ImpulsePal: A feasibility study to aid the planning of a randomised controlled trial and refinement of a smartphone app-based intervention to support weight loss

ImpulsePal: A Feasibility Study

Funding: University of Exeter Medical School PhD Studentship & NIHR Career Development Fellowship (CDF-2012-05-259)

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Study Sponsor: University of Exeter

Chief Investigator: Miss Samantha van Beurden (PhD Student; University of Exeter Medical School)

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1. Full title

ImpulsePal: A feasibility study to aid the planning of a randomised controlled trial and refinement of a smartphone app-based intervention to support weight loss.

2. Short study title

ImpulsePal: A Feasibility Study V1

3. Study identifiers

IRAS Project ID: 177205
NIHR Career Development Fellowship: (CDF-2012-05-259)
UKCRN portfolio ID: 19486
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4. Study management

4.1 Study investigators

University of Exeter Medical School (UEMS)

- Miss Samantha van Beurden, PhD Researcher (Study Researcher and Chief Investigator)
- Associate Professor Colin Greaves, NIHR Career Development Fellow (Principal Investigator and PhD student Supervisor)
- Dr Jane Smith, Research Fellow, (Co-investigator and PhD student Supervisor)
- Professor Charles Abraham, Professor of Psychology Applied to Health (Co-investigator and PhD student Supervisor)

4.2 Collaborators

- Katarina Kos, RD&E Wonford Hospital
- Jo Ratford, Dietitian, RD&E Wonford Hospital

4.3 Study sponsor

The sponsor for the study will be the University of Exeter, who will provide all necessary professional indemnity and insurance for the duration of the research.

4.4 Key Contact details

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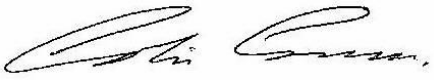
4.5 Signatures

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Role	Name	Signature	Date

Chief Investigator	Samantha van Beurden		22/05/15
PhD Supervisor / Co-investigator	Colin Greaves		02/06/15
Sponsor's representative	Gail Seymour		

5. Funding and duration

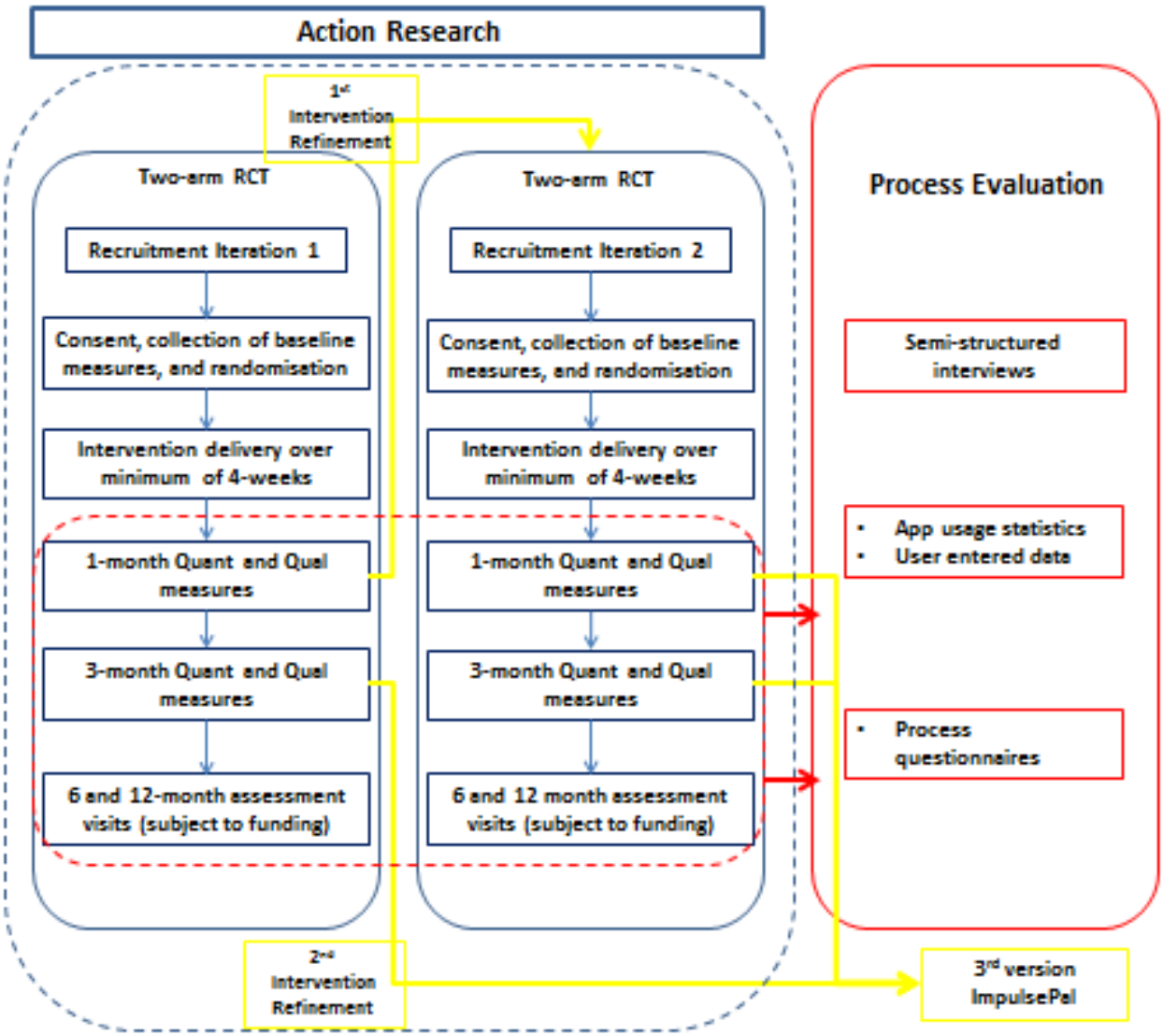
Research costs (App development /programming costs, postage, stationery. Equipment, other materials) and Colin Greaves' time on this project are funded by a National Institute for Health Research (NIHR) Career Development Fellowship (Grant Number CDF-2012-05-259). Co-funding from the University of Exeter Medical School supports Samantha van Beurden's time as part of a PhD scholarship award.

6. Study summary

Study Title	ImpulsePal: A feasibility study to aid the planning of a randomised controlled trial and refinement of a smartphone app-based intervention to support weight loss
Study Design	A two-arm randomised controlled feasibility study with parallel action research and process evaluation.
Study Participants	• People with a BMI **of 25kg/m^2 or more and** a desire to join a weight loss programme to lose weight • Aged 16 and above • In possession of a smartphone with an Android operating system
Intervention	**The intervention arm will receive the ImpulsePal smartphone app.**
Control condition	**Usual care (this may include no intervention or attending an existing weight management service).**
Study duration	**Total duration: months (August 2015 to Sep 2016; possible extension to May 2017 subject to funding)** Participant recruitment: 6 months Intervention delivery: 1 month Follow up: 1 month (0 months post end of intervention) 3months (2 months post end of intervention) Intervention refinement: 2 month 6 months (5 months post end of intervention) *Subject to funding:* 12 months (11 months post end of intervention)

	Total analysis and writing up: 4 months
Target Sample Size	A total of 90 people will be randomised in a 2:1 ratio (60 intervention : 30 control).
Setting	The community of Devon /Exeter. Recruitment will be organised by the University of Exeter, but research and intervention procedures will also take place in the patient's own home and in an ambulatory setting (via smart-phone).
Aims	This study aims to inform the research and intervention procedures for a future randomised controlled trial to assess the clinical effectiveness of the ImpulsePal intervention in people with **a BMI of 25 kg/m^2 or more and a desire to lose weight.** Research aims 1. To assess the feasibility and acceptability of the ImpulsePal intervention 2. To assess the acceptability to participants of the trial methods. This will include assessment of recruitment rates, study uptake, outcome completion, attrition, intervention attendance and qualitative feedback on acceptability and feasibility from participants. 3. To assess to what extent ImpulsePal is received and used as intended (intervention fidelity). 4. To use feedback from intervention users to further refine the ImpulsePal app for use in UK primary care /community settings. 5. To obtain estimates of the standard deviation of continuous outcome measures. This will help to determine the required sample size for the main study. Descriptive /explorative analysis of outcomes and process measures will also be conducted. 6. To select process and outcome measures for use in a future trial. 7. To estimate the resources needed for the planned future trial.
Inclusion Criteria (patients)	• Young adults and adults (aged ≥16 years). • BMI of ≥**25 kg/m^2** • In possession of smartphone with an Android operating system
Exclusion Criteria (patients)	• **Currently pregnant** • **Do not speak or understand written English** • **Participating in concurrent interventional research which may over-burden the patient or confound data collection (e.g., another weight loss trial).**

7. Trial Flowchart



8. Background and rationale

This study forms part of a programme of work on the development, evaluation, and implementation of interventions to support weight loss through lifestyle changes (changes in diet), with a particular focus on impulse management. In particular, the study aims to pilot and refine the intervention and trial procedures for a larger, future planned trial to establish the cost-effectiveness of a self-delivered smartphone app-based weight management intervention. The evidence generated by the larger trial will help inform the future commissioning of weight loss services for managing obesity in the NHS.

