter will include a £10 voucher and give the patient the option of not having a fasted blood sample taken if this is a barrier to attending the appointment.
2.Once the patient has arranged an appointment with the research nurse a letter of confirmation will be sent. This gives brief advice about the fasting blood sample.
3. If the patient does not contact the study team to arrange follow up within 2 weeks of the follow-up letter being sent, OR if the patient is not available for a researcher will telephone the patient Telephone calls from the study team will be limited to two conversations with the patient and if a follow up cannot be scheduled, the study team will present the patient with the option of self-reporting their current weight during the final telephone call.

If secondary outcome measures such as fasting blood samples appear to be presenting a barrier to attendance at follow up, the patient will be offered the option to have only a weight measure to obtain the primary outcome data. The patient will only be offered the option of providing a self-reported weight reading if the process above has been followed and a nurse-measured weight reading cannot be obtained.

Contact with the patient is limited to a maximum of two letters (one to confirm the appointment that the patient has agreed to) and two telephone conversations. The rationale for the study team making the calls is that the patient may prefer not to be weighed by their practice if they have gained weight or not lost weight during the trial, and it is more convenient for patients.

If at any point the patient confirms they will be attending the appointment, no further contact will be initiated with the patient. If the patient then fails to attend the appointment, the study team will call the patient as described above .

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: From 12 weeks post consent we will interview up to 16 patients from each of the groups. They will be purposively sampled 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. As a result of this no non-serious adverse events will be recorded in this study.

Project timetable.

0 to12 months secure local approvals; approach recruit and train practices; prepare practices for recruitment including preparing list of patient and letters; perform on-going qualitative work with existing pilot sample; pilot the website to address maintenance.
13 to25months recruit patients for main trial
19 to 37 months follow-up patients from main trial
37 to 39 months complete data collection, cleaning, analysis and report writing

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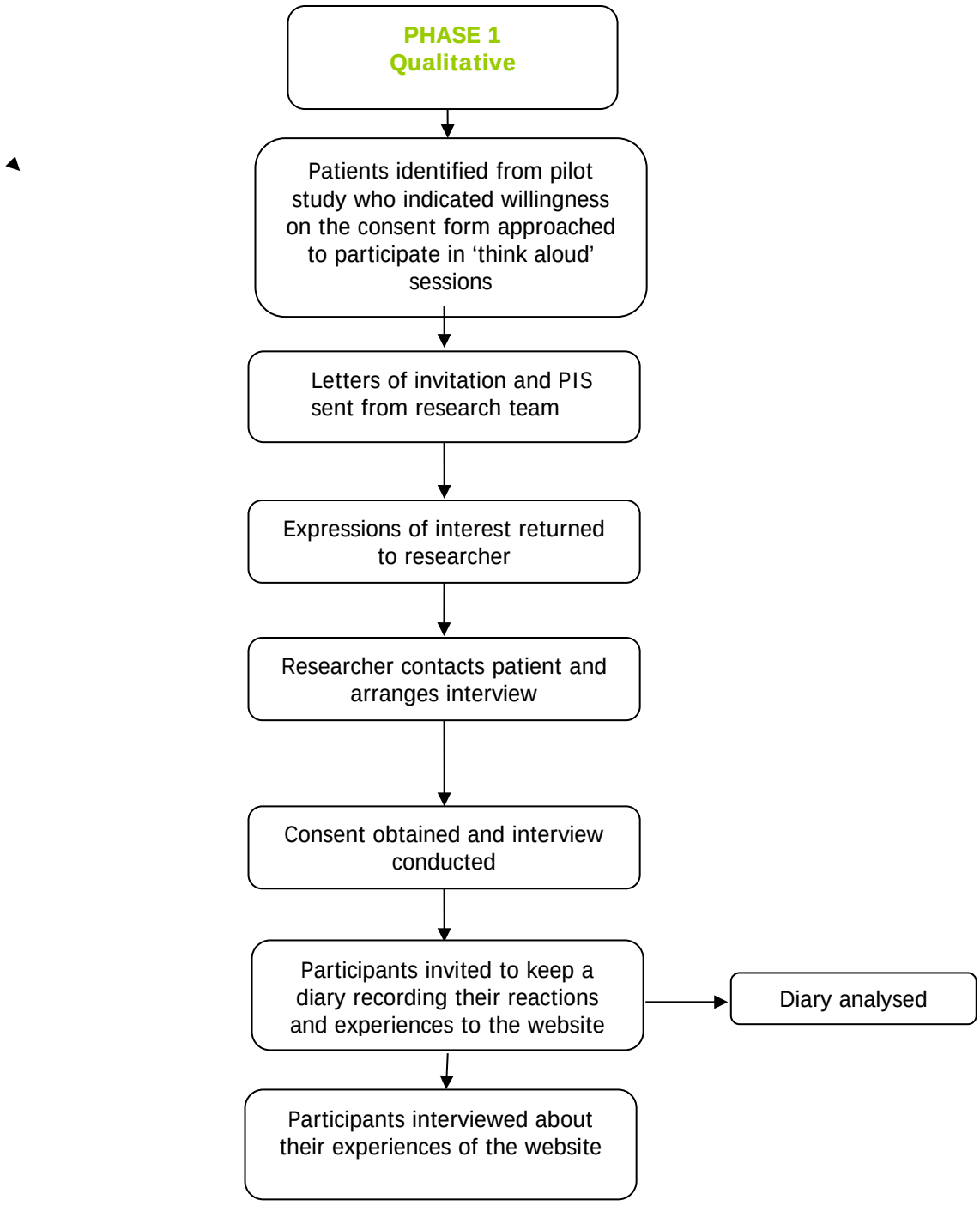
Table 1 Outcome Measures by Group

