‘HelpMeDoIt!’ a web, app and text based intervention to facilitate social support to achieve and maintain health related change in physical activity and dietary behaviour.

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This protocol has been authorised by:			
Name	**Role: Principal Investigator**	**Signature**	**Date**
Name	**Role: Director Social and Public Health Science Unit**	**Signature**	**Date**

General Information This protocol describes the HelpMeDoIt! study and provides information about the procedures for entering participants into the study. The protocol should not be used as a guide, or as an aide-memoire for the treatment/care of other patients/participants. Every care has been taken in drafting this protocol; however, corrections or amendments may be necessary. These will be circulated to the known Investigators in the study, but centres entering patients/participants for the first time are advised to contact the study staff in the Social and Public Health Sciences Unit (SPHSU) to confirm that they have the most up-to-date version of the protocol in their possession. Problems relating to the study should be referred, in the first instance, to the Trial Manager at SPHSU.

Compliance This study will adhere to the conditions and principles outlined in the EU Directive 2001/20/EC, EU Directive 2005/28/EC and the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95). It will be conducted in compliance with the protocol, the Research Governance Framework for Health and Social Care (Department of Health 2008), the Data Protection Act 1998, and other regulatory requirements as appropriate.

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Please contact the Trial Manager for general queries and supply of study documentation.

Randomisation

To randomise a participant call 0141 337 4186 and follow the automated instructions. Requirements include: fieldworker ID and pin; participant ID, gender and BMI.

Clinical or study queries

All queries should be directed to the Trial Manager who will direct the query to the most appropriate person.

SAE reporting

Where the adverse event meets one of the serious categories an SAE form should be completed by the responsible clinician or study researcher and faxed to the Trial Manager within 24 hours upon becoming aware of the event (See Sections 13 for more details).

Fax Number: 0141 353 7500

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Glossary of abbreviations

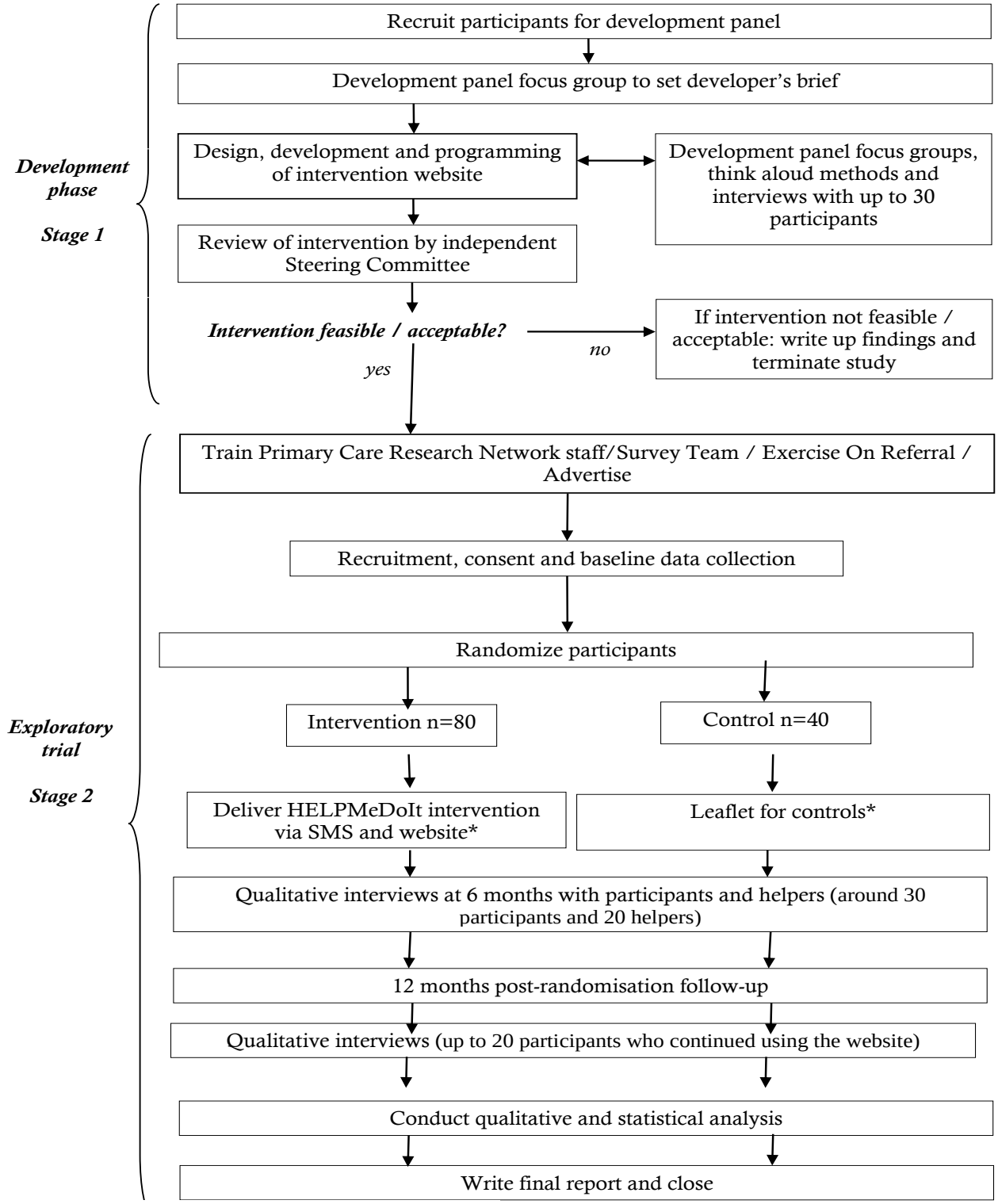
AE	Adverse Event
CF	Consent Form
PI	Principal Investigator
CRF	Case Report Form
CSO	Chief Scientist Office
CTU	Clinical Trials Unit
ICH	International Conference on Harmonization
GCP	Good Clinical Practice
GP	General Practitioner
HE	Health Economics
IC	Informed consent
IDMC	Independent Data Monitoring Committee
ISRCTN	International Standard Randomised Controlled Trial Number
MRC	Medical Research Council
NHS	National Health Service
NHS GGC	National Health Service Greater Glasgow and Clyde
NICE	National Institute for Clinical Excellence
NIHR-PHR	National Institute of Health Research Public Health Research
PIS	Participant Information Sheet
QALY	Quality-adjusted Life Years
QL (QoL)	Quality of Life
R&D	Research and Development
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
RGF	Research Governance Framework for Health and Social Care
SAE	Serious Adverse Event
SPCRN	Scottish Primary Care Research Network
SOP	Standard Operating Procedure
SPHSU	Social and Public Health Sciences Unit
SSA	Site Specific Assessment
TSC	Trial Steering Committee
TMF	Trial Master File
TMG	Trial Management Group

1. Amendment history

Amendment No.	Version no.	Date issued	Author(s) of changes	Details of changes made
1.	2.0	22.07.15	Sharon Simpson (SS)	***Section 2***: 'Think Aloud' methods added to Study Schema and main text. ***Section 3:*** (i) Some terminology reworded and missing aim added; (ii) Primary outcome terminology reworded; (iii) BP and cholesterol measures removed from the protocol. ***Section 4:*** 'Social support' amended to 'Managing social influences'; ***Section 5***: (i) Objective 8 reworded to include 'stage 1 and stage 2'; (ii) Objective 10 reworded to include 'modelling'. ***Section 8***: (i) Example of slimming club added; (ii) 'In stage 2 only' added to clarify recruitment sources. ***Section 10***: (i) 'think-aloud methods and the USE questionnaire' added to outcome measures; (ii) clarification of timing of smoking and alcohol questionnaires added; (iii) ICECAP-A measure added to compliment EQ5D quality of life measure; (iv) text and table updated to reflect decision to collect smoking and alcohol use at 12-months only. ***Section 11***: (i) 'We will have' reworded to 'we propose' throughout section 11; (ii) reference to 'forum' removed from experimental group; (iii) 'access via Facebook account' added; (iv) information added regarding 'participant specific' area of app and website. ***Section 12***: (i) Progression criteria updated; (ii) incorrect reference to TSC meeting at 6-months removed; (iii) Two questions added to assess researcher bias; (iii) 'Consent bias' amended and reworded; (iv) Secondary analyses section updated; (v) Sentence added regarding exploration of goal setting and self-monitoring.

				Section 13: (i) Reporting of SAEs to funder and ethics included; (ii) Trial Manager contact details added. ***Section 14***: (i) Economic analyses section updated; (ii) Process analyses and logic model testing added to analyses; (iii) thematic analysis replaces Framework Method. ***Section 17:*** Information related to Data Protection Agreement with software company added.
2.	3.0	08.03.16	SS	***Page 7:*** Randomisation telephone number added. ***Section 3:*** 'Social network' added to outcome measures. ***Section 5:*** Social network analysis added to the overall study objectives. ***Section 10:*** Social network analysis added to outcome measures/mediators. ***Section 12.2.1:*** Revised version of the logic model added.
3.	4.0	27.09.16	SS	***Section 12.3:*** Progression criteria added for stage 2 to full randomised controlled trial.
4.	5.0	28.02.17	SS	**Principle Investigator** job title of PI amended from Dr to Professor **Section 3:** Study summary p13 study duration amended from 30 months to 34 months due to delayed start. **Section 7:** Participant sampling p23 amended to ensure we select based on high, low or no usage of the app. **Section 8.2:** Recruitment process p24 removed the need for an additional consent form for participant stage 2 interviews in its place verbal consent will be obtained prior to interview.

2. Study schema



*All participants receive routine care and a leaflet

3. Study summary

Background: The internet and social media can be effective in influencing behaviour, and can reach large numbers of people. Previous research shows that setting goals, making plans and monitoring how well you are doing is important to facilitate behaviour change. The support of family, friends and others is also crucial in helping people to achieve and sustain behaviour change and healthier lifestyles.

Aims: We aim to develop and test the feasibility of an intervention to promote health behaviour change employing three key facilitators: goal setting, monitoring, and social support. We will explore how web, app and text interventions might facilitate use of these techniques to enable individuals to identify and monitor goals and to enlist social support to help them to achieve their goals and change behaviours in relation to diet, physical activity and weight loss.

Design: The study will be completed in two stages. Stage 1 will focus on the development and design of the intervention and stage 2 will explore whether this intervention helps people to improve their diet, increase their physical activity or lose weight. In stage two participants will be randomly allocated into two groups. The intervention group will complete the HelpMeDoIt! intervention for 6 months and the control group will receive a leaflet on healthy diet and lifestyle (HelpMeDoIt! Healthy eating and lifestyle leaflet v1.0).

Population: Adults aged 18-70 whose BMI is 30 or over and who are trying to lose weight. Participants need to have access to a mobile telephone and the internet.

Outcome Measures: In stage 1 the intervention will be tested by members of the public. Focus groups and interviews will be completed with up to 40 participants. At the end of this stage, we will produce a report which will be reviewed by an independent steering group who will decide whether to progress to the next stage. In stage two, we will recruit 120 participants and assess 3 primary outcomes: physical activity, diet and BMI. We will explore which of these is most responsive and sensitive to change for the definitive trial. At baseline and 12 month follow-up physical activity, diet, height, weight, waist circumference, health related quality of life, social support, social network, self-efficacy, motivation, mental health, NHS resource use and participant borne costs will be assessed. At 12 months we will also gather data on smoking and alcohol use, using this opportunity to assess the feasibility of additional questionnaires for data collection. Up to 30 participants and 20 helpers will be interviewed about their experience of the intervention at 6 months and up to 20 participants at 12 months. We will also look at methods to assess value for money and obtain estimates of key cost drivers to inform the design of a future cost effectiveness analysis.

Duration and follow-up: The study will last 34 months. Participants will be followed up at 12 months from randomisation into the study.

4. Introduction

4.1 Background

Poor diet, physical inactivity and high BMI have been highlighted in the top ten risk factors for burden of disease worldwide. Health related behaviours are a significant contributor to diseases such as diabetes, cancer, heart disease, hypertension and stroke. Preventative interventions which are accessible, engaging and which successfully improve health behaviours are necessary to reverse current trends particularly since interventions to date have had limited effectiveness and approaches known to work are not always adopted.[1]

Key issues with current intervention approaches which need addressing include: intensity, reach, uptake, motivation and maintenance. Evidence indicates that intervention effectiveness increases with the intensity or amount of intervention delivered (total contact time or number of contacts).[2,3] The challenge is how this can be achieved whilst keeping the intervention low cost. Successful interventions often employ intensive high cost one-to-one approaches.[2] These interventions have low reach as the intervention is only deliverable to a small proportion of the population. Given the scale of the problem of lifestyle related illness it is clear that alternative approaches need to be developed and tested. Ongoing motivation of participants and maintenance of behaviour change are also important issues.[1] At present there are few studies testing interventions for maintenance of behaviour change. Interventions often do not have a specifically defined theoretical basis linking intervention elements with outcomes and theory based interventions generally have better outcomes.[4] There are also issues around encouraging uptake and compliance with interventions. The intervention proposed here will seek to address these issues.