1: *Impact of obesity:* Obesity is associated with a reduction in life expectancy of up to 14 years,[1] primarily due to an increase in cardiovascular disease (CVD) risk. Because excess fat causes impaired glucose regulation (IGR), obesity also substantially increases the risk of developing type 2 diabetes.[2] People with a BMI of 35-45 kg/m2 have a relative risk of type 2 diabetes that is 8 to 11 times higher than for people of normal weight.[2] Obesity is also associated with an increased likelihood of developing kidney disease, fatty liver disease, osteoarthritis, several cancers, hypertension, dementia, depression and sleep apnoea.[3] Based

on current trends in obesity prevalence (currently 23% in adults), it is estimated that the combined cost of obesity to the NHS and to UK society will reach £49.9 billion/year by 2050.[4]

2. *Benefits of weight reduction:* Evidence from systematic reviews shows that, in people with increased cardiovascular risk, relatively modest reductions in weight (2-5Kg) reduce key cardiovascular risk factors (e.g. lipid profiles, blood pressure) to a clinically meaningful extent.[5], [6] Weight loss also reduces insulin resistance and can prevent progression to type 2 diabetes.[[7], [8]] In the Finnish Diabetes Prevention Study, a mean 3.4Kg of weight loss in people with IGR, reduced the incidence of type 2 diabetes at 4 years of follow-up by 58%.[9]

3. *Why focus on Impulse Management?* Traditional weight management interventions tend to focus on individual's deliberative (planned) actions and conscious strategies for managing their weight. However, people often struggle to lose or maintain weight, despite their strong intentions to do so [10], [11]. This is thought to be due, at least in part, people's tendency to make food choices impulsively with little conscious awareness [12]. Weight loss interventions focussing on deliberative processes alone therefore do not always bring about the desired long-term outcomes. Impulsive influences that are able to override the conscious deliberative processes are considered to be a major barrier to successful behaviour regulation. [13]–[16] There is a growing interest in "dual-process" theories of behaviour, which take into account both conscious deliberative processes and automatic, or impulsive, processes. This has resulted in the development and evaluation of a range of impulse management techniques aiming to promote healthier eating behaviour. These techniques may offer a way of facilitating weight loss that adds value to existing "standard" intervention techniques.

Prior work to develop the ImpulsePal intervention: Our intervention approach is informed by extensive "needs assessment" activities, including consultation with service users and behaviour change experts, systematic reviewing of the literature on impulse management techniques for eating behaviour. Our approach follows MRC guidelines for developing and evaluating complex interventions and the use of a formal intervention development framework called Intervention Mapping [17]. We have developed a smartphone application that encompassed five specific impulse-management techniques to support weight management through modifying eating related impulses. The techniques were chosen as being those that showed the most promise in our literature review [18] of the effectiveness evidence on impulse management techniques for modifying eating behaviour.

9. Aims and objectives

9.1 Aims

This explorative study aims to test the feasibility of and provide feedback to help refine the research and intervention procedures for a future randomised controlled trial to assess the clinical effectiveness of the **ImpulsePal app in people with a BMI of 25 kg/ m^2 or more and a desire to lose weight.**

9.2 Objectives

The specific objectives of the proposed study are:

1. To assess the feasibility and acceptability of the ImpulsePal intervention

2. To assess the acceptability to participants of the trial methods. This will include assessment of recruitment rates, study uptake, outcome completion, attrition, intervention attendance and qualitative feedback on acceptability and feasibility from participants.

3. To assess to what extent ImpulsePal is received and used as intended (intervention fidelity).

4. To use feedback from intervention users to further refine the ImpulsePal app for use in UK primary care /community settings.

5. To obtain estimates of the standard deviation of continuous outcome measures. This will help to determine the required sample size for the main study. Descriptive /explorative analysis of outcomes and process measures will also be conducted.

6. To select process and outcome measures for use in a future trial.

7. To estimate the resources needed for the planned future trial.

10. Study design

10.1 Summary of the study design

We will conduct a small scale randomised controlled trial with two arms, and outcomes measured at 1 and 3-months post baseline. The trial will include nested qualitative research to gather feedback on the intervention and study procedures and will be delivered in two distinct phases to allow refinement of the intervention using action research methods[19]. Additional outcomes data will be collected at 6, and 12 months post baseline subject to funding. The primary analysis in the future RCT will be a comparison of weight loss between the intervention and control arms. Design considerations for the main trial will be further researched and refined during the proposed study (e.g. development of a detailed analysis plan).The proposed study incorporates an Action Research (AR) approach, utilizing qualitative methods of data collection. As suggested by Gomm and Davies ([20]; p.188): "action research can be an effective form of feasibility study: make a change and see what happens." This approach will allow us to further refine the ImpulsePal intervention in close collaboration with its intended users. The proposed study involves three iterations of the intervention. An initial version of the intervention has been developed with the involvement of service users, experts in behaviour change and self-control, and app developers. Qualitative and some quantitative data from questionnaires and other process measures from the first version will be used to refine the intervention and a second iteration will be subject to the same mixed methods evaluation. Finally, a third version will then be developed for formal testing in a future randomised controlled trial.

The intervention period is a minimum of 4-weeks (participants can continue using the app beyond this if they find it useful and the app will be maintained on University of Exeter servers for a minimum of 2 years. Outcomes will be assessed at baseline, 1 and 3 months post-baseline, and potentially at 6 and 12 months post baseline subject to funding. Ninety participants will be randomised (in a 2:1 ratio) to the intervention or control group. In the first

phase of the study, 45 participants will be recruited. Following, refinements to the app, another 45 participants will be recruited to use "version 2" of ImpulsePal. This design is illustrated in the trial flowchart.

10.2 Participants

Participants will be adults who are overweight /obese (BMI over 25 kg/m2) and want to lose weight.

10.2.1 Inclusion Criteria

- Young adults and adults (aged ≥16 years).
- BMI **of ≥25 kg/m^2**
- In possession of smartphone with an Android operating system

In terms of the minimum specification for the smartphone, the app is designed to run on any smartphone that runs on any Android system of version 2.3 (Gingerbread) or higher. Based on phones accessing Google Play in early 2015, 99.6% of Android systems worldwide are 2.3 or higher, so the app should run on the vast majority of Android phones.

10.2.2 Exclusion Criteria

- **Currently pregnant**
- **BMI of below 25 kg/m2.**
- **Do not speak or understand written English**
- **Participating in concurrent interventional research which may over-burden the patient or confound data collection (e.g., another weight loss trial).**
- **Currently receiving treatment for an eating disorder.**

10.3 Methods for protecting against bias

11. Sample selection: We use stratification to ensure that allocation between groups is balanced for men, women, different age groups, and for different BMI groups (i.e., to ensure that possible biases due to having say a higher proportion of people with high BMI in the control group as opposed to the intervention group. In this feasibility study, any information gathered about the distribution of volunteers will help the development of the future planned RCT (e.g., to inform sample size calculations to allow examination of differences in effect between men and women).

12. Allocation concealment: To ensure allocation concealment until the point of randomization, we are using the web-based randomization services provided by sealedenvelope.com. This will ensure that the researcher is unaware of which arm the participant is allocated to until after baseline assessments have been collected, and the service has provided the researcher with the allocation code.

13. Blinding: In behavioural intervention studies it is not possible to blind study participants to treatment allocation.[21] Data will be collected by the same researcher at baseline and follow-up and therefore the researcher may be aware of group allocation at follow-up. We do not have sufficient resources to have different researchers collect data at different time points. However, this could be implemented in the planned future trial.

