

# Public title as of 17/09/2018 'Helpmedoit!' an app, web and social support based weight loss intervention for adults with obesity Previous public title: 'Helpmedoit!' a web and text based intervention to facilitate social support to achieve and maintain health-related change in physical activity and dietary behaviour.

<b>Submission date</b> 22/07/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 25/09/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/09/2020	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Plain English summary as of 17/09/2018:

### Background and study aims

The internet and social media can be good way to influence a person's behaviour, and they can reach large numbers of people. Research has showed that setting goals, making plans and keeping track of how well they are doing is important when someone is trying to change their behaviour. The support of family, friends and others is also crucial in helping people to achieve and sustain behaviour change and a healthier lifestyle. We want to develop and test the feasibility of a programme (intervention) that will include goal setting, monitoring, and social support using both the internet and though text messaging to help large numbers of people to make long lasting behavioural changes that lead to a healthier lifestyle.

### Who can participate?

Adults aged 18-70, with a BMI of at least 30 and trying to lose weight. Participants need to have access to a mobile telephone and the internet.

### What does the study involve?

The study has two stages. In stage 1, a development panel made up of members of the public, IT specialists and behaviour change experts work together to make sure the app and website are both useable and acceptable, how best to engage helpers and what sort of support from them might be the most useful. The intervention is then tested on other members of the public and focus groups and feedback collected via interview. For stage 2, participants are randomly allocated into one of two groups. Those in group 1 (the control group) are given a leaflet

containing information on healthy diet and exercise. Those in group 2 (the intervention group) will be given access to the Helpmedoit! intervention (programme) for 12 months. Helpmedoit! is an app and website that helps people to set goals and sign up their friends and family as 'helpers' to 'help them do it'. The helpers receive reminders to ask them to offer encouragement and support to the person trying to achieve these goals. Both participants and helpers can track the participants progress and participants can update their information through the app. The results of this stage is used to decide whether it is worth testing the intervention in a large-scale study. Physical activity, diet, height, weight, waist circumference, health related quality of life, social support, motivation, self-esteem, mental health, NHS resource use and participant borne costs is assessed for each participant before the trial begins and after 12 months. Some participants and helpers are interviewed about their experience of the intervention after 6 months. We also investigate whether the intervention is likely to provide good value for money as it has the potential to reach a lot of people at a low cost.

What are the possible benefits and risks of participating?

The study is low risk for participants. We will provide guidance to supporters to help them provide positive support and we will offer guidance to participants on healthy goal setting. The website and text messaging technology will be designed to protect the personal data of participants. All participants will have the opportunity of accessing the website and intervention which could potentially help them with weight loss. Intervention participants will be able to access it as soon as they enter the study and control participants will have access once the study is complete.

Where is the study run from?

The Social and Public Health Sciences Unit, University of Glasgow (UK)

When is the study starting and how long is it expected to run for?

January 2014 to June 2017

Who is funding the study?

National Institute for Health Research Public Health Research Programme (UK)

Who is the main contact?

Dr Sharon Simpson

sharon.simpson@glasgow.ac.uk.

Previous plain English summary:

Background and study aims

The internet and social media can be good way to influence a person's behaviour, and they can reach large numbers of people. Research has showed that setting goals, making plans and keeping track of how well they are doing is important when someone is trying to change their behaviour. The support of family, friends and others is also crucial in helping people to achieve and sustain behaviour change and a healthier lifestyle. We want to develop and test the feasibility of a programme (intervention) that will include goal setting, monitoring, and social support using both the internet and through text messaging to help large numbers of people to make long lasting behavioural changes that lead to a healthier lifestyle.

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### What are the possible benefits and risks of participating?

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sharon.simpson@glasgow.ac.uk.

## Contact information

### Type(s)

Scientific

### Contact name

Dr Sharon Simpson

**Contact details**

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**Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

v1.0 12/180/20

**Study information****Scientific Title**

Scientific title as of 17/09/2018

An app, web and social support based weight loss intervention for adults with obesity: the 'HelpMeDoIt!' feasibility RCT

Previous scientific title:

'Helpmedoit!' a web and text based intervention to facilitate social support to achieve and maintain health-related change in physical activity and dietary behaviour.

**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 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.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethical approval as of 17/09/2018:

Stage 1 approval by MVLS College Ethics Committee, approval date: 08/04/2015, approval number: 200140108. Stage 2 approval by NHS West of Scotland Research Ethics Committee, approval date: 18/12/2015, approval number: 15/WS/0288.