Internet and text (SMS) technologies present opportunities to enhance the effectiveness and reach of behaviour change interventions for health improvement. Evidence in the emerging field of using new technologies to promote health behaviour change suggests that they can be effective.[5-7] However, interventions have often been rather simplistic and not based on the best evidence and theory of effective behaviour change.[8] The effectiveness of these interventions could be enhanced by incorporating well-evidenced behaviour change techniques and promoting support from an individual's social network including family and friends to assist them to achieve health-related goals. Research indicates the importance of social support in initiating and maintaining behaviour change. In addition although studies show that ongoing contact is important this is difficult to achieve in a cost-effective way. New technologies may enhance interventions, by facilitating higher intensity (such as more frequent contact via texting) longer term interventions which may increase success at a lower cost than traditional methods.

We conducted a literature review to identify relevant studies to guide our research questions, intervention and study design. We searched Web of Knowledge and Medline for papers that

had 'health behaviour' or 'diet', or 'physical activity' and which also included the term 'social support' in the title or abstract. A search was also conducted for web-based and SMS interventions papers that had 'health behaviour' or 'diet', or 'physical activity' and also had "web" or "SMS" in the title or abstract. We included any type of social support, including social support from family and friends as well as 'constructed' social support groups such as Weightwatchers. We also included theoretical literature on behaviour change and social support and its effect on health behaviours to identify key concepts in this area.

We searched the internet for currently available websites or 'apps' offering behaviour change interventions around diet and physical activity. We identified a number of websites including www.Stickk.com, www.weightlosswars.com, www.myfitnesspal.com, www.livestrong.com, and www.minimins.com. These sites include different elements like monetary incentives or prizes, competing with others, behavioural goals and social support elements such as chat forums. However they are not designed to include families and friends whereas existing evidence indicates their positive role in promoting effective behaviour change rather than anonymous online contacts.[2,35] The perceived value of, and demand for, social support has resulted in many health behaviour change websites having chat forums, walls or bulletin boards which facilitate support from other users and are useful in providing empathy and encouragement, but are not able to build on evidence of the importance of who provides the social support or the many mechanisms through which social support can act or what impact this has on intervention outcomes. None of these sites offer the combination of elements that we plan to use in our intervention, most importantly social support from key individuals within that person's social network, i.e. existing friends and family who will in many cases be the people that participants eat and exercise with. Participants will be able to nominate those they think are most likely to be able to help them with specific behaviour change goals.

The proposed intervention will address both intrapersonal (internal cognitive processes) and interpersonal processes (mobilising individuals' social networks). The techniques included in the proposed intervention derive in the main from Social Cognitive Theory[9] and Control Theory,[10] these are the key theories on which the intervention is based.

Intrapersonal processes: Intrapersonal processes which are central to behaviour change include intrinsic motivation, self-efficacy, goal setting and self-monitoring. Other elements of effective behaviour change such as action planning and implementation intentions, are also key. Meta analyses have identified the importance of implementation intentions[11] and action planning.[12] Self-monitoring is key to successful behaviour change.[13] In a meta-analysis of behaviour change interventions of physical activity and healthy eating, more effective interventions were shown to combine self-monitoring with at least one other technique derived from Control Theory (e.g. intention formation, specific goal setting).[14] This core evidence will inform the main theoretical basis for the intervention which will be enhanced through 1) being delivered using new technologies and 2) by engaging social support for participants. The addition of social support

could aid adherence to and maintenance of these processes.[2,14] We seek to use the existing social relations and links between individuals so that social support from friends and family can be mobilised to aid those recruited into the study to achieve and maintain healthy behaviours.

Interpersonal processes - Social Support: Social support may operate in a number of ways to promote healthy behaviours such as reinforcement, encouragement, motivation, feedback, empathy, role modelling, increased self-efficacy, instrumental support (help), appraisal (e.g. affirmation), peer pressure for healthy behaviours or access to health information. There is evidence indicating that social support and health are related to each other[15] and that social support can promote better health behaviours, improving outcomes alongside goal setting and self-monitoring. Ferranti et al. found that social support is positively correlated with a good diet.[16] Also, social support is associated with increased physical activity. [17,18] Social support can improve weight loss maintenance, [19] encourage health-promoting behaviours and promote well-being. [20] There is also evidence that negative health behaviours are correlated with less social support. The current NICE behaviour change draft guidance notes that *"in existing NICE guidance social support was used in the majority of effective interventions for all behaviours (alcohol, diet, physical activity, sexual behaviour and smoking interventions)"* (p31).[21] Social support tends to be employed and theorised as one of several elements of behaviour change interventions[22] and in reviews has been identified as one contributing factor to effectiveness, alongside goal setting and self-monitoring. [2,14] Common intervention elements theorised to operate in conjunction with social support are self-efficacy,[23] perceived control,[17,23] and social norms. [24]

Social support and its relation to health behaviour change is under-theorized. This is partly because social support is a broad and somewhat loosely-used concept, for example it is an element in the widely-used terms of 'social capital' and 'social networks' which are used to frame ideas about social support. Social support is multi-faceted: there are various types of social support[25,26] and there are different kinds of support giving/receiving behaviours. [27] The draft NICE guidance on behaviour change (p41) identifies three categories of social support: practical, emotional and praise/reward and further notes that social support can have negative aspects, such as co-dependency or bullying.[21] It is not clear which type(s) of social support might be most effective for health behaviour change or how support might be best promoted, particularly as some types of social support may be negative or unacceptable and minimization of negative support might be a consideration as well as promoting positive support. [28] For example, a study by Tamer et al. found that social support was positively correlated with an unhealthy diet.[29] So while it is generally used as a positive construct it may also have negative elements.[28,30] It may be useful to think of think of this in terms of managing social influences; so exploring who can help and how (positive social influences) but also in the ways in which people can hinder individual's efforts in relation to improving health behaviours (negative social influences). This will be explored in the study.

A small number of studies have examined the relationship between social support and known mechanisms of behaviour change, for example George et al (2013) looked at the effect of social support on self-determination.[31] Molloy et al. (2010) suggest that social support is important during the planning (post intentional) phase of behaviour change, through 'perceived behavioural control and coping planning' and can promote increased physical activity.[17] Lim et al's (2010) study of health promoting behaviour theorized social support as a mediating factor between self-efficacy, perceived control and perceived health status, and health promoting behaviours.[23]

'Social support' is also conceptualised in varied ways in terms of who provides the support. Family,[32] friends,[19] influential people within existing social networks,[33] and fellow members of groups with a shared behavioural goal (e.g. weight loss, exercise)[34] have been found to be effective in supporting behavioural change in alcohol consumption, smoking prevention and cessation, physical activity, diet and sexual behaviour. We are defining a social support network for the purposes of this study as the existing personal (or 'ego-centred') network that an individual has, consisting of their friends and family members. Individuals draw on different types of support from different people in their network. For example, they may derive emotional support from a close friend in their network but may choose to recruit a more distant friend for their expertise in a particular area. Family and friends are significant social influences on health behaviour due to factors such as intimacy, influence and proximity to day-to-day health behaviours. They are also immediately accessible to participants because this type of support does not entail joining any kind of formal group. Evidence suggests the positive influence of friends and family on health behaviours.[35] Pearson et al. (2011) found that support from a best friend for healthy eating was positively correlated with increased vegetable consumption in adolescents.[36] Perceived norms of friends' activity predicts individual's activity level.[24] Mechanisms of change are likely to include: having a friend to change behaviour with, removing barriers that could be presented by friends/family who continue with the harmful behaviour, managing self-presentation in front of others[37] or it might relate to social affect and adjusting injunctive social norms. The impact of support from family and friends is likely to differ by gender.[17]

This study will build on the existing literature demonstrating the positive role of social support as a component of successful health behaviour change but will also develop theory concerning the types of social support that participants choose to draw on in their personal networks, which individuals they choose, the types of support provided in the context of a web and SMS based environment, the interaction with known behaviour change mechanisms such as goal-setting and monitoring, and the impact that this has on health behaviour change.
New Technologies and Health Behaviour Change: Emerging evidence in this field suggests that this type of intervention can be effective, for example texting to promote healthy behaviours[7] and in health education and goal setting via the internet. Internet web pages and apps can assist with goal setting and monitoring, through updating of website and reminders of goals.

Similarly, SMS can facilitate successful behaviour change.[7,38] A growing body of literature on web-based interventions employing social cognitive theory/goal setting/self-monitoring have demonstrated positive effects on program engagement and health behaviours.[4,39] Complex interventions have been found to be more effective than single mode interventions and adding SMS to web-based interventions was found in one systematic review to be more effective than other combinations of technology-based approaches.[4] There is also evidence that new technologies can be effective with both young and older people.[40,41]

While representing a promising new area for population health, studies of these interventions have been limited in that they tend to have small, short-term effects[42] and high attrition.[4,43] In addition, they are often not based on the best available evidence and theory of behaviour change. Incorporating well-evidenced behaviour change techniques into these types of interventions could enhance effectiveness since goal setting, self-monitoring and review of goals have well-established benefits.[40] Additionally, there is a need to improve our understanding of how interventions involving new technologies might most effectively facilitate change. For example, factors such as optimal website design, how to maximise exposure to websites or what type of prompting works best are still areas requiring development. [44] Therefore, while there have been promising signs in this emerging field, such as the potential for high reach and the opportunity to engage difficult to reach groups with whom traditional means of promoting behaviour change are challenging, e.g. lower socio-economic groups, there is a need to address research gaps in understanding how new technologies might support or enhance known health behaviour change mechanisms such as goal setting. Currently, while there are positive indications there is a lack of robust evidence in this area.[45]

Combining Social Support and New Technologies: Research on social support for health behaviour change indicates that it may be important in initiation and longer term maintenance of behaviour change,[2,19,46] It can also improve outcomes alongside goal setting and self-monitoring[2]. These techniques are also supported by NICE.[47] Internet, app and SMS technologies present opportunities to combine these techniques and to enhance the effectiveness and reach of behaviour change interventions for health improvement further. Particular aspects of new technologies may enhance interventions, such as through higher intensity (such as more frequent contact, via texting), which may increase the success of an intervention[2] but at a lower cost than traditional methods. Some applications may also allow for more personalisation or individual tailoring of an intervention to suit individual needs which may also improve success rates.[48] However, the evidence base is limited and to date somewhat mixed.[49]

Anderson-Bill et al.[50] found that perceived social support from family and friends and use of self-regulatory behaviours were strong predictors of improved physical activity and nutrition behaviour in an online intervention although this support was not specifically promoted as part of the intervention. Similarly, Neuhauser and Kreps[51] argue that communication that is

interpersonal, affective (not just rational), interactive, individually-tailored and is set within an individual's social context is more likely than other forms of communication to be effective in changing health behaviour, and that this should be incorporated within new technology and internet-based interventions. This type and quality of social support would be better facilitated through contact with family and existing friends, rather than anonymous online groups. However, social support from friends and families tends not to be incorporated into the formal design of online behaviour change interventions. Tailoring or personalisation of messages sent via SMS also seems to be an important factor in the success of interventions. However this could be further enhanced using messages sent by friends or family.

4.2 Rationale for current study

Improving health behaviours is a priority for government. However, current health behaviour change initiatives require improvements in their reach and effectiveness to have a significant impact on the population's health.[1] The House of Lords Scientific and Technology Committee Report on Behaviour Change highlighted that no single approach is likely to be effective in tackling priority health behaviours and that complex interventions addressing *multiple* levels of behavioural determinants are likely to be needed to bring about sustained change.[1] HelpMeDoIt! is a complex intervention which will address two of these levels; the individual and social support networks.

Lifestyle related illness represents a significant cost to the NHS; one-to-one individualised lifestyle interventions are unlikely to yield substantial population level improvements at a realistic cost to the public purse unless they are highly effective, whereas internet and SMS-based behaviour change interventions can reach substantial numbers at a lower cost. New technologies such as SMS present opportunities to promote healthy lifestyles cost effectively at large scale, in this case combining evidence based behaviour change components with the facilitation of community based social support resources in an engaging and accessible way.

The proposed intervention is based on the best available behaviour change theory and has a strong theoretical underpinning, incorporating components of Social Cognitive Theory[9] and Control Theory.[10] A review of efficacious technology-based weight loss interventions identified important components including self-monitoring, feedback, communication, social support and individual tailoring which we have incorporated in this intervention.[48]

While these intervention elements – goal setting, self-monitoring and social support – are well established and new technologies have shown promise, the evidence base is limited and mixed and theoretically under-developed in several areas.[8] Furthermore there are significant gaps in understanding how these elements work together, for example how social support operates through personal networks mediated by new technologies, and what impact this has on mechanisms such as monitoring. There is a need to explore the application and mechanisms of goal setting, monitoring and social support via internet and SMS interventions and how they

interact with each other and to test this type of intervention in both an exploratory and full scale effectiveness trial. Effect sizes, long term impact and retention could also be improved in web and SMS interventions.