14. Attrition: To minimize loss to follow up we will offer a draw-based incentive (i.e.., a prize draw for a £50 gift voucher) for trial completion and will follow recommendations on trial participant retention from the NIHR School for Primary Care Research (e.g. regular contact), as described in the recruitment section.[22]

15. Identification of potential participants

15.1 Route A: Identification via Tier 2 weight management services

Recruitment to existing Tier 2 weight management services in Devon is through referral by a GP or other NHS health professional. In areas around Exeter, referrals are directed to Health Promotion Devon (HPD), a lifestyle hub that helps individuals select a programme from a number that have been commissioned, including group and one-to-one programmes. Trained staff from HPD speak with referred individuals by telephone to screen for exclusion criteria, provide information and find a suitable weight management programme. Once a week a staff member of the HPD referral hub will do a database search generating a list of people who meet the inclusion criteria. They will check the person's records for any recorded exclusion criteria (where possible) and (if appropriate) send a study invitation on HPD letterhead. The inclusion /exclusion criteria checked for by the HPD at this stage are:

Specific HPD database search Inclusion Criteria:

- **Young adults and adults (16+)**
- **Eligible for Tier 2 weight management**

Specific HPD database search Exclusion Criteria:

- **Referred to Westbank Lot 3 (People referred to programmes involving both diet and physical activity)**
- **Being pregnant**

15.2 Route B: Identification via Tier 3 weight management services

Individuals who have been referred to local Tier 3 weight management services in Devon will be offered a Study Flyer providing basic information about the study. Interested individuals will be able to contact the researcher directly, who will screen for eligibility and provide more detailed information.

15.3 Route C: Recruitment via commercial weight management programmes

Individuals attending local commercial slimming classes will be provided with the study flyer offering basic study information. Interested individuals will be able to contact the researcher directly using the contact details provided on the flyer, who will screen for eligibility and provide more detailed information.

15.4 Route D: Recruitment via local General Practices

We may use a Study Poster in local General Practices to advertise the study. Interested individuals will be able to use the contact details provided on the poster to contact the researcher and request more information.

15.5 Route E: Recruitment via local advertising

If necessary we may need to advertise the study in a local newspaper or via University of Exeter newsletters and ask interested individuals to contact the researcher directly for more information about the study.

15.6 Route F: Identification via the Exeter 10 000 project

Exeter 10 000 is a research register managed by the Peninsula Research Bank (PRB) with individuals who are over the age of 18 with a permanent address within 25 miles of Exeter. This register acts as a research volunteer bank. Registered individuals will have provided samples and data including observed weight and height and have consented to being approached for research studies. A proportion of registered individuals who are eligible to take part in the current feasibility study will be sent a letter by the PRB which includes a two paragraph summary of the study (See Request to use PRB database volunteer) inviting them to contact the researcher for more information about the study. If we require more participants an additional number of eligible registered individuals will be sent the letter.

15.7 Route G: Identification via previous related research studies

People identified as interested in taking part in further research following the launch of a web-based "Go/No-go" impulse control intervention by a colleague (N. Lawrence) will be provided with a study flyer. A news story in the Daily Mail resulted in 1800 people signing up to receive information about future research studies.

15.8 Recruitment feasibility data collection

Anonymised data on the age, gender, BMI, ethnicity and the first part of the postcode (from which a level of social deprivation will be derived) of the total eligible sample will be recorded where possible (routes A,B,E) to allow assessment of the representativeness of the recruited sample. The research team will not have access to contact details at this point. Available data on the total numbers of potentially eligible people and the numbers reaching each stage in the recruitment process from each source, will be recorded to enable investigation of recruitment feasibility for a full trial.

16. Recruitment procedures

16.1 Participant invitation

Following identification as described in route A, a HPD administrator will write to the potential participant in a letter on Health Promotion Devon letterhead, co-signed by the

study researcher, asking whether they are interested in taking part in a research study at the same time as receiving their weight loss programme. A Participant Information Sheet, a return slip (to be returned to the study researcher) with contact details and stamped addressed envelope will be included to allow those interested in taking part to inform the study researcher. They will provide their contact details on the return slip so that further contact can be instigated by the research team. Those provided with only a Study Flyer (Route B-E) will be able to contact the researcher directly using the contact details provided on the flyer to discuss the study and request that additional information is sent. Interested potential participants who appear to be eligible at this point, will be sent the Participant Information Sheet (Route B-G), a decline to take part response and stamped addressed envelope.

16.2 Telephone screening

Potential participants who have expressed interest in the study by directly contacting the researcher or by returning the reply slip, will be contacted by telephone (using details provided by the participant) to confirm interest and eligibility. Those who, following this, received the Participant Information Sheet directly from the researcher (Route B-G) will be contacted by telephone again after 7-10 days if no 'decline to take part' response has been returned. If eligible and oral consent to take part has been provided, the potential participant will be invited to attend a "baseline assessment visit" at the University of Exeter or in their home (if they prefer). The baseline questionnaire pack will be posted to the participant before the baseline assessment meeting so that they can be read and completed beforehand (the researcher will not ask for the completed questionnaires until after written consent is obtained).

If the person is not eligible to take part in the study (e.g., does not own a smartphone running the appropriate Android operating system), the researcher will explain why and thank them for their time. If the person is eligible but declines to participate, they will be invited to give reasons to help feasibility assessment (but it will made clear that they are not obliged in any way to disclose reasons). If they agree to give reasons, a brief questionnaire will be used at that point, or sent to the individual with a reply paid envelope if they prefer.

16.2.1 Expected recruitment rate

The feasibility of identifying and recruiting patients with similar inclusion /exclusion criteria has been well demonstrated in previous and current weight loss studies [23], as well as in the Lighten Up trial and in Jebb et al ([24]). Data from these studies suggest a recruitment rate of 30-40 participants per month can be achieved per 1.0wte of researcher time. Hence, using 0.5wte of PhD researcher time, we expect to recruit 90 participants over a 6 month period.

16.3 Procedures to maximise retention

Improving retention to studies involving internet-based or mobile phone based interventions is considered a general challenge. We are using a number of strategies that have been linked to increased study retention[25], [26]:

- Draw-based incentive (£50 shopping voucher to be won on completion of 3 month data collection and again at 12 months).
- Systematic method for patient contact, scheduling of appointments and monitoring of retention.

- Scheduled assessment visit reminder calls.
- Offer of alternative assessment visit venue (participant's home or University of Exeter).

17. Research procedures

17.1 Procedures for baseline meeting

Overview: At the baseline visit, the researcher will first explain the study, answer any questions that the potential participant has and take written consent. Baseline questionnaires will then be checked for completeness and understanding and weight will be measured. After baseline measures have been taken the participants will be randomised to either the control arm or the intervention arm. The main outcome for the planned future RCT will be objectively assessed weight (measured by researchers using calibrated scales during scheduled follow-up visits at the University of Exeter, or at the person's home if preferred).

17.1.1 Informed consent

People who are willing to take part will be asked to provide written informed consent at the start of the baseline assessment, following an opportunity to ask any questions they may have. Consent will be obtained by the researcher prior to any baseline outcome measures being collected from the participant.

Participants will be informed that they may, at any time, withdraw from the study without giving a reason, and without it affecting their relationship with their clinical team, and/or their future treatment and care. Participants will be informed that although they are under no obligation to provide a reason for withdrawing from the trial, it would be helpful information when assessing the success of the future main trial.

17.1.2 Baseline data collection

The main outcome for the planned RCT will be objectively assessed weight (measured by researchers during scheduled follow-up visits at the University of Exeter, or at the person's home if preferred). Therefore, after written informed consent has been obtained the participants will be asked to:

- Complete the study baseline questionnaire booklet or to hand in the completed form for checking .
- Be measured for height and weight.
- Provide name and surgery of GP (to allow the researchers to inform their GP of study participation).
- Schedule a follow-up visit 1 month after baseline.

17.1.3 Group allocation

Once baseline data collection is complete, participants will be randomised to either the control arm or the intervention arm. Participants will be allocated to trial groups using a web-based randomisation service (sealedenvelop.com). For the randomisation we will use a 2:1 ratio. In addition we will use stratified randomisation in an attempt to achieve balance across the groups in terms of gender, age-bands (16-24, 25-35, 36-54, 55+) and BMI 25-35, 35-45 45+), and blocked randomisation (blocks of 3) in an attempt to achieve minimal variance from the desired 2:1 ratio between groups (60 in the intervention and 30 in the control arm).