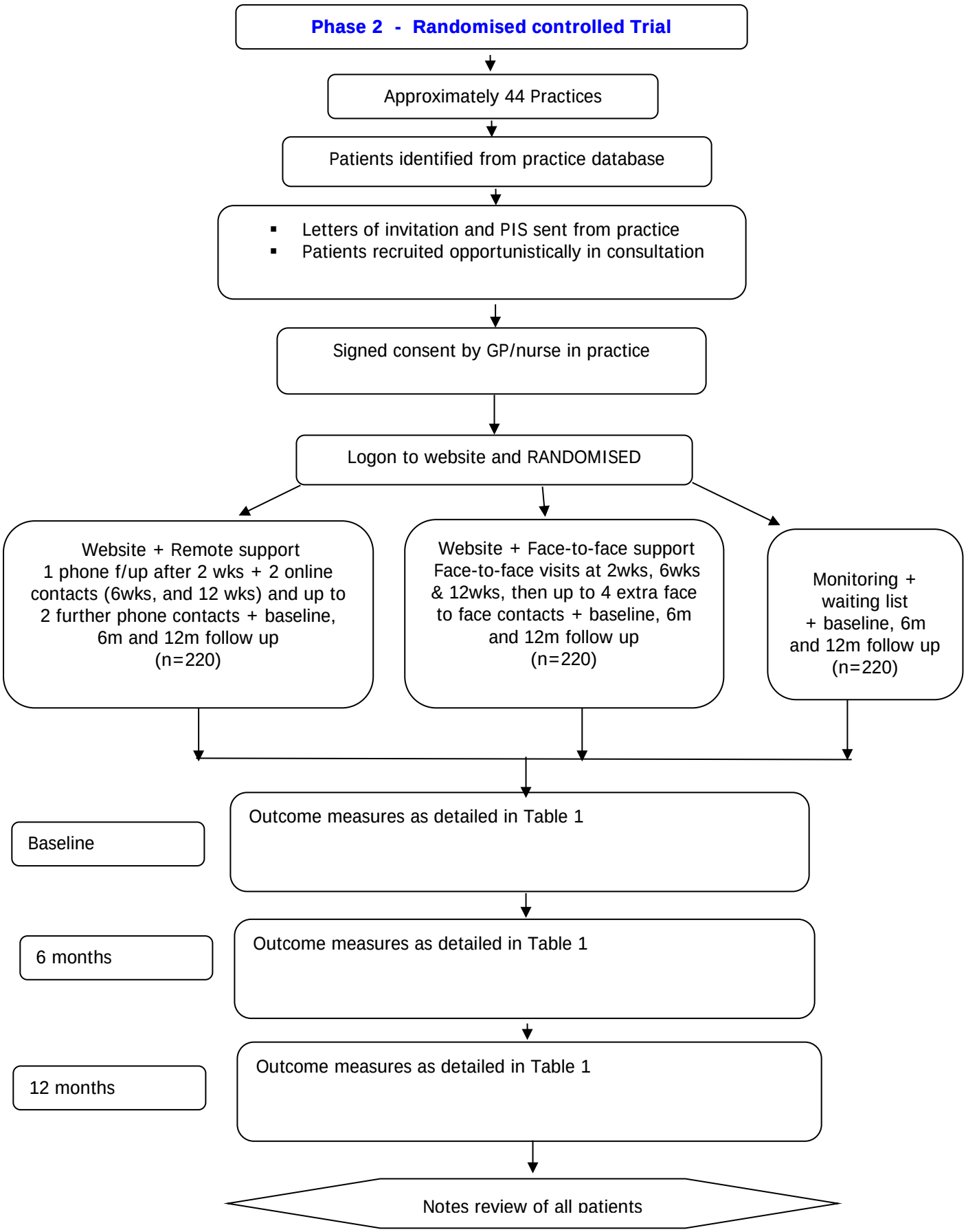
Group	Baseline	6 months	12 months
Website + Face-to-Face Support	weight, waist, height, bodyfat, blood pressure, Liver function test; AST, Gamma GT;T4, TSH fasting serum cholesterol / HDL / LDL/triglyceride(TG), glucose, Hb1Ac and insulin;	weight, waist , blood pressure,	weight, waist, bodyfat, blood pressure, Liver function test; AST, Gamma GT; fasting serum cholesterol / HDL / LDL/triglyceride(TG), glucose, Hb1Ac and insulin; ferritin
	EQ-5D, FFQ, Godin, , sociodemographic Q, patient enablement Q Habits Q,	EQ-5D, FFQ, Godin, , patient enablement Q Habits Q	EQ-5D, FFQ, Godin, , patient enablement Q Habits Q
	Attitudes & Intentions baseline	Attitudes & Intentions mid-trial	Attitudes & Intentions post-trial
	Motivation to take part Q	PETS adherence mid-trial	PETS Adherence
			Self-reported weight and if other weight loss support used during the last year
Website + Remote Support	weight, waist, height, bodyfat, blood pressure, Liver function test; AST, Gamma GT;T4, TSH fasting serum cholesterol / HDL / LDL/triglyceride(TG), glucose, Hb1Ac and insulin; ferritin	weight, waist, blood pressure	weight, waist, bodyfat, blood pressure, Liver function test; AST, Gamma GT fasting serum cholesterol / HDL / LDL/triglyceride(TG), glucose, Hb1Ac and insulin; ferritin
	EQ-5D, FFQ, Godin, , sociodemographic Q, patient enablement Q , Habits Q	EQ-5D, FFQ, Godin, patient enablement Q Habits Q	EQ-5D, FFQ, Godin, , patient enablement Q , Habits Q
	Attitudes & Intentions baseline	Attitudes & Intentions mid-trial	Attitudes & Intentions post-trial