HelpMeDoIt! will employ the best evidence of effective practice to help individuals change their health behaviours through identifying, achieving and maintaining a behaviour change goal to improve their health through the support of their friends and family. In doing so it will take a wider social determinants approach by influencing the family and friendship network of an individual and its impact on health behaviours while also supporting and empowering individuals to promote their own health. It will provide a holistic, early intervention across a range of key health behaviours. It will also indicate what types of social support participants choose to access, through which people in their personal networks and via which media (e.g. SMS, app, web or other communications). This will provide valuable data on the preferences and acceptability of these components of interventions. Obesity is associated with deprivation as there are higher rates in lower socio-economic groups. We will aim to recruit participants from across the social spectrum to assess acceptability and potential effectiveness. This intervention has the potential to have both reach and effectiveness in all socio-economic groups including traditionally hard to reach groups, e.g. lower socio-economic groups.

Exploratory trials of this nature are a necessary first step in developing public health improvement interventions, particularly where mechanisms, such as social support, are not well understood and where innovations such as SMS present new possibilities. It will also have high reach by being freely available on the internet and through its application via SMS and app, technologies which are engaging to use and accessible. The internet is now accessible to over 80% of the UK population in all socio-economic groups. In the UK 94% have mobile phones of which 60.4% are smart phones (http://www.mobilemastinfo.com/stats-and-facts/). If the intervention were proven effective it could be applied to other behaviour change areas and would be universally available through a free-to-access website and/or promoted in specific NHS and community settings across the UK.

5. Study objectives

We aim to develop and test the feasibility of an intervention (HelpMeDoIt!) to promote health behaviour change employing three key facilitators: goal setting, monitoring by self and others, and social support. We will explore how web, app and SMS interventions might facilitate use of these techniques to enable large numbers of individuals to identify and monitor goals, to enlist social support to help them to achieve their goals and change behaviours.

The study will be completed in two stages. The aim of stage one is to develop and pilot the intervention with the help of a panel of user representatives to address (i) the engagement and

ease-of-use of the web interface and app and its success in promoting the setting of realistic goals and plans, (ii) to assess acceptability of the social support content, iii) to assess the functionality of the SMS messaging and its facilitation of social support from helpers, and iv) the views of the panel on how the intervention will attract and support helpers. Stage two will be an exploratory trial with embedded process evaluation which aims to examine reach, feasibility, acceptability, trial parameters and potential effect.

Key objectives:
1. To develop an internet and SMS-based intervention which enables participants to set and monitor goals and facilitate effective social support.
2. To investigate recruitment and retention as well as feasibility and acceptability of the intervention.
3. To investigate how participants and helpers engage with goal-setting, monitoring and social support using new technologies and how these elements interact within a behaviour change intervention.
4. To explore the barriers and facilitators to implementing the intervention.
5. To assess the feasibility and acceptability of different outcome measures for diet and physical activity in this population.
6. To use outcome data (diet, physical activity, BMI) to help decide on a primary outcome and to estimate the potential effect size of the intervention to facilitate the calculation of an appropriate sample size for a full trial.
7. To develop a conceptual model of how the key mechanisms of goal setting, monitoring by self and others, social support and behaviour change are facilitated by the intervention.
8. To explore the characteristics of participants' social networks and the influence social networks has on participant experiences and outcomes of the intervention.
9. To test the logic model and theoretical basis of the intervention in stages 1 and 2.
10. To explore the potential of the intervention to reach traditionally 'hard to reach' groups (e.g. lower socio-economic groups).
11. To complete some modelling work to assess the value of a future trial and to obtain estimates of key cost drivers to inform the design of a future cost effectiveness analysis.
12. To assess whether an effectiveness trial is warranted.

6. Study design

The proposed project has 2 stages: intervention development and feasibility testing (stage 1) involving qualitative interviews and focus groups followed by an exploratory trial and process evaluation (stage 2). In stage one ten participants will be recruited to a development panel and will take part in interviews/focus groups and user testing of the developing website and app. We will also conduct interviews or focus groups and user testing with up to 30 other lay members. In stage 2, 120 participants will be recruited into an exploratory trial.

7. Participant selection

Stage 1
Participants in stage one will be selected to ensure a spread of gender, socio-economic background and age. They will be adults (BMI 30+) aged 18-70 trying to lose weight, with access to a mobile telephone and the internet. We will exclude potential participants if they have had previous bariatric surgery; have a terminal illness; dementia or poor competence in English.

Stage 2
Participants are eligible for the trial if they meet all of the following inclusion criteria and none of the exclusion criteria. All enquiries about eligibility should be directed to the HelpMeDoIt! Trial Manager before randomisation or registration.

Inclusion criteria:

- adults
- BMI 30+
- aged 18-70
- trying to lose weight
- access to a mobile telephone and the internet

Exclusion criteria:

- terminal illness
- previous bariatric surgery
- dementia
- pregnancy
- poor competence in English (resulting in an ability to complete study materials)
- contraindications to physical activity
- or *originally* being a nominated helper in the trial

We will assess contraindications to physical activity using an adapted Physical Activity Readiness Questionnaire[52] (HelpMeDoIt! 2014 PAR-Q+ v1.0) and anyone with any medical conditions or taking any medication or who thinks they may have a contraindication to physical activity will be advised to check with their own GP before commencing any physical activity. We will ask women of childbearing age to let the study team know if they become pregnant at any point during the trial. Once recruited, pregnant women will not be excluded from the study but will be given a leaflet on diet and exercising safely during pregnancy (HelpMeDoIt! Pregnancy Leaflet v1.0).

Around 30 participants at 6 months and up to 20 at 12 months will be asked to complete telephone interviews. Participants will be sampled on high, low, or no use of the app/website and we will ensure a reasonable spread of gender, age, and socioeconomic status. At 6 months we will also approach up to 20 nominated helpers to take part in an interview. They will have the study explained and be fully consented to take part in the interviews. There are no specific inclusion criteria for the 'helper' interviews, other than that we will try to ensure a reasonable spread of various demographic characteristics as well as engagement with the 'support' aspect of the intervention.

8. Recruitment

8.1 Number of participants

We will recruit around 40 participants in the development stage of the research and in the exploratory trial 120 participants will be recruited.

8.2 Recruitment process

Participants for both stage 1 and 2 will be identified via: slimming clubs like Scottish Slimmers or Slimming World; other ongoing studies in the Social and Public Health Sciences Unit (SPHSU) where participants have given permission to be contacted about future studies; exercise referral schemes; GP practices (stage 2 only), and by advertising in the community, weight management clinics (stage 2 only), large employers (via their intranet) and gyms as well as through Facebook and Twitter and other social media. Recruiting men into trials of this type is notoriously difficult. A systematic review of male inclusion in RCTs of weight-loss interventions found an average split of 27% male compared to 73% female, despite similar prevalence of obesity for both sexes.[53] In order to improve recruitment of men we will target the advertising in places in the community which men are likely to frequent, e.g. gyms, barbers, rugby and football clubs. The website, app and study materials will be gender neutral and the website and app individually tailored. In order to recruit participants from lower socio-economic groups we will specifically target advertising as well as GP practices in areas of high deprivation. During the set up phase we will develop a recruitment strategy based on our considerable experience of recruiting into trials of complex interventions in health.

We will advertise (HelpMeDoIt! Advert v1.0) for potential participants via community centres, local press, pharmacies, GP practices (stage 2 only), slimming clubs, weight management services (stage 2 only), exercise on referral schemes, large employers, barbers, football clubs, gyms etc. We will ask exercise on referral staff to approach potential participants when they see them and point the study advert out. We will engage with slimming clubs like Slimming World or other commercial slimming clubs to ask their staff to approach potential recruits and point the study advert out as well as to email members the advert and advertise the study on their websites. We will monitor the effectiveness of these different recruitment strategies.

Individuals who are interested will be able to contact the study team for further information. When they contact the study team we will then take potential participants details and send them the study information sheet (HelpMeDoIt! Stage 1 Participant Information Sheet v1.0 or HelpMeDoIt! Stage 2 Participant Information Sheet v1.0). A week later we will contact them to arrange to meet them at a place of their choice, which could include their home (SPHSU policies for lone working will be followed), SPHSU, or a community venue, to take consent (Stages 1 and 2) and collect demographic information (in Stage 1 using HelpMeDoIt! Demographics Questionnaire for Panel Members v1.0 and in Stage 2 HelpMeDoIt! Baseline CRF v1.0). In Stage 2 we will also to collect baseline measures (HelpMeDoIt! Questionnaire Booklet v1.0).

We will write to potentially eligible participants from other studies using the HelpMeDoIt! Approach Letter 1 v1.0 and the HelpMeDoIt!! Contact Details Form v1.0 and enclose the appropriate information leaflets depending on study stage. Once they have returned the contact details form, we will contact them to arrange to meet them at a place of their choice, which could include their home, SPHSU, or a community venue, to take consent (Stage 1 and 2) and collect baseline measures (stage 2).

With regards to the other recruitment sources: in stage 2 only Scottish Primary Care Research Network (SPCRN) staff will identify potential participants from GP records and check with clinicians if there is any reason they should not be approached and then send them letters (HelpMeDoIt! GP Approach Letter v1.0) and a participant information leaflet (HelpMeDoIt! Stage 1 Participant Information Sheet v1.0 or HelpMeDoIt! Stage 2 Participant Information Sheet v1.0) explaining the study and inviting them to take part. If potential participants are interested they will fill in their contact details (HelpMeDoIt! Contact Details Form v1.0) and return the form to the study team. Staff in exercise referral schemes will be asked to send letters and contact details form out to potential participants (HelpMeDoIt! Approach Letter 2 (EOR) v1.0 and the HelpMedoIt! Contact Details Form v1.0), interested individuals will then complete with their contact details and this will be returned to the study team. All potential participants can call, text or email the study team expressing an interest if they do not wish to return the contact details form by post and the team will take down their details and send them the relevant study information sheet depending on stage. As above we will then arrange to meet them to take informed consent and collect baseline measures. We will also seek to recruit individuals to test out the developing system and do brief interviews and they will be approached as described above and given an information sheet (HelpMeDoIt! Participant Information Sheet for Stage 1 Interview v1.0) and consent form (HelpMeDoIt! Participant Consent Form for Stage 1 Interview v1.0).

In stage 2 of the study participants will also be approached to complete interviews. If they are willing to take part in an interview they will be sent a separate information sheet (HelpMeDoIt! Participant Information Sheet). Helpers will also be recruited to take part in interviews, the study team will contact helpers to ask if they would be willing to do an interview about their

experiences. If they are willing they will email/text/call the study team and the researcher will send an information leaflet (HelpMeDoIt! Helpers Interview Information Sheet). In both cases the interviewer will check participant or helper received the information sheet and verbal consent will be gained prior to the interview commencing.

For those taking part in stage 2, we will notify GPs of their participation (HelpMeDoIt! GP Letter) and this will be detailed in the relevant information leaflets.

8.3 Informed consent

For both stages 1 and 2, after receiving information sheets about the study (HelpMeDoIt! Stage 1 Participant Information Sheet and HelpMeDoIt! Stage 2 Participant Information Sheet) participants will have at least a week to consider taking part in the study. Potential participants will meet with the researcher and they will explain the details of the study and they will have the opportunity to ask any questions they may have. The researcher will then take informed consent (HelpMeDoIt! Stage 1 Consent Form). Informed consent to participate in the study will be taken either by SPCRN network staff or by the study team from the Social and Public Health Sciences Unit in the University of Glasgow, they are fully trained in Good Clinical Practice (GCP) and taking informed consent.

The 'helpers' will be nominated by the study participants. If they agree to be helpers, they will go to the study website and will be able to access an information sheet about the study (HelpMeDoIt! Helper Online Information Sheet v1.0) and they will be asked signify their consent using an online form (HelpMeDoIt! Helper Online Consent Form v1.0). This will indicate their consent to be a helper, for the study team to keep their contact details (for the purposes described below) and also to signify whether they are willing to be contacted to see if they would be willing to complete an interview at a later date (for which they will give separate, written consent). On the website there will be contact details for the study team so that the helpers can call or email if they have any queries or need any further information. After completing the consent to be a helper they will then enter brief demographic details and their contact details on the website in the form of a postal address, mobile phone number and email address (where available), as this information is required to give them updates on participants' progress and to send reminders to them as well as voucher payment for interviews and vouchers to cover mobile phone costs. The demographic data will be used to describe the characteristics of the helpers and so we can sample them for the interviews according to gender, age and relationship to participant.

Participants for the stage 2 interviews (study participants and Helpers) will have at least a week to consider taking part and will be sent an information sheet (HelpMeDoIt! Participant Information Sheet for Stage 2 Interview v1.0 or HelpMeDoIt! Helpers Interview Information Sheet v1.0).. A member of the study team will contact study participants and helpers who are

willing to take part in interviews by email or telephone to answer any questions they may have and arrange a suitable time to conduct the interview.