We will put eligible participants who return data at both baseline and 3 months into a prize draw for a £50 voucher (choice of Amazon or M&S) as an incentive to complete the study and return data.

17.1.4 Information provided to GPs

Following successful completion of the baseline visit, the researcher will ensure that the patient's GP is informed of study participation.

18. Intervention

18.1 Overview of ImpulsePal

The ImpulsePal weight management intervention aims to modify impulsive processes associated with eating behaviour in order to reduce unhealthy eating behaviour. The intervention is self-delivered and is provided via a smartphone app. Due to the self-delivered nature of the intervention, there is no need to train any intervention providers reducing the overall costs.

The intervention has been developed using Intervention Mapping (IM) [17], which includes a) a needs assessment stage consisting of literature searches, stakeholder involvement and expert opinion, with theory, and existing evidence in the research literature on impulse management and b) a 'mapping' stage where performance objectives (identified as part of the needs assessment) are examined to identify determinants of change and strategies or techniques for facilitating achievement of the objectives and overcoming any barriers to change.

For research purposes, currently, the ImpulsePal app has been programmed for use on Android phones only. Using Android allows us to make immediate changes to the programming code during the intervention refinement stages of the feasibility study without having to go through external channels to be able to release the updated app (e.g., iPhone requires any new app, including new updates to go through a time-consuming approval process before release). The final version arising from this study will also be programmed for iPhone and potentially Microsoft phones as to not exclude potential users from being able to access the intervention.

A full smartphone application functional specification is provided in Appendix II and a brief summary is provided below.

18.2 Intervention structure, content, and delivery

The ImpulsePal app is a self-delivered smartphone application. Detailed instructions are provided within the app and the link to download the app will be provided to those allocated to the intervention arm following randomisation. We will advise a minimum of a month of using the app, but would encourage ongoing use until the participant feels comfortable that they have learned all the skills that might be useful to them in managing their weight.

Procedure: The intervention user downloads the app, and is recommended to play the "brain training" game 3-times a week, for four weeks, with in-app reminders being sent out when the user has not completed the task for two consecutive days. In addition, the app offers a choice of 4 strategies for moments when the user struggles managing their impulses and finds

it hard to resist temptations, these can be accessed at any point in time when the users feels the need to do so.

18.3 Intervention content

The ImpulsePal intervention targets the impulsive processes associated with eating behaviour [14], using a number of impulse management techniques that were identified in a recent systematic review [18] as being potentially promising for reducing food cravings and /or facilitating weight loss. The choice of the incorporated techniques was also informed by the feasibility of translating the eligible techniques into strategies that are deliverable via a smartphone app platform. The following Impulse Management Techniques are included in the ImpulsePal app:-

- Dynamic Visual Noise (presenting a visual interference pattern to block 'elaboration' of impulse imagery via the brains visuo-spatial sketchpad[27])
- If-then Planning (pre-emptive problem-solving for 'high risk' situations where there is a strong 'risk' of giving in to temptations for unhealthy eating
- Inhibition Training (using a stimulus-response task or "brain trainer game" to help people to break the learned /automated association between visual stimuli (pictures of unhealthy foods) and the "reaching out" motor cortex response)
- Goal reminders (text messages or notifications to remind people of their weight loss /healthy eating goals (which they are asked to provide when they first use the app)
- Urge surfing (a mindfulness based meditation technique to help people to recognise, 'hold' and process urges towards unhealthy eating when they occur)
- Emergency button (a button that is to be used when the user is in need of "in the moment" support, this leads to the above mentioned strategies with Dynamic Visual Noise presented straight away. 15 minutes following pressing this button the app will send a question about the temptation strength).

In addition, further behaviour change techniques have been included such as information and feedback to help people to learn from experience and build their confidence about successfully resisting temptations; promoting mental rehearsal of successful performance; encouraging behavioural practice /repetition to increase habit and skill. These were considered important for increasing engagement with the intervention and the successful implementation of the required behaviour changes (i.e. reduction in overeating episodes and unhealthy snacking behaviour).

18.4 Control group

Control group participants will receive usual care, which may include an existing weight management programme or no treatment at all (depending on the recruitment route). The research team will take note of any weight management programmes undertaken during the study period.

19. Follow-up data collection

Data will be collected from intervention and control group participants at baseline, 1-,3 months post baseline (with 6 and 12 month follow up being subject to additional funding as they would be beyond the timeframe of the PhD study). Two weeks prior to the follow-up visits at 1 and 3 months post baseline questionnaires will be posted to participants by the

researcher and a request to complete the questionnaires before the visit. At the meeting, the researcher will:

- Go through the questionnaire booklet to ensure completeness and understanding.
- Take weight measurements

Participants will be asked to identify any newly diagnosed conditions, or new medications started during the intervention period, as well as any other management services or interventions used (including commercial weight loss programmes) and any smoking cessation attempts (which can cause substantial weight gain).

In addition at 1 (face-to-face) and 3 months (telephone), a subsample will be involved in qualitative interviews (see below) this data will be used for the refinement of the intervention. Feedback on the trial procedures will be collected at 3-months post baseline.

20. Duration of participant involvement

Each recruited patient is expected to be involved in the study for up to 3 months, or 6 months subject to funding between the initial baseline visit and the final follow-up visit.

21. Outcomes and measures

21.1 Study Measures

12.3.1 Trial feasibility measures

To assess the feasibility of a trial of the ImpulsePal intervention, the following measures will be used:

- *Recruitment rate* (number of participants per month recruited)
- *Uptake rate* (the proportions of participants invited who are randomised)
- *Study completion rate* (the proportion of those starting the study who provide data at 6 and 12 months). Reasons for dropout or loss to follow-up will be recorded where possible.
- *Outcomes completion rates* (proportions of participants who complete each measure at each time point)
- *Intervention usage* (the proportion actively using the app for specified minimum 4-week period).
- *Trial resource use* (the costs and time-requirements of delivering trial procedures).

12.3.2 Demographic and health data

We will collect the following data on participant characteristics:-

- Age
- Gender
- Education level
- Ethnicity

- Multiple Deprivation index (derived from postcode and national census data)
- Smoking status
- Co-morbidities including diabetes and other metabolic disorders, or any other conditions that might influence diet.
- Impulsiveness
- Restraint
- Smartphone model

These variables have been selected because they may moderate the effects of intervention.

12.3.3 Intervention outcome measures

The outcome measures planned for the future trial will also be collected from participants in this study. This will allow the researchers to test processes for collection, their acceptability /feasibility, and to assess outcome completion rates. We will also assess measurement burden qualitatively over the phone at 6-months.

These outcomes include the primary outcome:

- Independently assessed change in body weight (kg) between baseline (randomisation) and 1-, 3-, 6, and 12-months of follow-up as measured by a researcher using scales (Seca 899 Weighing Scale).

We will follow a standard operating procedure (SOP) for taking weight measurements and scales will be calibrated every 6-months.

Proposed secondary outcome measures for the trial are:

- Body Mass Index (BMI)
- Snacking behaviour
- Overeating episodes

All participant outcomes will be assessed at baseline and at 1, and 3 (and possibly 6 months with weight only at 12) months post baseline. Outcome questionnaires will be self-completed but checked for completeness by a researcher during assessment visits, and body measurements will be taken by the researcher. See Appendix III for a schedule of procedures.

22. Process evaluation

22.1 Design

Aims: In line with the recommendations of the MRC Framework for development and evaluation of complex interventions,[24] we will conduct a process evaluation with the following aims:-

a) To examine to what extent the intervention is received and used as intended (fidelity)

b) To elicit experiences of engaging with the intervention, including identification of processes of impulse management and lifestyle behaviour change that work well or badly (e.g., what components of the app seem to work well /or badly, for what type of person?; are people reducing their portion sizes? Snacking less? or both?)

c) To explore factors that may influence the success of the intervention (e.g., participant demographic and other characteristics, concurrent weight loss interventions).

d) To identify possible barriers to engagement with the intervention and ways in which the app could be improved

22.2 Measures (participant interviews, questionnaires, and in-app data collection)

We will explore the research aims above using individual face-to-face semi-structured audio-recorded interviews at 1 month after baseline, with 12-15 participants from the intervention group, and again at 3 months after baseline but over the telephone instead. We aim to interview the same participants at the time points where possible and using a mixture of face-to-face and telephone interviews depending on location and availability of participants. A topic guide based on our previous qualitative study investigating facilitators and barriers to internet-based weight loss intervention usage will be adapted and used [28]. We will purposively sample to achieve diversity in age, gender , BMI and type of weight loss service used. Further data will comprise of app usage statistics and feedback data collected via the app (as below). This will allow assessment of intervention delivery and receipt as well as providing a basis for intervention refinement. Consent to take part in the study will include consent for these recordings to be made.