Previous ethical approval:

MVLS College Ethics Committee, 08/04/2015, 200140108

## **Study design**

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

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Other

### **Study type(s)**

Quality of life

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Obesity

### **Interventions**

Intervention as of 17/09/2018:

Stage 1:

1. Focus groups of a panel of user representatives will be audio recorded and analysed using a thematic approach.
2. A 3-month testing phase of the prototype app and website will be conducted with a user testing group.
  - 2.1. Feedback from think-aloud interviews will inform further refinement of the app and website.
3. The following will be considered by researchers:
  - 3.1. How to promote engagement with the app/website
  - 3.2. The app/website's success in encouraging realistic goal setting and self-monitoring
  - 3.3. The acceptability and functionality of the social support content
  - 3.4. The views of users on how the intervention might attract and support helpers.

Stage 2:

1. Participants will be randomised in a 2:1 ratio to the intervention or control group.
2. The control group will receive a leaflet on healthy lifestyle and will be given access to the app and website after follow-up is complete.
3. The intervention group will be given access to the HelpMeDolt! app and website for 12-months.
  - 3.1. The website will provide evidence based information on weight loss, setting and monitoring goals and harnessing positive social support from family, friends and/or colleagues.
  - 3.2. The app will allow participants to: set appropriate goals for weight loss, monitor their progress and invite one or more helpers from their existing social network.
  - 3.3. Helpers who agree to provide support will also be able to access the website and app, and see participants' goals and progress. They can provide support to the participant via the app and also outside of the app (e.g., face-to-face, phone call).

Previous intervention:

Participants will be allocated to one of two groups, intervention or control:

1. The control group will be given a leaflet giving information on healthy diet and physical activity.

2. The Helpmedoit! intervention will consist of a website that will help people in the intervention group set a behaviour change goal and sign up friends or family as 'helpers' to 'help them do it'. These helpers will then be prompted by SMS (text) messaging to enthuse, support or commiserate and help the person to achieve their goal. The programme will allow monitoring of progress and celebration of goals achieved. The Helpmedoit! website will have 7 key elements supporting the intrapersonal and interpersonal elements of the intervention:

2.1. Support for goal setting and planning

2.2. Nominate your helper to identify goal-specific social support group

2.3. Obtain agreement from nominated helper(s) to provide support

2.4. Helper-specific advice on how to provide effective support

2.5 'Track your progress' for monitoring

2.6. Behaviour specific information (including 'tips' and case stories)

2.7. The SMS, goal updates, support element of the intervention and forum

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Stage 1:

1. Acceptability and feasibility will be collected using interviews and focus groups.

Stage 2:

1. Physical activity will be measured at baseline and at 12 months using the 7-Day Physical Activity Recall and an accelerometer.

2. Diet will be measured at baseline and at 12 months using the DINE questionnaire and 4x repeat 24 hour multiple pass recall.

3. BMI will be measured at baseline and at 12 months using height and weight measurements.

## **Secondary outcome measures**

1. Waist circumference will be measured at baseline and at 12 months

2. Social support will be measured at baseline and at 12 months using Exercise & Eating Habits Social Support Scales

3. Self efficacy will be measured at baseline and at 12 months using Weight & Exercise Efficacy Lifestyle Scales.

4. Motivation will be measured at baseline and 12 months using the Treatment Self Regulation Questionnaire.

5. Mental health will be measured at baseline and at 12 months using the GHQ12 questionnaire.

6. Health-related quality of life will be measured at baseline and at 12 months using

7. Blood pressure will be measured at baseline and 12 months.

8. Cholesterol will be measured at baseline and 12 months using using a validated non-invasive point-of-care test (Cholestech LDX).

9. Use of NHS and participant borne costs will be measured at baseline and 12 months.

10. Participant and helper experiences of the intervention will be measured at 12 months.

## **Overall study start date**

01/01/2014

**Completion date**

30/06/2017

## **Eligibility**

**Key inclusion criteria**

1. Adults aged 18-70
2. BMI 30+
3. Access to a mobile telephone and the internet
4. Actively trying to lose weight

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

70 Years

**Sex**

Both

**Target number of participants**

120

**Total final enrolment**

109

**Key exclusion criteria**

1. Previous bariatric surgery
2. Terminal illness
3. Dementia
4. Pregnancy
5. Poor competence in English (resulting in an ability to complete study materials)
6. Being a nominated helper in this trial
7. We will ask women of childbearing age to let us 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.

**Date of first enrolment**

01/01/2014

**Date of final enrolment**

30/10/2017

# Locations

## Countries of recruitment

Scotland

United Kingdom

## Study participating centre

MRC/CSO Social and Public Health Sciences Unit

Glasgow

United Kingdom

G2 3QB

# Sponsor information

## Organisation

NHS Greater Glasgow and Clyde (UK)

## Sponsor details

R&D Management Office

Tennent Institute

38 Church Street

Glasgow

Scotland

United Kingdom

G11 6NT

## Sponsor type

Hospital/treatment centre

## ROR

<https://ror.org/05kdz4d87>

# Funder(s)

## Funder type

Government

## Funder Name

National Institute for Health Research Public Health Research Programme, Ref: 12/180/20 (UK)



# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	19/09/2020	25/09/2020	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No