8.4 Exploring the feasibility of participants also acting as helpers

This study also aims to explore how the HelpMeDoIt! intervention might work in a real-world setting. Due to the social support focus of the intervention it may be that two or more friends/relatives wish to lose weight together and support each other. It is important to allow for and explore this for several reasons, including:

- this approach may have potential benefits for participants via increased support and motivation.
- participants who also act as helpers might have more beneficial outcomes than participants who don't act as helpers.
- identifying a spill-over effect in line with the diffusion of innovation theory[54] (i.e. the HelpMeDoIt! intervention gains momentum and spreads through a specific social network).

Our feasibility study will therefore allow participants in the intervention arm to act as a helper for a friend/relative. Their helper will then also have access to the participant aspect of the intervention (i.e. so that they can be both participants and helpers to each other). However, to avoid contamination of the findings the second individual will not be registered as a 'study participant' or randomised. If they were to be registered as a study participant this could potentially contaminate the randomisation (i.e. one individual may be randomised to the intervention group and the other to the control group). It is unknown if participants will choose to act as helpers but it is important to allow for and explore this as part of the feasibility study. We intend to try to include in the interviews any participants who also act as helpers, as well as helpers who had access to the intervention (but were not study participants), to gather their insights on the feasibility, acceptability and impact of this approach. Interview findings will help refine any necessary software changes for delivery of a future effectiveness trial.

8.5 Randomisation/registration

We are most interested in the intervention arm and so will randomise in a 2:1 ratio into treatment and control. Overall 80 participants will be allocated to HelpMeDoIt! and 40 to the control group. Subjects will be allocated using a minimisation algorithm to ensure balance with respect to gender and BMI (<40, ≥40 kg/m^2). In blocks of 15 participants, 12 will be assigned according to the minimisation algorithm and 3 will be allocated (in a 2:1 ratio) at random. The minimisation/randomisation schedule will be prepared by a statistician within the Robertson Centre for Biostatistics who will have no further involvement with the study, using the method of randomised permuted blocks.

Participants will be remotely randomised using an automated telephone service operational 24 hours a day. Randomisation can only be performed after the participant has signed the consent form and completed baseline data collection procedures.

A randomisation form must be completed before telephoning the randomisation line. Participants will be randomised to HelpMeDoIt! Intervention or control and upon randomisation will be allocated a unique study number. The unique trial number will then be entered onto the randomisation form and faxed to the HelpMeDoIt! Trial Manager. The Trial Manager will also be notified that a participant has been randomised via an automated e-mail alert mechanism. The unique trial number will be the primary identifier for all participants in the trial.

9. Withdrawal & loss to follow-up

Participants have the right to withdraw consent for participation in any aspect of the HelpMeDoIt! study at any time. The participants' care will not be affected at any time by declining to participate or withdrawing from the study.

If a participant initially consents but subsequently withdraws from the study, clear distinction must be made as to what aspect of the study the participant is withdrawing from. These aspects could be:
1. Withdrawal from study intervention
2. Withdrawal from study follow-up
3. Withdrawal from entire study and does not want any data to be used

A participant may withdraw or be withdrawn from the intervention for the following reasons:

- Withdrawal of consent for intervention by the participant
- Any alteration in the participant's condition or circumstances which justifies the discontinuation of the intervention in the Investigators opinion

A helper can also withdraw consent to participate in the trial at any stage. They can withdraw from the SMS messages or from any other aspect of the study.

In all instances participants who consent and subsequently withdraw should complete a withdrawal form (HelpMeDoIt! Withdrawal Form v1.0) or the withdrawal form should be completed on the participant's behalf by the researcher based on information provided by the participant. This withdrawal form should be sent to the HelpMeDoIt! Trial Manager. Any queries relating to potential withdrawal of a participant should be forwarded to the Trial Manager immediately.

There is a possibility that there may be issues related to compliance to the intervention (participants and helpers) as well as retention at follow-up. One of the key reasons for doing an exploratory trial is to assess the likely compliance and retention rates. We have addressed these issues in a number of ways. During the development stage we will involve user representatives who will help design the intervention to be engaging and acceptable and address issues around retention of participants and helpers. If participants drop out of the intervention this is an important finding which may indicate that the intervention is unsuitable for testing in a larger trial or that it needs significant adaptation. The qualitative data will identify pertinent issues for the design of the intervention with respect to acceptability, usage and effect size, reducing the risks of low usage and small effect size through an improved design at the full trial stage. Furthermore, while the aim of this research is to develop an intervention which maximises effect size and participation rate, an intervention such as this has a potentially high reach and can therefore tolerate small effects and low usage while still remaining cost-effective.

With regards to retention at follow-up, we will develop a retention strategy for the trial based on our experience with other studies of behaviour change. This will include flexibility regarding where data collection takes place, newsletters, obtaining mobile numbers and alternate contact details. To try to minimise loss to follow-up we will offer participants who are not keen to complete the full data set the option to just be weighed at 12 months rather than also complete the questionnaires or alternatively to complete a brief minimum data set of the key questionnaires to be collected over the telephone which includes self-reported weight (HelpMeDoIt! Minimum Data Set v1.0). We have also included voucher payments to participants for their time to complete data collection at the different time-points as well as the interviews. We have used this approach in other studies leading to much improved follow-up rates. In one study of a behaviour change intervention rates improved from 35% in the pilot to 82% in the main study.[55] We plan to give participants/helpers a £20 voucher for each of the qualitative interviews completed and a £20 voucher per participant for completing all data collection time-points including baseline and follow-ups to cover time and travel etc. We will also give helpers a £20 voucher to cover telephone costs and a £20 voucher payment to intervention participants to cover the costs of using their phone as part of the intervention. Finally we plan to pay panel members in stage 1 £75 per meeting to cover time and travel expenses.

10. Outcome Measures

In stage 1 we will assess acceptability and feasibility using interviews, focus groups, user testing, think-aloud methods and the USE questionnaire[56]. We will also collect brief demographic details of participants in stage 1 (Brief Demographics Questionnaire version 1.0). Outcome measures for Stage 2 are presented in Table 1. In stage 2, although the primary focus is on feasibility and acceptability, we will assess different outcome measures for the main trial. So for the exploratory trial we will have three candidate primary outcomes: physical activity, diet and BMI. We will assess which of these is most responsive and sensitive to change for the definitive trial. It is likely, however, that in a full scale trial BMI would be the best measure since it is objective and therefore less likely to be influenced by response bias. It is cheap to measure and easier to measure more accurately than diet and physical activity. It's arguably more important than diet and physical activity in terms of health and finally weight change is addressed by both changes in diet and physical activity making BMI a natural composite measure of the two. Since measuring diet[57] and physical activity[58] in community based trials is challenging we will assess two ways of measuring these outcomes: self-report questionnaire or more objective measures. This will inform both the choice of primary outcome for the main trial as well as method of measurement. Secondary outcomes include: weight, waist circumference, waist-to-hip, mental health, health related quality of life, use of NHS services, and participant borne costs. At 12 months we will use the USE questionnaire to assess feasibility and acceptability. We will also gather data on smoking and alcohol use, using this opportunity to assess the feasibility of additional questionnaires for data collection.

Measures at both outcome points will be completed face-to-face. At baseline we will collect demographic data including relevant medical conditions and at baseline and 12 months physical activity, diet, height, weight, waist and hip circumference, health related quality of life, social support, social network, self-efficacy, motivation, mental health and NHS resource use will be assessed.

Table 1 – Stage 2 outcome measures

Outcome	Measure	When
Demographics	Case Report Form	Baseline
Anthropometrics	Height, weight, waist and hip circumference	Baseline and 12 months
Physical activity	7 Day PAR[59,60] and accelerometer	Baseline and 12 months
Diet	DINE[61], 4x repeat 24 hour multiple pass recall[62] (dietary interview completed by telephone over 4 days within a 10 day period)	Baseline and 12 months
Health related quality of life	EQ5D-5L[63] and ICECAP-A [64]	Baseline and 12 months
Mental health	GHQ12[65]	Baseline and 12 months
NHS and PSS Resource Use	Specially designed resource use questionnaire	Baseline and 12 months
Alcohol use	Alcohol Use Disorders Identification Test (AUDIT-C)[66,67]	12 months
Smoking	Heaviness of Smoking Index (HSI)[68]	12 months
Feasibility and acceptability	USE questionnaire[56]	12 months

Mediators

Although not 'outcomes' as such, assessment of mediators is important in order to identify the processes by which the intervention brings about change. The exploratory analyses will identify both the extent to which the intervention was successful at changing these mediators and the extent to which mediator change was associated with change in BMI. The mediators to be evaluated are presented in Table 2. An important mediator is the potential influence of participants'' social networks on their behaviour change outcomes. We will therefore explore participants' social networks by asking them to draw a sociogram of their broad social circle followed by completion of an egocentric questionnaire for their nominated helpers. The social network data collection is presented in greater detail in the following document: 'HMDI Social Network Analysis overview for ethics v1.2 10.02.16'. All data on participants' social networks will be gathered anonymously via the use of initials (no names will be collected).

Table 2 – Assessment of mediators of behaviour change

Mediators	Measure	When
Social Support	Exercise & Eating Habits Social Support Scales[69]	Baseline and 12 months
Self efficacy	Weight[70] & Exercise Efficacy Lifestyle Scales[71,72]	Baseline and 12 months
Motivation (extent to which behaviours is autonomous/self-determined)	Treatment Self Regulation Questionnaire[73]	Baseline and 12 months
Social Networks	Sociogram Egocentric questionnaire	Baseline and 12 months

11. Study/trial intervention

11.1 Experimental Group

We propose that the HelpMeDoIt! Website will have 7 key elements supporting the intrapersonal and interpersonal elements of the intervention. The focus groups and panel will assist in the development of the following elements and may suggest additional elements or ideas:

- support for goal setting and planning
- 'nominate your helper' to identify goal-specific social support group
- obtain agreement from nominated helper(s) to provide support
- helper-specific advice on how to provide effective support
- 'track your progress' for monitoring
- behaviour specific information (including 'tips' and case stories)
- the SMS, goal updates, and support element of the intervention.

All participants will be encouraged and reminded to access the website as well as use the app. They will be given an individual login for the HelpMeDoIt! Website or access via their Facebook account. The website will allow specific tailoring for individuals. The website will provide guidance in setting behaviour change goals and making plans as well as managing negative social influences. It will ask the individual to nominate one or more helpers and enter their contact details. The HelpMeDoIt! programming will contact these helpers via SMS or email, and invite them to help the individual. Participants will be able to choose as many helpers as they wish, but we are anticipating an average of around 3-5 per participant. They will also be able to choose not to share certain potentially sensitive bits of information (e.g. body weight) with

helpers. Participant and their helpers will be able to access a 'participant specific' area of the app and website (the participant and their nominated helpers) to share information and offer further support.

Participants will be able to log on to add updates to their goals, plans, monitoring pages and also to 'deselect' helpers as well as nominate new helpers or change helpers' access to information. A version of the website will be accessible by smart phones to facilitate entry of information. Participants will also be able to update their goals and progress via SMS texts to update the website, as studies have shown this can enhance internet interventions.[4] The system will monitor the goal dates and gaps in updating and will send reminders to participants. An app will support some of these functionalities including information giving, goal setting and planning, problem solving and progress tracking.

Helpers who accept will be given some SMS support and guidance and a login for the website which will give more detail on the most effective ways to help people to achieve health goals such as increased physical activity or improved diet. These will be tailored to participant characteristics such as age and gender. They will then be sent regular prompts to remind them to provide encouragement, celebration or commiseration and further support, depending upon the progress towards goals. How this support is given is up to the helpers: it could be via text, phone call or face-to-face. Helpers will also be prompted for support through updates sent by the website on targets or new goals set, depending on the preferences of the participant. Text message reminders will be sent out to participants and helpers by the system when the goal date is close. Also, if the participant reaches their goal or decides they don't want to tackle this goal any more a message will be sent to the helpers. Outgoing text messages will be designed to be accessible and engaging, according to best practice[74] and based on consultation with the development panel.

Intervention delivery duration:
The 'active' phase of the intervention will run for 6 months where we will remind participants/helpers to use the system, after this period they will still be able to access the intervention but we will no longer send reminders, other than push notifications which are automatically sent out as part of the app. Controls can access the website and app after follow-up is complete at 12 months. A smartphone is not necessary to take part in the study and most packages, including pay as you go, have free texts, however we will give participants and helpers a voucher to cover any costs associated with using their phone for the study.