The ImpulsePal app will collect the following data (see section 24 for data management procedures):

- App-usage statistics, which will indicate which components of the intervention have been used (e.g., frequency of use and "dwell-time" for each page /element of the app).
- Performance data on the inhibition training component of the app to assess whether the participant is engaging with the training appropriately.
- Selected and self-created if-then plans
- Temptation strength rating on a visual analogue scale ranging from 0 to 100 (not at all to extreme). This is input by the user following any use of the "emergency button" feature of the app.
- Impulse management success rate as well as the associated successful strategy.

Consent to take part in the study will include consent for the audio recordings and the collection of app usage data.

22.3 Intervention fidelity assessment

The primary data to assess intervention fidelity will be the semi-structured interviews and app usage statistics (e.g., the proportion of people achieving the recommended weekly or total amount of the brain training activity, frequency of use of the emergency button and the strategies adopted in these situations). If parts of the intervention are not being used or are not considered to be working as intended, this may suggest changes to the intervention. We will be able to refine the intervention materials during this feasibility study before phase 2 allowing us to collect further data on the improved version of the intervention.

22.4 Satisfaction questions

Questions about the feasibility (e.g.,How easy is ImpulsePal to understand and use and how easy were the trial procedures to understand and complete), satisfaction (e.g., To what extent is this judged as suitable, satisfying or attractive to the users) and ideas for improvement will be asked of the intervention participants at the 1month assessment visit for the app satisfaction measure. Similar questions will be asked for satisfaction with the research study, this will be done at the 3 month assessment visit with all participants.

23. Data analysis

23.1 Quantitative Analysis

Samantha van Beurden will lead the analysis of outcomes, under supervision from Prof Colin Greaves, Jane Smith, and Charles Abraham. Recruitment, intervention adherence, measures-completion and attrition rates will be calculated using descriptive statistics with 95% confidence intervals. Given the feasibility nature of this trial we do not propose to formally test for differences in outcomes and costs between groups. However, differences between groups will be reported with confidence intervals. We will report the mean and standard deviation or confidence intervals for all outcomes at baseline and for changes in scores between baseline and follow up time points. Participant flow through the study will be summarised using the CONSORT diagram (adapted for complex interventions) and will reflect the number of recruitment letters sent, numbers consenting, numbers participating, number undertaking intervention, and number of completed outcomes.

Any differences between the recruited sample and the wider eligible sample, and between those completing and lost to follow up /withdrawn will also be reported descriptively.

23.2 Qualitative analysis

Qualitative process evaluation data (interviews with participants) will be analysed using thematic analysis [29] to elicit common themes relating to the qualitative research aims of the study (in particular to assess the feasibility and acceptability of the interventions). Techniques to enhance objectivity and depth of analysis will include second coding of a sample of interviews (10%), negative case seeking /analysis, participant feedback and triangulation (both within the data and against other data from the study (e.g. outcomes data, other process measures)[19].Discussion with the service user advisory group will help to ensure the relevance, credibility and trustworthiness of emergent themes.

23.3 Sample size considerations

The sample size is calculated to provide realistic estimates (and confidence intervals (CIs)) for the recruitment rates and retention rates for the proposed full scale trial. The sample size will also provide an ample pool of patients for qualitative sampling. From recent UK-based trials of interventions to support dietary, it is estimated that 25-30% of those contacted will take part and of those 70-75% is retained at 12 months [24], [30]. With a sample size of 90 we will be able to estimate retention rate of 75% at 12 months to within 95% CI of +/- 8.9%. To recruit 90 people, we will need to approach 300, assuming an uptake rate of 30%. This will yield an estimate of the study uptake rate with 95% CI of +/- 5%. If the uptake ranges between 20 and 40% the CI will range between 4.5% to 5.5%.

23.4 Revising the intervention materials

The results of the satisfaction questionnaires and semi-structured interviews will be used to revise the ImpulsePal intervention. This work will be conducted after the 3-month data collection of the first cohort and again at the end of the study, so that a final version is available to be taken forward to a trial if appropriate.

24. Data management and entry procedures

All research data collected will be documented on forms identified only by a unique participant identification number. Hard copies collected by the researcher will be stored on university premises in a locked filing cabinet, in a locked office. A password-protected electronic decrypt file linking minimal personal details (e.g., name, address, preferred contact methods /times) to participant identification numbers will be maintained only for the purpose of arranging follow up visits on a password-protected computer accessible to the researcher and supervisors where necessary. Individual participant contact details will also be provided as and when necessary on a temporary basis to one of the study co-investigators to ensure the researcher's safety when a home visit is necessary for data collection in accordance with our home visiting policy. Should any personal data need to be transferred electronically at any point, this will be done in a password protected file via an encrypted email, encrypted password protected USB memory stick, or an encrypted password protected external hard drive. At the end of the study data will be archived by the sponsor (see below).

24.1 Quantitative data

Quantitative data will be entered into an SPSS data file for processing and analyses. Anonymised app data will be downloaded by the researcher from the University of Exeter secure servers, with summary data (minutes spent in various components of the app) and outcome data (impulse management success rate; strategy use; inhibition training performance; and average temptation strength week 1 and average temptation strength week 4 and other process variables) entered into the SPSS file. Ten percent of all data entered will initially be double entered to check the accuracy of data entry, and more checks will be undertaken if any problems are identified. The researchers will screen the entire data set for errors, out-of-range and missing values and correct against data from raw data as necessary. Qualitative data such as the self-formed if-then plans will be used to inform further refinement of the intervention.

24.2 Qualitative data

Qualitative audio recordings will be transcribed. To ensure anonymity, during the semi-structured interviews no names will be provided, instead the researcher will start the recording by stating the participants unique identifier code. When any information arises that allows for the identification of the participant during the interview (e.g. if the participants mentions specific locations, or uses names when referring to other people) this will be masked /omitted during transcribing. Transcriptions will be imported into N-VIVO version 10 or above to organise and code the data. The audio files will be encrypted and stored on secure servers at the University of Exeter. Access will be password protected and limited to the ImpulsePal research team.

24.3 In-app data

Data collected through the app, will be stored on University of Exeter servers encrypted, password protected and accessible to the research team at any time. No personal identifiable information will be stored via the ImpulsePal app.

24.4 Archiving

Following completion of study data analysis, the Sponsor will be responsible for archiving the study data and essential documentation in a secure location for a period of 5 years after the end of the study following which study data will be destroyed. No study-related records will be destroyed unless or until the Sponsor gives authorisation to do so.

25. End of Study

The study will end on completion of data collection for the last participant for whom data is collected at the 6 or 12 month follow up (subject to funding).

26. Plans for public involvement

We will use the briefing notes provided by INVOLVE (http://www.invo.org.uk/) to help guide the engagement of service users in research. A service user group of 10 people who have experience of weight loss and/or weight regain has already been involved in the development of the ImpulsePal intervention and will continue to be involved during the study. This group who have previously participated in the development of the intervention will assist with interpretation, write up for lay audiences, and dissemination of findings. The service users will be supported in this role via face-to-face group meetings during the middle and end of the study.

27. Dissemination and publication plans

The study will end on completion of data collection for the last patient for whom data is collected at 3 months of follow up (or 12 months of follow up subject to funding). We will write up and publish the results of the study in a peer-reviewed journal and a PhD thesis, aiming to place the main study report in an open access journal, in line with NIHR Open Access policy.

28. Discontinuation / withdrawal

Participants are free to withdraw from the study at any time. This will be emphasised during the consent process. If a participant chooses to withdraw he /she will be asked to provide a reason and the reason for withdrawal will be noted. To minimise dropout due to perceived measurement or intervention-attendance burden, they will be asked if they are willing to provide minimal data (weight-only) at 6 or 12 months, even if they do not wish to be involved in other study activities. Participants do not have to provide a reason for withdrawal and this will be reiterated by the PI (or authorised delegate) in the event that a participant requests to be withdrawn. Data collected on participants prior to withdrawal will be retained for analysis unless the participant requests otherwise.