	Motivation to take part Q	PETS adherence mid-trial	PETS Adherence
			Self-reported weight and if other weight loss support used during the last year
Control Group: Monitoring + Waiting List Group	weight, waist, height, bodyfat, blood pressure, Liver function test; AST, Gamma GT;T4, TSH fasting serum cholesterol / HDL / LDL/triglyceride(TG), glucose, Hb1Ac and insulin; ferritin	weight, waist, blood pressure,	weight, waist, bodyfat, blood pressure, Liver function test;AST, Gamma GT fasting serum cholesterol / HDL / LDL/triglyceride(TG), glucose, Hb1Ac and insulin; ferritin
	EQ-5D, , FFQ, Godin, sociodemographic Q,	EQ-5D,	EQ-5D, FFQ, Godin, patient enablement Q Habits Q ,
			Self-reported weight and if other weight loss support used during the last year

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

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



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



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		Website automatically randomises patient
Notify participant of random allocation		website automatically notifies patient and practices of allocation
Randomisation options	A	Website + Remote support (1 follow up after 2 wks + 2 online contacts (6 and 12 wks) and up to 2 further phone contacts
	B	Website + Face-to-Face Support (face-to-face visits at 2wks, 6wks & 3m, then up to 4 extra face to face contacts)
	C	Monitoring + Waiting List group
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 research nurse
Notes review	A B, C	Completed by practice or research team