Assessment of harms:
The intervention is low risk to participants. There is a risk that participants may set unhealthy goals and that helpers may not provide support in a positive way. However, we will give guidance to helpers to ensure they provide positive support for participants. We will ensure that there are limits on the website and app to prevent unhealthy goals being set, e.g. excessive

weight loss. We will include information about healthy diet in line with government recommendations as well as advice on safely increasing physical activity levels and information will be given on possible warning signs to stop exercising. Participants will be encouraged to discuss any health concerns with their GP who will be informed of their participation (in the feasibility trial). In addition, at recruitment participants will be asked to complete the Physical Activity Readiness Questionnaire (adapted) to assess any risks to increasing physical activity levels. We will advise participants that although exercise can help prevent and improve many medical conditions that if they have a medical condition which may affect their ability to exercise that they should discuss it with their GP first. We will provide guidance to participants on goal setting to try and ensure that they do not set unhealthy goals. For those attempting to set unhealthy goals, we will suggest e.g. seeing their GP to discuss weight loss. We will involve user representatives from the beginning of the study and we will explore the issue of potential harm and ways to minimise this wherever possible. We will encourage participants and helpers to report negative outcomes or experiences to the study team via email, telephone or the website (whereby an automatic notification will be sent to the study team) and we will explore the issue of 'harm' in the interviews with both participants and helpers.

11.2 Control Group

The control group will receive a leaflet about the health benefits associated with behaviour change in these domains and some relevant tips which the team will put together using information from sites like NHS Livewell and the British Heart Foundation. They will not receive any social support or personalised content.

12. Study procedures

The proposed project has 2 stages (see flow diagram above): intervention development and piloting (stage 1) and exploratory trial and process evaluation (stage 2).

12.1 Stage 1 Development and Piloting

The intervention will be developed over 9 months, using team expertise in web-based health behaviour change and social support projects. The intervention is web, app and SMS based and will involve participants interacting with the website and app and setting goals and action plans as well as nominating 'helpers' from within their social network to help them achieve their goals in relation to diet, physical activity and weight loss. During the development stage, these health behaviour change experts and an IT company specialising in behaviour change programmes will work with user representatives to establish the optimal usability and acceptability of the website, app and SMS aspect. It will particularly explore how to engage helpers and what type of support to helpers might be effective.

We will explore the use of formal development methods like intervention mapping[75] or the 6SQUID (Six Steps for Quality Intervention Development) approach (being developed in SPHSU)

as well as the behaviour change wheel[76] to help aid this development process to identify needs, targets and processes for change (specifying target behaviours in detail) and identify possible barriers and facilitators that influence people's ability to perform the target behaviour, e.g. maximising uptake of the website/app and identifying barriers as well as techniques and strategies to address these which may become components of the intervention and which translate into the architecture of the website or app. This essential early development and modelling work, and later feasibility testing (see below), follows the MRC guidance for the development and evaluation of complex interventions in health.

For stage 1 we will recruit around 10 user representatives to a development panel to provide input into the design and content of the website and app. We will take care to ensure a spread of relevant factors including gender, age and socio-economic background. This number provides for good discussion and a range of views whilst keeping the group manageable and focussed and allowing everyone to contribute.

There will be three phases of data collection, interspersed with two phases of design, and development. In months 1-2 the development panel will be recruited; this will provide input into the developer's brief to design the content and layout of the app and website and how it will link with SMS messages to participants and helpers. In months 2-9, six months of design and programming work will be interrupted by two phases of user testing and repeat focus groups (in months 5 and 7) to test the panel's views on and responses to the developing intervention. We will also conduct additional user testing using think-aloud methods (where users verbalise what they are thinking while they use the website or app) and interviews with up to thirty other lay members between the focus groups as and when new aspects of the website/app develop. The lay members' contributions will be informed by their testing of the website/app and texting facility between each focus group meeting. Some of the testing work will take place in university buildings and some in people's own time. Focus groups, interviews and think-aloud sessions will take place in university buildings, people's homes or in appropriate community settings. Some interviews may take place over the telephone. Focus groups, think-aloud sessions and interviews will be audio recorded for later analyses. We will ensure a reasonable mix of gender, age and socio-economic status. Participants in stage 1 will continue to have access to the app and website for the duration of the study. A report focusing on the data collected during the testing phase will examine key outcomes and variations in participant response. In month 11, an independently chaired Trial Steering Committee (TSC) will review the intervention and the report. The TSC will meet at the beginning of the study and then again at month 11 to make the final decision as to whether the study will progress to the exploratory trial. The TSC will begin discussion about the stop-go criteria at the first meeting and these will be based on the criteria described below. However the TSC will be responsive to developing concerns or issues and thus these may be developed further or new criteria added. The Independent Chair will finalise these in consultation with the other TSC members and

implement them in the meeting in month 11. For progression from stage 1 to stage 2 we suggest the following:

Criterion 1: Was the software and associated SMS facility developed to a good standard in the timescale available? Did the software company produce the intervention as specified in the detailed design document? (This document will be produced during the development process in collaboration with the company and based on the findings from the focus groups and interviews). Did the software include the appropriate intervention elements to facilitate social support and behaviour change? This will be assessed by tabulating the logic model elements and the software will be compared to this to ensure it includes the key elements and addresses the aims and objectives of the logic model.
Criterion 2: Was it feasible to implement the HelpMeDoIt! intervention via the web-based platform, app and SMS? If there were issues with the app, the website or other technical problems were the company responsive and able to provide solutions to any issues? This will be evidenced by the qualitative findings, page usage statistics, records of 'bug' reporting on the website and other measures of adherence.
Criterion 3: Was the intervention acceptable and did the majority of the development group members find the intervention usable and acceptable? This will be assessed using the results from the usability questionnaire (which assesses ease of use and usefulness), the think-aloud results, the interview and focus group data and an expert heuristic evaluation.

At this point, the study will either be terminated to end at month 12 after a brief write-up period, or the TSC will agree to progression to the stage 2 exploratory trial. In months 8 and 9, the software company will proceed with further development of the programming in anticipation of proceeding to stage 2. If the TSC decide that the study should not continue onto the next stage, we would discuss a revised plan. Since much of the resource will be used to develop the intervention up to this point, it would seem reasonable to consider using the rest of the time and resource available on the grant to do additional development work to improve the intervention in preparation for a future feasibility study, this will be discussed with the TSC.

12.2 Stage 2 Exploratory Trial

This stage will test the web, app and SMS service developed in stage 1 and explore how the intervention works and whether it is worth subsequent testing in a full trial. The exploratory trial will assess the feasibility and acceptability of delivering the HelpMeDoIt! intervention and trial methods including data collection methods prior to a potentially larger, definitive trial. This is an exploratory trial therefore the sample size is not powered to detect a difference between groups. However, we will recruit 120 participants who will be randomised 2:1 into intervention or control group. Helpers will be recruited via text or email messages from the website inviting them to take part, once participants have nominated them as helpers.

12.2.1 Data Collection

All staff involved in recruitment and data collection (SPHSU Survey team and SPCRN staff) will be given training in study procedures by the study team. At baseline and 12 month follow-up we will collect data mainly using paper-based questionnaires. However, we will also collect anthropometrics at both time points. These data will be collected face-to-face at a place of the participant's choice. In addition, we will collect some dietary information using four repeat 24 hour multiple pass recalls which will be obtained over the telephone at baseline and follow-up and inputted directly by study staff into dietary analyses software. These will be completed on three weekdays and one weekend day within a ten day period. We will also give participants accelerometers to wear at baseline and follow-up. At both baseline and follow-up time points we will ask participants to wear them for a seven day period including two weekend days.[77,78] We will develop a standard operating procedure (SOP) for managing accelerometry data to deal with issues such as defining sleep time versus sedentary time and dealing with missing data or invalid data, valid wear time (minimum 10-13 hours) and non-wear time. When participants are due for follow-up we will contact them to arrange an appointment at a suitable time. If we are unable to reach them we will attempt to reach them via their nominated contact, if this fails we will send them a letter asking them to contact us if they would either like to withdraw or if they are interested in continuing. Once appointments are arranged, participants in both arms will be reminded of their follow-up appointments and phone calls via email, text message or a phone call prior to the meeting, according to their preference. If an individual fails to attend an appointment we will try to rearrange for another time. However, it they fail to attend three times in a row we will contact them to see if they wish to be withdrawn from the study.

12.2.2 Process evaluation

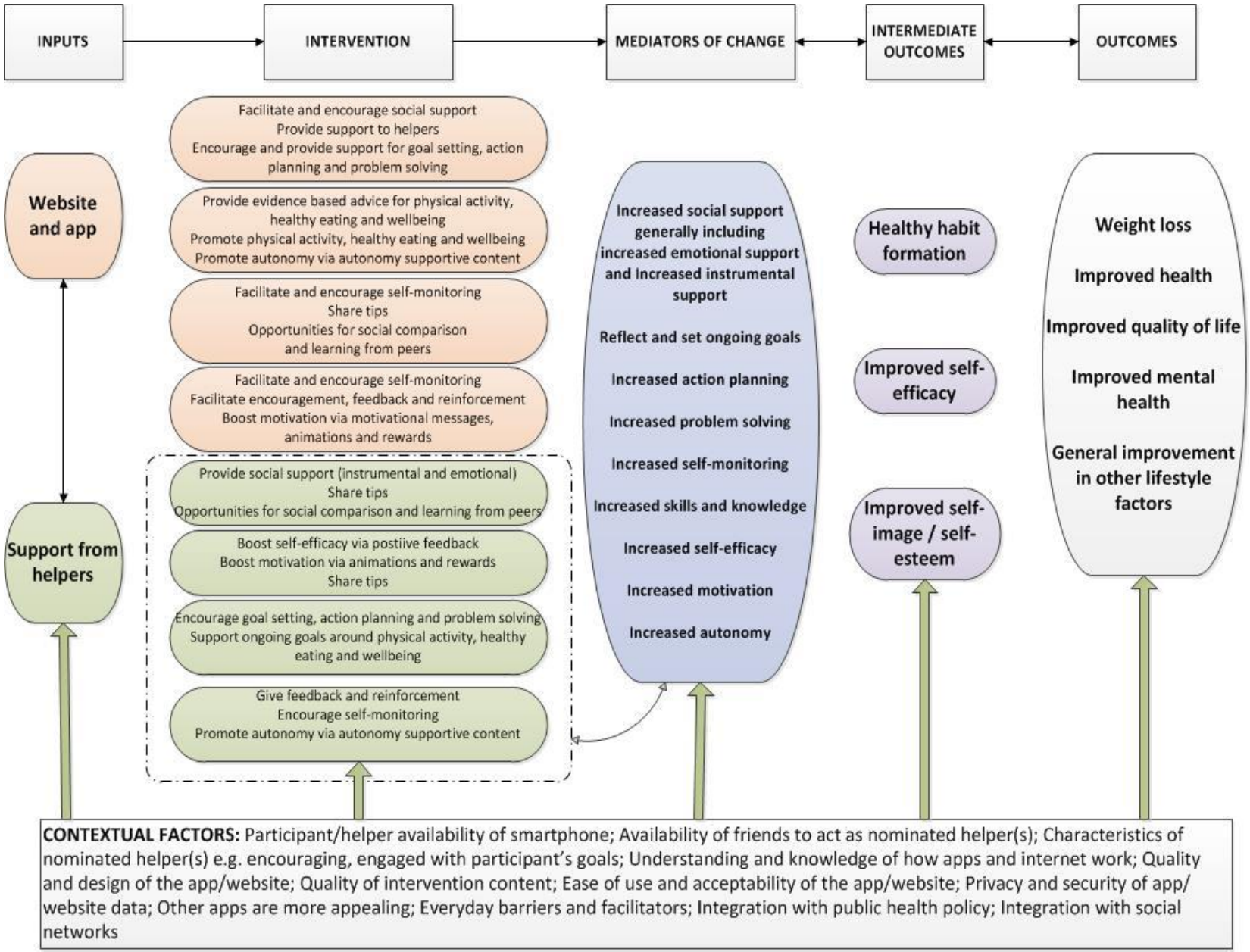
This work will assess four key components of process evaluation: fidelity, feasibility, acceptability and reach.[79] It will also assess the intervention theory /mechanisms of change. In stage 1, user testing, think-aloud methods, the USE questionnaire, semi-structured interviews and focus groups will be completed to inform the intervention development and to assess feasibility and acceptability of the intervention with participants. In stage 2, during the intervention period, use of the app and the website will be monitored (by the website programming), through records of logging in and updating progress against goals, in order to capture data on the extent of use of the goal setting and monitoring features of the intervention by both participants and helpers. Demographic data on the helpers including their relationship to the participant and their use of the website will also be collected. We will also be able to explore use of specific aspects like the forum as well as analyse the content of the posts to that forum.