29. Governance arrangements

29.1 Sponsor

The research sponsor will be the University of Exeter, which has extensive experience of managing/monitoring NHS and community-based trials.

29.2 Ethics and NHS approvals

The study will be conducted in accordance with the Research Governance Framework for Health and Social Care (second edition, 2005), the principles of Good Clinical Practice, and the Data Protection Act, 1998. Ethics and NHS R&D approvals will be obtained prior to the commencement of the trial. **The study has been adopted by the NIHR Clinical Research Network.**

30. Ethical issues

This study aims to examine the feasibility and acceptability of the ImpulsePal intervention whilst incorporating a user-centred approach in the development and refinement of the app based on user experience data. The main ethical issues relate to the study design, gaining consent for trial participation and randomisation, and data collection/management such as secure storage of data generated by the app and any associated personal details (e.g., mobile phone number).

30.1 Study design

In order to assess the trial procedures for the planned future effectiveness evaluation of ImpulsePal, a randomised controlled trial design incorporating the independently assessed objective outcomes, such as weight and height, has been chosen for this study. **Our control group will be given access to the app at completion of the study, should they wish to use it. This requires no excess treatment costs as the app is, at present, free of charge and fully self-delivered.**

30.2 Informed consent

Clear and complete participant information sheets, provision of opportunities to discuss with others and ask questions, and time to reflect on the decision to participate prior to gaining written informed consent will ensure that participants have a full understanding of the implications of participating in the study. This will include discussion of the randomisation and data collection procedures required for the study.

30.3 Stopping conditions

No serious adverse events are expected during this intervention. However, we will consider not continuing on to a large trial if a) serious adverse events are reported or are revealed by the qualitative data b) the recruitment rate is less than 15% of those approached unless trial process data informs ways of increasing this. These criteria will be developed further by the Research Team prior to analysis.

30.4 Data collection/ management

The main outcome for the planned future RCT will be objectively assessed weight (measured by researchers during scheduled follow-up visits at the University of Exeter or at the person's home if preferred). ImpulsePal will also collect in-app data which will be stored on

University of Exeter secure servers and is accessible by the research team only, at any time. Issues surrounding anonymity and confidentiality are addressed by providing the participants with secure log-in details, consisting of their unique identifier code and associated password. These accounts will be set up by the researcher prior to study commencement. Participants will be made aware of the data collection procedure, prior to providing written informed consent.

Identifiable data will only be available to the researchers when there is a need to contact the participant to schedule, or send a reminder of, a study visit. This data will be stored securely only for those providing informed consent to participate and solely used to organise data collection visits and participant's subsequent involvement in the study. All individual level research data will be anonymised, stored and transferred separately from identifiable data and only shared within the research team for the purpose of conducting the study and delivering the intervention. Digital recordings of qualitative interviews will be labelled with study number and date and transcribing will include redacting (removal of) any information that identifies the participant or other people by name. Audio files will be kept on a secure encrypted file space as for other electronic study data. Once they are downloaded from the recording device they will be deleted from the device.

31. Safety issues

31.1 Adverse events

For the purposes of this study an Adverse Event (AE) is defined as any untoward medical occurrence or reaction in a participant whether or not it is causally related to the trial intervention or procedures. It can be considered a Serious Adverse Event (SAE) if it results in death, is life-threatening, required hospitalisation or prolongs existing hospitalisation, results in persistent or significant disability or incapacity, or leads to any other condition judged to be significant by a clinician. Non-serious AEs might include, for example, ongoing discomfort or distress stemming from assessment procedures, or breaches of confidentiality. As documented above, procedures are in place to minimise the chances of these occurring.

AEs and other complaints can be identified and reported by anyone in contact with participants including the researchers, participants' GP or next of kin and by participants themselves. In the researcher's (Samantha van Beurden) absence, or if the researcher does not acknowledge receipt of the notification before the end of the working day, the PhD supervisors and co-investigators (Colin Greaves or Jane Smith) should be contacted and act on behalf of the researcher. At follow up visits the researcher will ask participants about any potential AEs or complaints that may have arisen since the previous contact. To facilitate recognition and reporting of AEs all staff will be familiarised with the above definitions and procedures.

When made aware of a potential AE or complaint, the researcher or designated other (supervisors) will judge whether the incident meets the definition of an AE or SAE and if it does, or they are uncertain, they will complete an AE/SAE reporting form and send this to the sponsor's representative (Gail Seymour).The sponsor's representative will then advise, with arrangements made for further discussion with an independent clinical expert if necessary, within 3 days on whether it can be considered an SAE and appears to be related to the study intervention or procedures.

For all SAEs that are related to the study, the researcher or designated other (supervisors) will contact the participant or their representative (next of kin, GP) for further details on the exact date, location, circumstances and nature of the event as necessary, and will complete and send a detailed reporting form to the main Research Ethics Committee (copied to the sponsor's representative, and participant's GP) within 15 days of becoming aware of the event. If the nature of the event implies a safety concern for existing participants or new recruits the trial may be temporarily suspended pending any discussion by the Research Ethics Committee.

As this study is not a clinical trial of an investigational medicinal product (CTIMP), we are not required to log all non-serious AEs and complaints, however, these will be documented using the reporting form to ensure that no SAEs are missed and all AEs will be reviewed and monitored at PhD supervision meetings. Stopping the trial completely is considered to be highly unlikely given its low risks and short-term follow up, but will happen if the supervisors judge that there are an excessive number of adverse events or complaints.

31.2 Researcher and participant safety during home visits

As the study may involve lone worker travel to participants' homes (where the participant is unable to attend any visits at the University of Exeter) we have a procedure in place for ensuring researcher and participant safety during home visits. The researcher will be familiarised in using the home visiting procedure, and measures taken to minimise and handle risks will include:

1. The researcher will have an identity card with their photo clearly displayed upon it.
2. When a researcher visits a participant they will let their supervisor or another colleague know in advance, detailing time, location and estimated start and anticipated end time of the visit.
3. When visiting participants, the researcher will carry a mobile phone and will notify their supervisor or another colleague when they leave. If this notification is not made within 30 minutes of the estimated end time, the supervisor/colleague will take action to contact the researcher or the participant and then, if necessary, notify emergency services.
4. If the researcher is in any way concerned in advance of a visit, they will request to be accompanied. If they are concerned during a visit about the participant's behaviour e.g. inappropriate comments, signs of intoxication, aggression etc they will leave immediately. They will notify their supervisor (or colleague) of the problem. An emergency speed-dial number will also be entered onto the phone, and a code word agreed, to notify the supervisor of any emergency situations arising. If this number is called during the visit, the supervisor will take action immediately to contact the researcher or the participant and if necessary to notify emergency services.
5. When the participant's GP is notified of the study, the GP will be asked to notify the research team of anyone whose history implies risk so that the appropriate measures can be taken (e.g. researcher is accompanied).
6. Should a participant make a complaint about a member of the research team who has visited their home that member of staff will not undertake any further home visits to, or have any contact with that participant, until the matter has been fully investigated.
7. If on contacting or seeing a participant the researcher has serious concerns about the participant's physical or mental health (e.g. participant unwell, suicide risk), or the welfare of others in contact with the participant (e.g. risk of abuse), if appropriate they

will discuss and agree a course of action with the participant, or contact the participant's GP or the police direct when there is an imminent danger.

8. If the researcher encounters any sort of problem on a home visit such as documented above they will notify their supervisor (or colleague) immediately. The supervisor will interview them as soon as possible after the event, providing a debriefing and general support. The researcher will write an account of the reasons for their concern or the incident.

32. Study participants complaints procedure

If programme participants are unhappy about any aspect of their participation in the study, they will be invited to contact the study CI. In either case, if the CI cannot resolve the issue, the matter will be raised with the research team. If they cannot resolve the issue they will refer to the University of Exeter's Research Complaints Procedure via the Study Sponsor, who is responsible for Study Governance. At each stage of the procedure, an acknowledgement of the complaint will be made within 24 hours, and the issue will be addressed within 5 days. The CI will ensure regular and positive communication with the complainant until the issue is resolved, and will report its outcome to the research team, and to the Sponsor and other bodies as recommended by GCP guidance.

33. Statement of indemnity

This is a University-sponsored research study. If an individual suffers negligent harm as a result of participating in the study, University indemnity covers University staff and those people responsible for conducting the study who have honorary contracts with the University.

34. Timelines

A detailed timeline for this study is presented in the Gantt chart (Appendix IV).

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Appendix I – Eligibility Criteria of Health Promotion Devon

Eligibility

- Age ≥ 16y
- BMI 35-50 (32.5-50 for Black/Asian populations) WITHOUT co-morbidities
- BMI 30-50 (27.5-50) WITH co-morbidities
- Considered ready to change by health professional

Co-morbidities are

- Type 2 diabetes or previous gestational Diabetes
- Uncontrolled hypertension (≥140/90)
- Patients whose Hyperlipidaemia is uncorrected by maximum tolerated doses of Statins (total C.5.2mmol/l or Total C:HDL ratio 6.0mmol/l
- Sleep apnoea
- Severe Osteoarthritis eg: requiring listing for joint replacement or in severe pain uncontrollable with analgesics.

For those with co-morbidities, a risk assessment algorithm is used to determine whether or not the individual should be offered a programme including supervised physical exercise

Appendix II- Smartphone Application Functional Specification

This document aims to provide an overview of the components in the 'Impulse Pal' app. It provides a product description, the product components, user roles, use cases, general constraints, and any assumptions that were made in specifying the requirements.

Product Description

'Impulse Pal' is an app that aims to help people change their eating behaviour by reducing the impulsive influences that hinder healthy eating. The app provides in the moment support through use of the 'emergency button' but also strengthens the users temptation resistance via the 'Go-nogo game' and 'Implementation Intentions tool'.

Functional Capabilities

Base App	Main menu, 'how to use' instructions, preferences page, implementation of a database on the device to store user behaviour as well as a functionality to send the database information to a server when users are in a WiFi area.
Implementation Intentions	Instructions page, page where users can create plans, using drop-down boxes and open-text boxes. This user entered data is saved for later review, is amendable by the user, can be added to, and is stored as research data for the University of Exeter.
Go-nogo game	Consists of the go-nogo task with a statistics page. Task performance will be collected as research data. This game requires a functionality that notifies users if they have not used the task the required number of times per week.
Danger Zones: An integrated map of 'high-risk' locations	A map where users can add high-risk locations and high-risk times. This component requires a functionality to notify users when they are in the immediate vicinity of these specified locations.
Urge-surfing	Consists of a number of information pages, with step-by-step instructions on Urge-surfing and images.
'Emergency'-button	A page where users can access any of the components of the application. This button needs to be directly accessible from the phone home screen (as allowed by the user) as well as the app's home screen. This component requires users to choose one of the strategies offered. A functionality is required to subsequently prompt whether the user was successful in controlling their impulse or not after using this button. An end of week message will prompt them to check their progress. This progress is based on the frequency of 'emergency button' use, the strategies used, and the percentage and number of successful

	attempts of controlling impulses. This feedback will be presented in table/graph format.
Information pages for all the components	The home screen of the app requires a drop down list that directs to all the information pages for each of the components of the app.
Log-in/registration functionality	On first use the users will be required to log-in with a username and password. The user will stay automatically logged in after this.

Application versions

In addition to providing the full version of 'ImpulsePal', the Service Provider will also compile a reduced version that only contains instructions and the go-nogo game.

User roles

The intended users of the 'Impulse Pal' are any type of person who wishes to manage their eating behaviour through resisting their impulses. Therefore the user may not have a specialized knowledge in using apps. This means the app needs to be user-friendly and easy to navigate.

Expected use

The individuals may or may not use the app consistently, depending on their needs. The components vary in required usage. Although the user will be required to engage in the Go-nogo game for a specified number of times per week, and will be prompted when failing to do so, other components, such as the 'Emergency button' and 'Urge-surfing' information pages will likely only be accessed on an as-and-when needed basis. The individual will be required to access the 'Implementation Intentions tool' and the 'high-risk locations' on first use, to set their plan and locations. However, subsequent use will be on an as-and-when needed basis.

General constraints

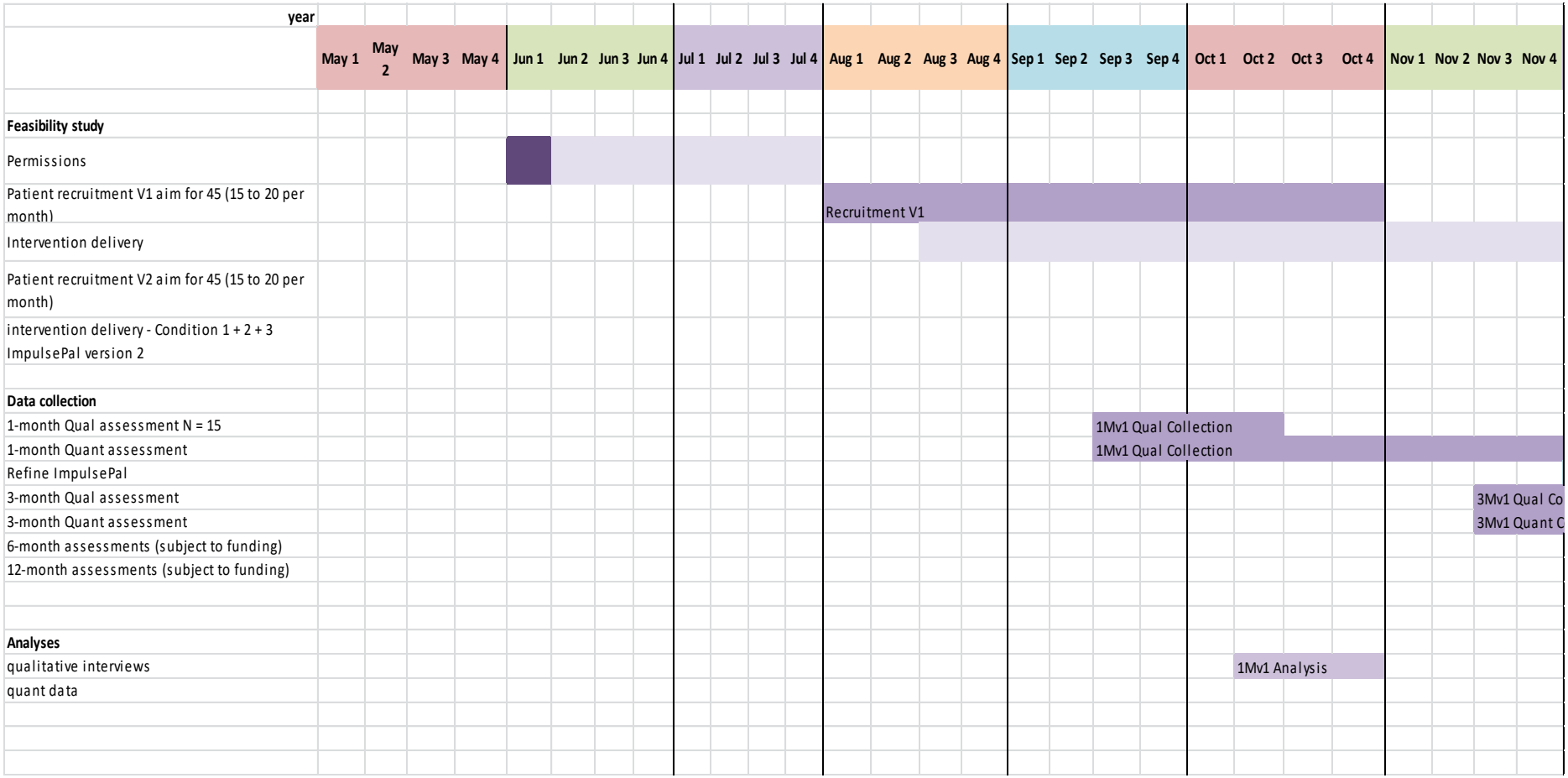
Due to the features of the app, location services need to be enabled. The user has the ability to turn this functionality on/off. If the location services are disabled, the user will not be able to make use of the 'high-risk locations' component of the app.