In stage two, at 6 months up to 30 participants and 20 helpers (depending on data saturation) will be interviewed. These will either be completed face to face at a venue of the participants choice (e.g. their home, university or community setting) or over the telephone. Semi-

structured interviews using topic guides will obtain information on: acceptability; patterns of use of the intervention; help received; barriers and suggested improvements. The use of goal setting and self-monitoring will be explored in relation to how these behaviours interact with the social support and the effects on outcome behaviours. We will explore the helpers' experiences of the intervention and collect in-depth qualitative data, on social support and on the ways that positive behaviour among helpers can be supported and encouraged and on how negative social influences can be identified and managed. We will explore the perceived value of the helpers' support as well as information on both positive and negative social support. We will examine virtual versus in-person support as well as the type of social support given, e.g. informational, instrumental or emotional and whether this is related to participant characteristics like gender. We will also look at the frequency of contacts, the numbers of helpers identified by participants and whether they actually 'helped' (via the qualitative interviews) as well as whether participants nominated different helpers for different tasks or goals.

Participants will be purposively sampled to maximise diversity in age, gender, socio-economic status and intervention usage and we will specifically seek to interview those who did not take up the intervention and reasons for this as they may have important information for development of the intervention. We will also conduct semi-structured telephone interviews at 12 months with up to 10 participants who continued using the website/app to explore ongoing use following on from the 'active phase' and also seek to interview up to 10 who ceased to use it, to explore ongoing use of the website, app, SMS and other types of social support and reasons for ceasing to use the web, app and SMS facility. We will also seek to include those achieving and not achieving weight loss or changes in diet or physical activity at follow-up.
We have developed a draft logic model which explains how we expect the intervention to work which will be tested in Stage 1 and updated in Stage 2 (see Figure 1). We will assess key mediators of intervention effect (i.e self-efficacy, social support, motivation) via questionnaires and we will also explore this in the qualitative work.

Figure 1 Proposed Logic Model



12.2.3 Exploratory economic evaluation

A costing exercise will be undertaken to provide an indication of the direct costs of the intervention. This will involve monitoring all resources used in delivering the intervention and valuing them in relevant units. An estimation of any intervention effects on NHS and Personal and Social Services (PSS) costs (e.g. GP visits) and personal costs (e.g. gym membership) will be collected by a specially designed resource use questionnaire. Together, these will indicate the relative importance of the economic evaluation in any future trial. A value of information (VOI) analysis will provide information on the likely return on investment of the intervention.[80]

We will also assess the feasibility of using the EuroQol EQ-5D-5L instrument[81] and the ICECAP-A[64] measures as a means of capturing any short term effects the intervention may have on health related quality of life. This will help to determine whether the definitive economic evaluation should be a cost effectiveness (effect = primary outcome selected for the effectiveness trial) or cost utility (effect = quality adjusted life years) study. This, together with preliminary evidence on who takes up the intervention (e.g. young/old, male/female) will help to inform the design of long term economic modelling that might be undertaken as part of a future study.

12.2.4 Methods to protect against sources of bias

Confounding: The threat of confounding due to baseline differences will be reduced by random allocation with minimisation for key variables that might affect outcomes. The main analysis will be conducted by an independent statistician with a pre-specified analysis plan and adjusted for hypothesized baseline confounders. Attrition bias: We will minimise attrition by engaging participants via newsletters, birthday cards etc. We will also be collecting data face to face at a venue that suits participants. We will give all participants vouchers for completing follow-ups and interviews and we will offer the controls the intervention after the follow-up period. Detection bias: Researchers undertaking the assessment of the outcomes will not have any involvement in the delivery of the intervention, and where possible different researchers will complete follow-up assessments. As far as possible researchers will be blinded to the allocation of the participants, participants will be asked not to reveal their allocation to the researchers, although during interaction the group allocation may become apparent. This will be assessed by asking researchers to respond to two questions: (Q1) Did the participant reveal what group they were in?; (Q2) If not, what group do you think the participant was in? To avoid contamination between arms in the trial each participant and helper will have their own login to the website and only one person per household will be able to take part.

12.3 Progression criteria from exploratory trial to full randomised controlled trial

The findings from the stage 2 exploratory feasibility study will be assessed against progression criteria to determine whether the study should progress to a full randomised controlled trial. The following progression criteria have been approved by both the TMG and TSC.

1. Is the intervention feasible to deliver and acceptable to participants and their helpers?
   - Measured by the USE questionnaire and participant/helper interviews.

2. Are participants willing to be randomised to the intervention?
   - Measured by the recruitment experiences of the study team and fieldworkers and insight from qualitative interviews with participants.

3. Are appropriate and effective routes of recruitment available to achieve a powered sample size in a full trial?
   - Measured by coming close to the sample size, as judged by the TSC, with reasonable expectations of being able to address any recruitment issues.

4. Are identified barriers and challenges to implementation of the intervention planned for and surmountable?
   - Measured by our process evaluation which will present a SWOT analysis and action plan.

5. Are appropriate retention rates achieved at 12-month follow-up:
   - Measured using the following scale in both the intervention and control group at 12-months: If ≥70% followed up proceed; if 50-69% followed up discuss with TSC; if ≤49% followed up do not proceed.

6. Do the majority (>50%) of participants within the intervention group visit the app at least twice OR do 25% of participants randomised use it three or more times?
   - Measured by app usage statistics and/or participant interviews.

7. Do the data collection procedures effectively collect the data required for a full trial?
   - Successful completion of *at least one* data collection method (BMI, physical activity *or* healthy eating) at both baseline and at 12 months <u>in those retained</u> measured using the following scale:
   i. If >90% *of at least one* data collection measure completed proceed;
   ii. If 70-89% *of at least one* data collection measure completed discuss strategies for improvement in future trial with TSC;

iii. If <70% *of all three* data collection measures completed do not proceed without further modification and pilot.

8. Are the intervention costs of a full trial covered?
   - Measured by identification of a source to pay access and treatment costs.

13. Adverse and serious adverse events

Adverse Event (AE): Any untoward medical occurrence in a trial participant which does not necessarily have a causal relationship with the treatment. An AE can therefore be any unfavourable and unintended sign (including abnormal laboratory finding), symptom, or disease.

Serious Adverse Event (SAE): Any adverse event that:
• Results in death
• Is life-threatening*
• Required hospitalisation or prolongation of existing hospitalisation**
• Results in persistent or significant disability or incapacity
• Consists of a congenital anomaly or birth defect
• Other medically important condition ***
* Note: The term "life-threatening" in the definition of serious refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.
** Note: Hospitalisation is defined as an inpatient admission, regardless of the length of stay, even if the hospitalisation is a precautionary measure, for continued observation. Pre-planned hospitalisation e.g. for pre-existing conditions which have not worsened or elective procedures does not constitute an adverse event.
*** Note: other events that do not result in death are not life-threatening, and do not require hospitalisation may be considered as a serious adverse event when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

There are no expected AE's/SAE's and no AE's or SAE's expected to be related specifically to the study intervention.

13.1 Causality

There are no local investigators in this trial, therefore assignment of the causality for AEs and SAEs will be made by the clinical member of the team and the Principal Investigator. In addition, all SAEs will be referred to the independent clinician on the Trial Steering Committee

for a second opinion. In addition, SAEs of 'possible and above' should be reported to the sponsor and ethics committee. Causality should be assigned using the definitions in the table below. In the case of discrepant views on causality the event will be handled at the highest event categorisation.

Relationship	Description
Unrelated	There is no evidence of any causal relationship with the trial/study or intervention
Unlikely	There is little evidence to suggest there is a casual relationship (e.g. the event did not occur within a reasonable time after intervention) with the study/trial or intervention. There is another reasonable explanation for the event (e.g. the participant's clinical condition, other treatment).
Possible	There is some evidence to suggest a causal relationship with the trial/study or intervention (e.g. because the event occurs within a reasonable time after intervention). However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other treatments).
Probable	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.
Definite	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.
Not assessable	There is insufficient or incomplete evidence to make a judgement of the causal relationship.

13.2 Reporting procedures

Adverse events can be reported in this study by the participant's GP or nurse, the participant themselves via email, telephone or the website or by researchers collecting follow-up data. Depending on the nature of the event, the reporting procedures outlined in this protocol should be followed. Any queries concerning adverse event reporting should be directed to the Trial Manager in SPHSU in the first instance. The Principal Investigator and clinical member of the team will judge whether the event is an AE or SAE according to the definitions above within 48 hours of receiving the form.

If the participant is reporting the AE or SAE by telephone the Trial Manager will complete a SAE form at that point for them. However, if they contact the team via the website or email the study manager will contact them as soon as we hear from them to complete a SAE form on their behalf. If a GP or nurse is reporting an SAE then they should use the SAE form which will have been sent with the GP letter notifying them of the participant being in the study. However, if for some reason they do not have this form to hand then they should contact the Trial Manager by phone. The Trial Manager will then fax through the SAE form immediately and the clinician should then send the completed SAE form to the study team in SPHSU within the following 24 hours. If the researcher is reporting the SAE then they should contact the Trial Manager by phone within 24 hours of becoming aware of the event and then they should complete the SAE form and return it to the Trial Manager within the following 24 hours.

Please note, hospitalisations for elective treatment of a pre-existing condition do not need reporting as SAEs. The research team will report all related SAEs as required by their Research Ethics Committee and/or Research and Development Office within 15 days of the Principal Investigator becoming aware of the event as per the NRES guidance.

Contact details for reporting SAEs
Fax: 0141 353 7500, for the attention of Trial Manager

Please send SAE forms to:
Dr Lynsay Matthews
MRC/CSO Social and Public Health Sciences Unit,
University of Glasgow,
Top floor, 200, Renfield Street
Glasgow G2 3QB
Lynsay.Matthews@glasgow.ac.uk
Tel: 0141 353 7633 (Mon to Fri 09.00 – 17.00)

14. Statistical considerations

14.1 Randomisation

Randomisation will be carried out following baseline data collection procedures, when the researcher will telephone an interactive voice response system developed and maintained by the Robertson Centre for Biostatistics, University of Glasgow. Participants will be allocated using a mixed minimisation/randomisation method. The allocation schedule will be prepared by a statistician with no further involvement with the study, using the method of randomised permuted blocks.

14.2 Sample size

This is a feasibility study and so the main focus is to assess the acceptability of the intervention and estimate parameters for a larger study. In stage 1 up to 40 participants will participate in interviews or focus groups. In the stage 2 exploratory trial we are most interested in the intervention arm and so will randomise in a 2:1 ratio into treatment and control. We will recruit 120 participants and expect dropout of approximately 30%.[82] This sample size of 84 for analysis is not powered for effectiveness but will provide enough precision to estimate any proportion to within 11 percentage points using a 95% confidence interval. This would also allow for the estimation of a continuous outcome (such as BMI) in the treatment arm to within 0.262 of a standard deviation. No appreciable clustering is expected in this individually randomised study. In the process evaluation, at 6 months we will interview up to 30 participants and 20 helpers and at 12 months we will complete up to 20 brief telephone interviews.

14.3. Analysis

14.3.1 Quantitative Analysis

Descriptive analysis will be used to summarise the recruitment rates, intervention use and response rates of the stage 2 exploratory trial along with 95% confidence intervals. We will assess bias in loss to follow-up between groups. We will also obtain an estimate of the treatment effect size of the intervention for each of diet, physical activity and BMI, to assist the sample size calculation for a larger effectiveness study. This analysis will predict follow-up scores one year post randomisation, controlling for individual baseline scores and minimisation factors using analysis of covariance, as well as other important individual characteristics such as age. Point estimates of effectiveness will be reported alongside their 95% confidence intervals. Standard transformations will be explored if visual inspection of the outcomes indicates non-normality. A decision based on effect size, amount of missing data and interpretability will be made by the TSC about which of these outcome measures is best to take forward as the primary outcome in the full trial.

Secondary analyses will compare intervention and control groups in terms of weight, waist circumference, percentage weight lost, quality of life, and mental health. These analyses will also be interpreted using 95% confidence around the point estimates of effectiveness. All analyses will be conducted under intention to treat principles and complete case analysis used (unless more than 20% of cases are lost due to missing data, in which case multiple imputation will be performed). Every effort will be made to avoid and reduce missing data. We will compare the efficiency of analyses with various combinations of baseline variables which will allow an assessment of the value of collecting baseline measures of all outcomes. For example, a baseline measure of weight/BMI used as a covariate in an analysis of dietary (DINE) outcome may be as efficient as an analysis with baseline measure of DINE as the covariate.

Exploratory sub-group analysis whilst underpowered will investigate potential differences between gender, age, socio-economic status, starting BMI for hypothesis generation purposes, but also to inform the design of a larger study. We may identify other potential sub-groups for analyses in the main trial via the qualitative or other work. These results will be interpreted using 95% confidence intervals. Social support, motivation and self-efficacy will be measured at follow-up also and used in a mediation analysis to determine whether they are indeed on the causal pathway and to test the logic model.

A per-protocol analysis will also be conducted using simple proxies for adherence (e.g. website login/% of webpages accessed) in order to identify the treatment effect associated with adherence. All analyses will be performed in SAS for Windows v9.3 and/or R for Windows v3.0.0, or higher versions of these programmes. Further details of the proposed analyses will be written in the Statistical Analysis Plan.

14.3.2 Qualitative Analysis

Analysis of the user testing, think-aloud, interview and focus group data will concentrate on determining the acceptability of the intervention, the extent to which users (and helpers) engaged with it, and the value of helpers' support. This data will also be used to improve the intervention design architecture and to provide additional sources of advice for the website and app.

Qualitative data from both stages will be analysed using thematic analyses.[83] Due to the focus of the semi-structured interviews the identified themes are likely to be on areas of interest to the evaluation (such as recruitment, retention, acceptability, patterns of use of intervention, who is chosen as a helper, helping behaviour) but this method also allows for unexpected themes to emerge and to be added to the coding framework. The analyses will seek to identify how various elements of the intervention - such as goal setting, monitoring and social support - operate through new technologies and will examine whether and how they promote health behaviour change. The analyses will test the hypothesised causal pathways expressed in the logic model and will also develop the intervention's theory of change where little is currently known (for example how social support and web-based goal monitoring operate together to change health behaviours). This will inform the study design of any future trial by determining which elements of the intervention work well for health behaviour change in participants, how they interact with each other and which need adjustment or further development.

We will also aim to explore the 'cost' of baseline data collection, in terms of monetary cost, impact on the control group and whether respondent burden from the outcome measures might have had an impact on recruitment and whether participants completed follow-up. We will test and refine the logic model in Stage 1 and test it further in Stage 2 using both qualitative and quantitative data. As part of this we will examine the potential mediators of the effect of the intervention. This will also assist in the decision as to whether we need the mediation

measures in a full trial. Qualitative data will also be triangulated with quantitative data. Further details of the proposed analyses will be written in the Qualitative Analysis Plan.

14.3.3 Economic analysis

The economic analysis will comprise a feasibility study to identify the key cost drivers of the intervention and control arms. Use of the EQ-5D-5L and ICECAP-A instruments will also be explored. Data collection during stage 1 and 2 will focus on identification and measurement of the resource use related to the development and running costs of the HelpMeDoIt! website including specialist IT costs (labour, hardware and software), staff costs of SMS support and guidance tailored to participants and their helpers (3-5 per participant), voucher costs to participants to cover the costs of smart phone texts, resource use and costs associated with behaviour change relating to physical activity (gym costs, exercise class costs etc) and diet (for example, increased costs of improved diet in relation to purchasing healthy foods such as fruit and vegetables). Costs for the control group will relate to the costs of developing an information leaflet compiled using the NHS and British Heart Foundation websites. In addition to the resource use and costs involved in the development and delivery of the intervention any impacts of the intervention (or control) on NHS and Personal Social Services (PSS) costs will also be collected using a specially devised resource use data collection form.

The feasibility work will inform a value of information (VOI) analysis. VOI is a means of valuing the expected gain from reducing uncertainty in key parameters.[80] VOI will be used to assess the cost-effectiveness of a larger scale RCT where the expected value of the RCT is the expected reduction in the probability of making the 'wrong' decision multiplied by the average consequence of being 'wrong' (namely the opportunity cost of the decision). This is compared with the expected cost of the research project (the possible full scale RCT) and if the expected value exceeds the (expected) cost then the project should be undertaken. This study will adopt the analytic approach using cost and QALY information from the feasibility study to calculate the VOI, following the step-by-step guide reported by Wilson.[80] An economics section of the Statistical Analysis Plan will give further details of the proposed analyses.

15. Data storage & retention

All data will be kept for 10 years in line with University of Glasgow Research Governance Framework Regulations for clinical research. This data will be stored confidentially on password protected servers maintained on the University of Glasgow network.

16. Study closure

The end of the study will be considered to be the date on which the last participant has completed their follow-up assessment or last interview.

17. Regulatory issues

17.1 Ethical approval

The study will be conducted in accordance with the recommendations for physicians involved in research on human participants adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions. The study will be submitted to University of Glasgow, MVLS College Ethics Committee for stage one and for stage two the West of Scotland Research Ethics Service for approval prior to study commencement. Research governance approval will be granted by NHS Greater Glasgow and Clyde.

17.2 Consent

Consent will be sought for participation in the development panel and for the qualitative elements of stage 1 of the study. It will also be sought for both the exploratory trial and the qualitative process evaluation elements. All participants and helpers in the study will receive an information sheet on the study and will give full informed consent before taking part. The study is low risk for participants and for those in the intervention group taking part in the study may actually benefit their health. Withdrawal from the study will have no detrimental effect on current or future health care.

17.3 Confidentiality

The Principal Investigator and the research team will preserve the confidentiality of participants in accordance with the Data Protection Act 1998. All participants will be allocated a unique identifier and all clinical data collected will be held in linked anonymised form. Identifiable information will be stored separately from clinical data.

The website, app and text messaging technology will be designed to protect the personal data of participants. Access to data will be restricted to the research team and nominated representatives from the software company, who have signed a data protection agreement with the University of Glasgow. Individual's names will be replaced with pseudonyms in interview/focus group transcripts. Digital recordings of interviews/focus groups will be stored securely, and will be held separately from transcripts and information on participant identities. In reporting the results of the interviews and focus groups, care will be taken to use quotations which do not reveal the identity of respondents. All data collected as part of the project will be treated as confidential and will only be viewed by members of the research team; anonymised data will be used wherever possible. A formal privacy risk assessment will be undertaken to

manage any potential risks of conducting the study. All procedures for data storage, processing and management will comply with the Data Protection Act 1998.

The main circumstances under which the researchers would break confidentiality are where participants were at risk of serious harm or they were at risk of harming others. This would be most likely to occur as a result of a disclosure during a focus group, or if responses to questionnaires raised serious concerns regarding individuals' wellbeing. All participants will be informed that if they disclose information about neglect, abuse, serious suicidal thoughts or self-harm that we will pass this information on to an appropriate authority. Consent for this will be sought prior to the collection of any data. A standard operating procedure to deal with this will be developed and followed.

17.4 Indemnity

NHS Greater Glasgow and Clyde will provide indemnity and compensation in the event of a claim by, or on behalf of participants, for negligent harm as a result of the management of the research. University of Glasgow will provide indemnity and compensation in the event of a claim by, or on behalf of participants for negligent harm as a result of the study design and/or in respect of the protocol authors/research team. Both University of Glasgow and NHS Greater Glasgow and Clyde will provide indemnity with regards to the conduct of the research. The University has in force a Professional Indemnity and/or Clinical Trials Policy which provides cover for negligent harm and the activities here are within that coverage

17.5 Study sponsorship

NHS Greater Glasgow and Clyde (NHS GGC) will act as sponsor for trial.

17.6 Funding

The study is funded by NIHR Public Health Research Board (PHRB).

17.7 Audits and inspections

The study is participant to inspection by the NIHR PHRB as the funding organisation. The study may also be participant to inspection and audit by NHS GGC under their remit as sponsor.

18. Study management

This is a single-centre study and the Principal Investigator (PI) will have overall responsibility for the conduct of the study. The Trial Manager will complete the day-to-day management of the study and will be supported and mentored by the PI. The study will be managed by three separate groups.

Project Team (PT): This group will consist of the co-ordinating team within SPHSU and staff employed on the project who will meet weekly to discuss the day to day issues that arise. All important discussions will be relayed to the TMG for final decision.

Trial Management Group (TMG): The TMG will consist of the Principal Investigator, co-applicants and research staff including the Trial Manager and Trial Administrator. The role of the TMG will be to assist in the study set up by providing specialist advice, input to and comments on the study procedures and documents (information sheets, protocol etc). They will also advise on the promotion and the running of the trial and deal with any issues that arise. The group will meet, either face-to-face or using audio-conferencing facilities at least bi-monthly throughout the course of the study and if necessary, additional/more frequent meetings may occur particularly at crucial time points during the study. The TMG members will be required to sign up to a charter explaining the roles and responsibilities of the TMG.

19. Data monitoring & quality assurance

19.1 Trial Steering Committee (TSC)

An independent steering committee (TSC) will be established and will meet at least four times during the course of the study, consisting of an independent chair, and three other independent members. The TSC will be chaired by Dr Colin Greaves who is an expert in behaviour change. Other members include Dr Ruth Jepson who has expertise in qualitative methods and public health interventions, Dr Marilyn Lennon who is an e-health expert and a patient representative (yet to be recruited) and finally Dr Harry Ahmed who is a clinical academic and a GP. The first meeting will be before the study commences to review the protocol and begin discussion about the stop-go criteria. The TSC will then meet again at month 11 in the development stage and twice more in the exploratory trial stage. The decision will be made in month 11 as to whether the study should proceed to the exploratory trial. The Principal Investigator, Trial Manager and Statistician will attend as observers. The TSC will provide overall supervision for the trial and provide advice through its independent chair. The ultimate decision for the continuation of the trial lies with the funder and the sponsor but the TSC will advise them. The project will use standardised research protocols and adherence will be monitored by the PT, TMG and TSC.

19.2 Data Monitoring and Ethics Committee (DMEC)

The nature of this study means that it unlikely that a Data Monitoring and Ethics Committee will be required for this exploratory trial, since the study is low risk and we will not be conducting interim analyses. The TSC have agreed that they will cover the functions of the DMEC in this instance, in particular in relation to ethical issues, patient safety including monitoring adverse events and the continuation of the trial.

20. Publication policy

The publication policy will be drafted and approved by the Trial Management Group. It will state principles for publication, describe a process for developing output, contain a map of intended outputs and specify a timeline for delivery. The publication policy will respect the rights of all contributors to be adequately represented in outputs (e.g. authorship and acknowledgments) and the study to be appropriately acknowledged. Authorship of parallel studies initiated outside of the Trial Management Group will be according to the individuals involved in the project but must acknowledge the contribution of the Trial Management Group and SPHSU.

21. References

1. House of Lords Science and Technology Select Committee. Behaviour Change. London: United Kingdom Parliament, 2011.
2. Greaves CJ, Sheppard KE, Abraham C, et al. Systematic review of reviews of intervention components associated with increased effectiveness in dietary and physical activity interventions. *BMC public health* 2011; **11**(1): 119.
3. Shaw K, O'Rourke P, Del Mar C, Kenardy J. Psychological interventions for overweight or obesity. *Cochrane Database Syst Rev* 2005; **2**(2).
4. Webb TL, Joseph J, Yardley L, Michie S. Using the internet to promote health behavior change: a systematic review and meta-analysis of the impact of theoretical basis, use of behavior change techniques, and mode of delivery on efficacy. *Journal of medical Internet research* 2010; **12**(1).
5. Bacigalupo R, Cudd P, Littlewood C, Bissell P, Hawley M, Buckley Woods H. Interventions employing mobile technology for overweight and obesity: an early systematic review of randomized controlled trials. *obesity reviews* 2012.
6. Wei J, Hollin I, Kachnowski S. A review of the use of mobile phone text messaging in clinical and healthy behaviour interventions. *Journal of Telemedicine and Telecare* 2011; **17**(1): 41-8.
7. Free C, Knight R, Robertson S, et al. Smoking cessation support delivered via mobile phone text messaging (txt2stop): a single-blind, randomised trial. *The Lancet* 2011; **378**(9785): 49-55.
8. Cole-Lewis H, Kershaw T. Text messaging as a tool for behavior change in disease prevention and management. *Epidemiologic reviews* 2010; **32**(1): 56-69.
9. Bandura A. Health promotion from the perspective of social cognitive theory. *Psychology and Health* 1998; **13**(4): 623-49.
10. Carver CS, Scheier MF. Control theory: A useful conceptual framework for personality–social, clinical, and health psychology. *Psychological bulletin* 1982; **92**(1): 111 - 35.
11. Gollwitzer PM, Sheeran P. Implementation intentions and goal achievement: A meta-analysis of effects and processes. *Advances in Experimental Social Psychology* 2006; **38**: 69-119.