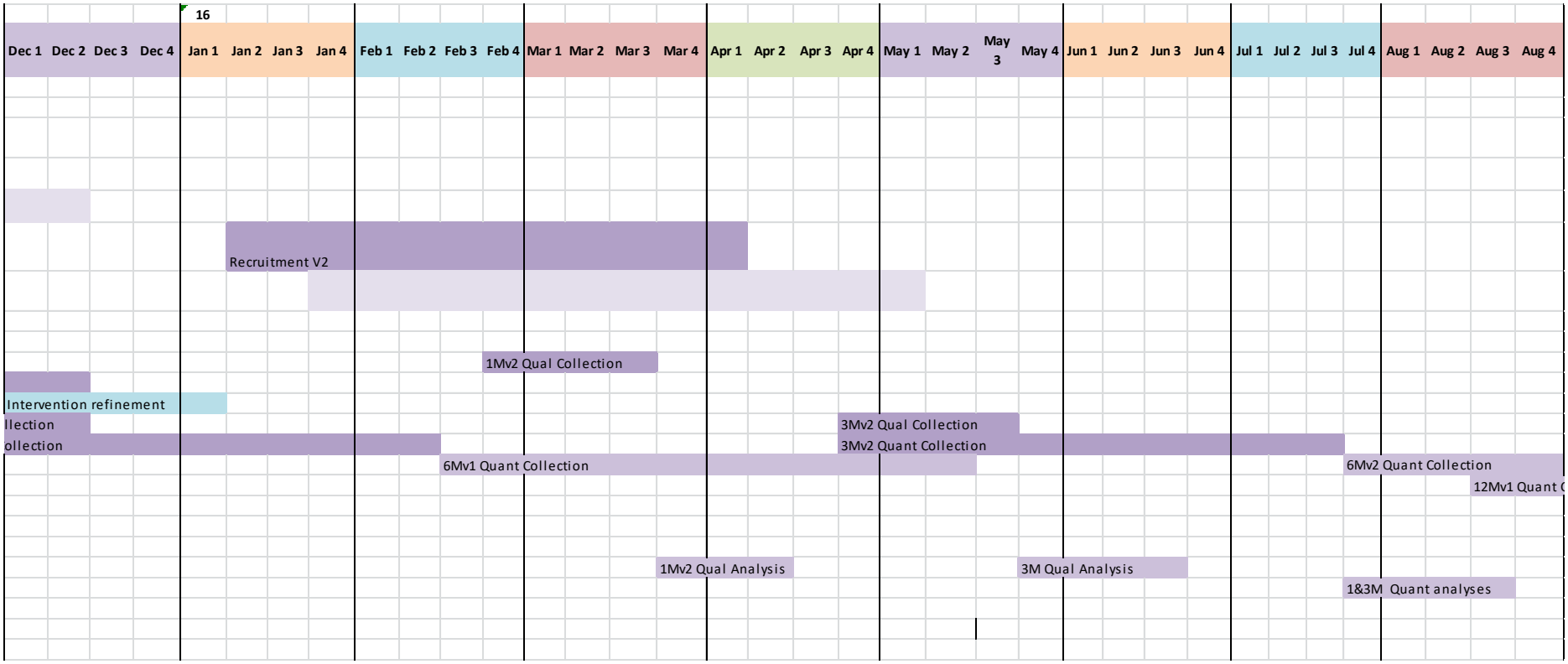
Appendix III – Schedule of Procedures

	Assessment visit 1 (Baseline*)	Assessment visit 2 (1 month)	Assessment visit 3 (3 months)	Assessment visit 4 (6 months)	Assessment visit 5 (12 months)

Questionnaire booklets	X	X	X	X	
Face-to-Face Interviews (subsample)		X			
Telephone Interviews (subsample)			X		
Body measurements (Weight, height)	X				
Body measurements (Weight)		X	X	X	X
App Satisfaction (intervention only)		X			
Study Satisfaction			X		
In app data (researcher download)		X	X		

Appendix IV – Gantt Chart

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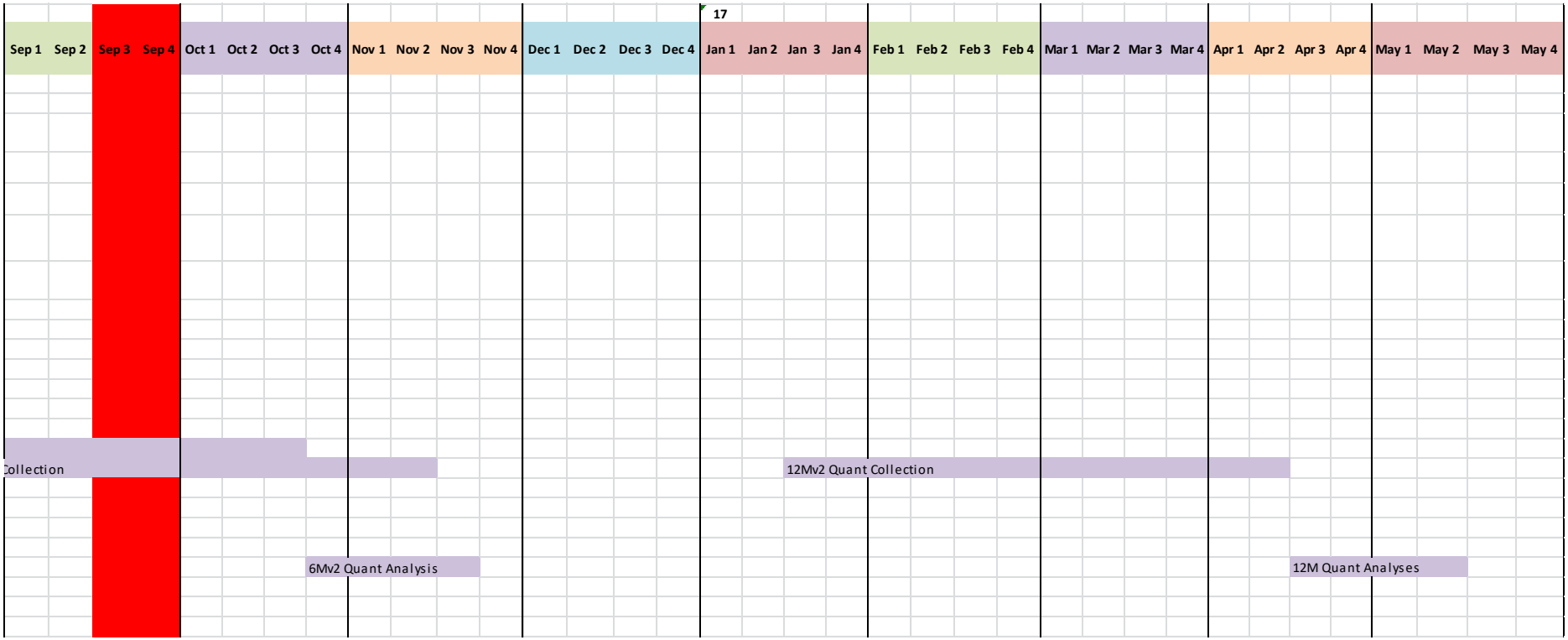
Dec 1 Dec 2 Dec 3 Dec 4 Jan 1 Jan 2 Jan 3 Jan 4 Feb 1 Feb 2 Feb 3 Feb 4 Mar 1 Mar 2 Mar 3 Mar 4 Apr 1 Apr 2 Apr 3 Apr 4 May 1 May 2 May 3 May 4 Jun 1 Jun 2 Jun 3 Jun 4 Jul 1 Jul 2 Jul 3 Jul 4 Aug 1 Aug 2 Aug 3 Aug 4
Recruitment V2
1Mv2 Qual Collection
Intervention refinement
llection
ollection
3Mv2 Qual Collection
3Mv2 Quant Collection
6Mv1 Quant Collection
6Mv2 Quant Collection
12Mv1 Quant
1Mv2 Qual Analysis
3M Qual Analysis
1&3M Quant analyses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Sep 1 Sep 2 Sep 3 Sep 4 Oct 1 Oct 2 Oct 3 Oct 4 Nov 1 Nov 2 Nov 3 Nov 4 Dec 1 Dec 2 Dec 3 Dec 4 Jan 1 Jan 2 Jan 3 Jan 4 Feb 1 Feb 2 Feb 3 Feb 4 Mar 1 Mar 2 Mar 3 Mar 4 Apr 1 Apr 2 Apr 3 Apr 4 May 1 May 2 May 3 May 4
Collection
12Mv2 Quant Collection
6Mv2 Quant Analysis
12M Quant Analyses