12. Williams S, French D. What are the most effective intervention techniques for changing physical activity self-efficacy and physical activity behaviour—and are they the same? *Health Education Research* 2011; **26**(2): 308-22.
13. Burke LE, Wang J, Sevick MA. Self-monitoring in weight loss: a systematic review of the literature. *Journal of the American Dietetic Association* 2011; **111**(1): 92-102.
14. Michie S, Abraham C, Whittington C, McAteer J, Gupta S. Effective techniques in healthy eating and physical activity interventions: a meta-regression. *Health Psychology* 2009; **28**(6): 690 - 701.
15. Nieminen T, Prättälä R, Martelin T, et al. Social capital, health behaviours and health: a population-based associational study. *BMC public health* 2013; **13**(1): 613.
16. Ferranti EP, Dunbar SB, Higgins M, et al. Psychosocial factors associated with diet quality in a working adult population. *Research in nursing & health* 2013.
17. Molloy GJ, Dixon D, Hamer M, Sniehotta FF. Social support and regular physical activity: Does planning mediate this link? *British Journal of Health Psychology* 2010; **15**(4): 859-70.
18. Aggarwal B, Liao M, Mosca L. Predictors of Physical Activity at 1-Year in a Randomized Controlled Trial of Family Members of Patients with Cardiovascular Disease. *The Journal of Cardiovascular Nursing* 2010; **25**(6): 444.
19. Wing RR, Jeffery RW. Benefits of recruiting participants with friends and increasing social support for weight loss and maintenance. *Journal of Consulting and Clinical Psychology* 1999; **67**(1): 132 - 8.
20. Strine TW, Chapman DP, Balluz LS, Moriarty DG, Mokdad AH. The associations between life satisfaction and health-related quality of life, chronic illness, and health behaviors among US community-dwelling adults. *Journal of Community Health* 2008; **33**(1): 40-50.
21. National Institute for Health and Care Excellence. Public Health Draft Guidance: Behaviour Change2013. (accessed.
22. O'Connell KA. Theories used in nursing research on smoking cessation. *Annual Review of Nursing Research* 2009; **27**(1): 33-62.
23. Lim YM, Sung MH, Joo KS. Factors affecting health-promoting behaviors of community-dwelling Korean older women. *Journal of Gerontological Nursing* 2010; **36**(10): 42 - 52.
24. Priebe CS, Spink KS. When in Rome: Descriptive norms and physical activity. *Psychology of Sport and Exercise* 2011; **12**(2): 93-8.
25. Stewart DW, Gabriele JM, Fisher EB. Directive support, nondirective support, and health behaviors in a community sample. *Journal of behavioral medicine* 2012; **35**(5): 492-9.
26. Heaney CA, Israel BA. Social networks and social support. In: K. Glanz, B. K. Rimer, Viswanath K, eds. Health Behavior and Health Education: Theory, Research, and Practice. San Francisco, CA: John Wiley & Sons; 2008: 189-210.
27. Ballantine PW, Stephenson RJ. Help me, I'm fat! Social support in online weight loss networks. *Journal of Consumer Behaviour* 2011; **10**(6): 332-7.
28. Smith KP, Christakis NA. Social networks and health. *Annu Rev Sociol* 2008; **34**: 405-29.
29. Tamers SL, Okechukwu C, Allen J, et al. Are social relationships a healthy influence on obesogenic behaviors among racially/ethnically diverse and socio-economically disadvantaged residents? *Preventive medicine* 2012.

30. Christakis NA, Fowler JH. The spread of obesity in a large social network over 32 years. *New England journal of medicine* 2007; **357**(4): 370-9.
31. George M, Eys MA, Oddson B, Roy-Charland A, Schinke RJ, Bruner MW. The role of self-determination in the relationship between social support and physical activity intentions. *Journal of Applied Social Psychology* 2013.
32. Wen LK, Shepherd MD, Parchman ML. Family support, diet, and exercise among older Mexican Americans with type 2 diabetes. *The Diabetes Educator* 2003; **30**(6): 980-93.
33. Kelly JA, Murphy DA, Sikkema KJ, et al. Randomised, controlled, community-level HIV-prevention intervention for sexual-risk behaviour among homosexual men in US cities. *The Lancet* 1997; **350**(9090): 1500-5.
34. Maton KI. Social support, organizational characteristics, psychological well-being, and group appraisal in three self-help group populations. *American Journal of Community Psychology* 1988; **16**(1): 53-77.
35. Baird J, Cooper C, Margetts BM, Barker M, Inskip HM, Food Choice Group UoS. Changing health behaviour of young women from disadvantaged backgrounds: evidence from systematic reviews. *The Proceedings of the Nutrition Society* 2009; **68**(2): 195-204.
36. Pearson N, Ball K, Crawford D. Predictors of changes in adolescents' consumption of fruits, vegetables and energy-dense snacks. *British journal of nutrition* 2011; **105**(5): 795-803.
37. Newman MW, Lauterbach D, Munson SA, Resnick P, Morris ME. It's not that I don't have problems, I'm just not putting them on Facebook: challenges and opportunities in using online social networks for health. Proceedings of the ACM 2011 conference on Computer supported cooperative work; 2011: ACM; 2011. p. 341-50.
38. Shapiro JR, Koro T, Doran N, et al. Text4Diet: a randomized controlled study using text messaging for weight loss behaviors. *Preventive Medicine* 2012.
39. Broekhuizen K, Mireille van Poppel NM, Lj LK, Brug J, van Mechelen W. Is the process of delivery of an individually tailored lifestyle intervention associated with improvements in LDL cholesterol and multiple lifestyle behaviours in people with Familial Hypercholesterolemia? *BMC public health* 2012; **12**(1): 348.
40. Aalbers T, Baars M, Rikkert M. Characteristics of effective Internet-mediated interventions to change lifestyle in people aged 50 and older: A systematic review. *Ageing research reviews* 2011; **10**(4): 487-97.
41. Militello LK, Kelly SA, Melnyk BM. Systematic Review of Text-Messaging Interventions to Promote Healthy Behaviors in Pediatric and Adolescent Populations: Implications for Clinical Practice and Research. *Worldviews on Evidence-Based Nursing* 2012; **9**(2): 66-77.
42. Carr LJ, Dunsiger SI, Lewis B, et al. Randomized controlled trial testing an internet physical activity intervention for sedentary adults. *Health Psychology* 2013; **32**(3): 328.
43. Brindal E, Freyne J, Saunders I, Berkovsky S, Smith G, Noakes M. Features Predicting Weight Loss in Overweight or Obese Participants in a Web-Based Intervention: Randomized Trial. *Journal of medical Internet research* 2012; **14**(6).
44. Ritterband LM, Thorndike FP, Cox DJ, Kovatchev BP, Gonder-Frederick LA. A behavior change model for internet interventions. *Annals of Behavioral Medicine* 2009; **38**(1): 18-27.

45. Vodopivec-Jamsek V, de Jongh T, Gurol-Urganci I, Atun R, Car J. Mobile phone messaging for preventive health care. *The Cochrane Library* 2012.
46. Sherwood NE, Jeffery RW. The behavioral determinants of exercise: implications for physical activity interventions. *Annual review of nutrition* 2000; **20**(1): 21-44.
47. National Institute for Health and Care Excellence. Behaviour Change at population, community and individual levels *NICE Public Health Guidance 6* 2007.
48. Khaylis A, Yiaslas T, Bergstrom J, Gore-Felton C. A review of efficacious technology-based weight-loss interventions: five key components. *Telemedicine and e-Health* 2010; **16**(9): 931-8.
49. Eysenbach G, Powell J, Englesakis M, Rizo C, Stern A. Health related virtual communities and electronic support groups: systematic review of the effects of online peer to peer interactions. *British Medical Journal* 2004; **328**(7449): 1166.
50. Anderson-Bill ES, Winett RA, Wojcik JR. Social cognitive determinants of nutrition and physical activity among web-health users enrolling in an online intervention: the influence of social support, self-efficacy, outcome expectations, and self-regulation. *Journal of medical Internet research* 2011; **13**(1).
51. Neuhauser L, Kreps GL. Rethinking communication in the e-health era. *Journal of Health Psychology* 2003; **8**(1): 7-23.
52. Warburton DER, Jamnik VK, Bredin SSD, Collaboration. GNobotP-Q. The Physical Activity Readiness Questionnaire for Everyone (PAR-Q+) and Electronic Physical Activity Readiness Medical Examination (ePARmed-X+). . *Health & Fitness Journal of Canada* 2011; **4**(2): 3-23.
53. Pagoto SL, Schneider KL, Oleski JL, Luciani JM, Bodenlos JS, Whited MC. Male inclusion in randomized controlled trials of lifestyle weight loss interventions. *Obesity* 2012; **20**(6): 1234-9.
54. Rogers E. Diffusion of Innovations. New York: Simon and Schuster; 1962.
55. Butler CC, Simpson SA, Hood K, et al. Training practitioners to deliver opportunistic multiple behaviour change counselling in primary care: a cluster randomised trial. *British Medical Journal* 2013; **346**: 1-25.
56. Lund AM. Measuring Usability with the USE Questionnaire. *STC Usability SIG newsletter* 2001; **8**(2).
57. Bingham SA. Limitations of the various methods for collecting dietary intake data. *Annals of Nutrition and Metabolism* 1991; **35**(3): 117-27.
58. Prince S, Adamo K, Hamel M, Hardt J, Gorber S, Tremblay M. A comparison of direct versus self-report measures for assessing physical activity in adults: a systematic review. *International Journal of Behavioral Nutrition and Physical Activity* 2008; **5**(1): 56.
59. Sallis JF, Haskell WL, Wood PD, et al. Physical activity assessment methodology in the Five-City Project. *American journal of epidemiology* 1985; **121**(1): 91-106.
60. Hayden-Wade HA, Coleman KJ, Sallis JF, Armstrong C. Validation of the telephone and in-person interview versions of the 7-day PAR. *Medicine and science in sports and exercise* 2003; **35**(5): 801-9.
61. Roe L, Strong C, Whiteside C, Neil A, Mant D. Dietary intervention in primary care: validity of the DINE method for diet assessment. *Family Practice* 1994; **11**(4): 375-81.

62. Holmes B, Dick K, Nelson M. A comparison of four dietary assessment methods in materially deprived households in England. *Public health nutrition* 2008; **11**(5): 444-56.
63. Brooks R. EuroQol: The current state of play. *Health Policy* 1996; **37**(1): 53-72.
64. Al-Janabi H, Flynn T. Development of a self-report measure of capability wellbeing for adults: the ICECAP-A. *Quality of Life Research* 2012; **21**: 167-76.
65. Goldberg DP, Williams P. A user's guide to the General Health Questionnaire. Basingstoke: NFER Nelson; 1988.
66. New York Academy of Sciences. Prevention and Treatment of Childhood Obesity. Proceedings of a conference. Bethesda, Maryland, March 9-11, 1993. *Ann N Y Acad Sci* 1993; **699**: 1-310.
67. Bradley KA, DeBenedetti AF, Volk RJ, Williams EC, Frank D, Kivlahan DR. AUDIT-C as a brief screen for alcohol misuse in primary care. *Alcoholism-Clinical and Experimental Research* 2007; **31**(7): 1208-17.
68. Heatherton TF, Kozlowski LT, Frecker RC, Rickert W, Robinson J. Measuring the heaviness of smoking -using self reported time to the first cigarette of the day and number of cigarettes smoked per day. *British Journal of Addiction* 1989; **84**(7): 791-800.
69. Sallis JF, Grossman RM, Pinski RB, Patterson TL, Nader PR. The development of scales to measure social support for diet and exercise behaviors. *Preventive Medicine* 1987; **16**(6): 825-36.
70. Clark MM, Abrams DB, Niaura RS, Eaton CA, Rossi JS. Self-efficacy in weight management *Journal of Consulting and Clinical Psychology* 1991; **59**(5): 739-44.
71. Rodgers WM, Sullivan MJL. Task, Coping, and Scheduling Self-Efficacy in Relation to Frequency of Physical Activity. *Journal of Applied Social Psychology* 2001; **31**(4): 741-53.
72. Rodgers WM, Wilson PM, Hall CR, Fraser SN, Murray TC. Evidence for a multidimensional self-efficacy for exercise scale. *Research Quarterly for Exercise and Sport* 2008; **79**(2): 222-34.
73. Levesque CS, Williams GC, Elliot D, Pickering MA, Bodenhamer B, Finley PJ. Validating the theoretical structure of the Treatment Self-Regulation Questionnaire (TSRQ) across three different health behaviors. *Health Education Research* 2007; **22**(5): 691-702.
74. Woolford SJ, Barr KLC, Derry HA, et al. OMG do not say LOL: obese adolescents' perspectives on the content of text messages to enhance weight loss efforts. *Obesity* 2011; **19**(12): 2382-7.
75. Bartholomew LK, Parcel GS, Kok G, NH G. Planning health promotion programs: an intervention mapping approach. . San Francisco: Jossey-Bass; 2006.
76. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implementation science* 2011; **6**: 42.
77. Hart TL, Swartz AM, Cashin SE, Strath SJ. How many days of monitoring predict physical activity and sedentary behaviour in older adults? *The international journal of behavioral nutrition and physical activity* 2011; **8**: 62.
78. Trost SG, McIver KL, Pate RR. Conducting accelerometer-based activity assessments in field-based research. *Medicine and science in sports and exercise* 2005; **37**(11 Suppl): S531-43.
79. Steckler A, Linnan L. Process Evaluation for Public Health Interventions and Research. San Francisco: Jossey-Bass; 2002.

80. Wilson E. A practical guide to Value of Information Analysis. *Pharmacoeconomics* 2015; **33**: 105-21.
81. EuroQol Group. EuroQol - a new facility for the measurement of health related quality of life. . *Health Policy* 1990; **16**: 199-208.
82. Franz MJ, VanWormer JJ, Crain AL, et al. Weight-loss outcomes: a systematic review and meta-analysis of weight-loss clinical trials with a minimum 1-year follow-up. *Journal of the American Dietetic Association* 2007; **107**(10): 1755-67.
83. Braun V, Clark V. Using thematic analysis in psychology. *Qual Res Psych* 2006; **3**: 77-101.