Participant Information Sheet (Stage 2)

Study title: 'HelpMeDoIt!' a web, app and text (SMS) based intervention to facilitate social support to achieve and maintain health related change in physical activity and healthy eating.

Part 1 of the HelpMeDoIt! Study Information Sheet

What is the purpose of this study?
This study will evaluate HelpMeDoIt! which is a website and mobile phone application or 'app' that will help people set a behaviour change goal, like eating more healthily or doing more physical activity, and sign up friends or family as 'helpers' to 'help them do it'. We would like to invite you to take part in this research study. Before you decide if you would like to take part, you need to understand why the research is being done and what it would involve for you. Please take time to read the information carefully. Talk to others about the study if you wish, such as your GP, or members of your family or friends.
Part 1 of this information sheet tells you the purpose of this study and what will happen if you take part. Part 2 gives more detailed information about how the study will be organised. Please ask if anything is not clear or if you would like more information. Take time to decide whether you wish to take part.

We want to recruit people to the study who are trying to lose weight. The study aims to see whether using the website and app and getting help from family and friends has any impact on people's healthy eating and physical activity habits as well as their weight. The intervention seeks to motivate people to stick with their goals in relation to physical activity, healthy eating or weight loss and to get their friends and family to help them.

Why have I been approached?
You have been invited to take part in this study because:

- your Body Mass Index (BMI) is at least 30;
- you are between the ages of 18 and 70 years.

Do I have to take part?
No. Taking part is entirely voluntary. The researcher you meet with will give you more information and answer any questions that you have about the study. Once you have had time to think about it and understand what is involved, and if you decide to take part in the study, we will ask you to sign a consent form to show you have agreed. However, you are free to withdraw at any time, without giving a reason. Your usual NHS care will not be affected.

What will happen to me if I agree to take part?
The researcher will meet with you and weigh you, measure your height and take hip and waist measurements. We will also ask you to complete a questionnaire which includes questions about physical activity, eating habits, general health and your social network. This will take about 90 minutes. You will then be allocated randomly to one of two groups. One group which we call the 'intervention group' will have access to the website and app and one group which we call the 'control' group will receive an information leaflet on healthy eating and physical activity. People in the control group will have access to the website and app about 12 months after they are recruited into the study. We will write to you and let you know which group you have been allocated to and what will happen next.

Intervention Group: If you are in this group you will have the opportunity to access a website and app for twelve months which contains information about healthy eating and physical activity and guidance on how to set goals. You will be able to nominate a friend or relative to help support you, and they will also have access to the website and app.

Control Group: If you are in the control group you will receive an information leaflet on healthy eating and physical activity for weight loss. Participants in the intervention groups will also receive this leaflet. About twelve months after the study starts you will be given access to the website and app.

No matter which group you are in, you can continue to follow any weight loss programmes, e.g. if you attend a Weight Watchers, Slimming World or an exercise on referral scheme or gym you may continue to follow their advice and attend that group as usual. What we will offer you will be in addition to this and aims to help you to be successful in your goals.

What will I have to do?
We will ask you to spend some time filling in questionnaires. We will ask you to meet up with a researcher at a convenient time and a convenient place, twice over a period of one year (when you enter the study and then 12 months after you entered the study). Each session will take about 90 minutes. We will weigh you, measure your waist and hips and ask you to complete a questionnaire which includes questions about physical activity, eating habits, general health and your social network. You will also be given or sent a device called an accelerometer (it looks a bit like a belt) which measures your physical activity. The researcher will explain how it works. You will be asked to wear this for seven days including a weekend day when you enter the study and 12 months later. We will also call you on the phone to ask you about what you have eaten in the last 24 hours, this will happen for four days over a ten day period. We will ask you to do this just after you enter the study and again at 12 month follow-up. We may also contact you to see if you are willing to do a short interview about your experiences of taking part in the study. If you are willing we will ask you to sign a separate consent form for this.

What are the possible benefits of taking part?
This study is being undertaken to find out if this intervention is helpful for people who are trying to eat more healthily, do more physical activity and lose weight. As well as helping us answer this question, we hope that taking part in the study could help you set healthy lifestyle goals and get help from your friends to achieve these goals. It may help you lose weight and you may also improve your overall health.

What are the possible disadvantages and risks of taking part?
The study will take up some of your time. Everyone taking part will have to spend some time with the researcher being measured and filling in questionnaires as well as wearing the accelerometer. Those in the intervention group will also spend time using the website and app and contacting friends and family for support in their goals. We do not think there are any risks of taking part in the study, but we suggest you discuss your healthy eating and physical activity with your GP if you have any concerns. Healthy eating and physical activity advice will follow government guidelines and will encourage moderate physical activity and a low fat and high fibre diet. Those in the intervention group will be setting their own goals and our intervention is aimed at helping people achieve these.

Although I am a participant, can I act as a helper for someone else?
Maybe. It depends on what group you are randomly allocated to. If you are allocated to the intervention group then yes, you can act as a helper to someone else. If you are allocated to the control group, then you cannot act as a helper. We understand this may be disappointing. However, this helps us assess the actual impact of the website and app. This lets up compare the people who did and did not see the website and app. If you are a control participant, you **will** be able to use the website and app in approximately 12-months time once the study has ended.

This completes Part 1. If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2 of the Information Sheet

What will happen if I don't want to carry on with the study?
You can withdraw from the study at any time, without giving a reason. If you withdraw or decide not to take part, we will use the data collected up to that point (unless you ask us not to) but we will collect no more data.

What if there is a problem?
If you have a concern about any aspect of this study, you can speak to the researchers at the University of Glasgow who will do their best to answer your questions (contact details below). If you remain unhappy and wish to complain formally, you can do this using these contact details:
The Senate Office, The University of Glasgow, Glasgow, G12 8QQ. Email: complaints@glasgow.ac.uk. Telephone: 0141 330 2506.

Harm
In the event that something does go wrong and participants are harmed during the research and this is due to someone's negligence then they may have grounds for a legal action for compensation from the University of Glasgow but they may have to pay their own legal costs. 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.

Will my taking part in this study be kept confidential?
Yes, we will follow ethical and legal practice and all information about you will be handled in confidence. All information which is collected about you during the course of the research will only be seen by the research team. Contact details will be retained so that we can contact you about follow-up appointments

and for sending vouchers. Study data will be stored at the University and be kept separate from personal information (names and addresses). Only members of the research team will have access to view identifiable data. However, in some instances, official people from regulatory authorities may need to access data to check the quality of the research. Members of the research team and regulatory bodies are trained and bound by the terms of the Data Protection Act 1998. Once it is no longer necessary to keep identifiable information or contact details, we will destroy our records of this personal information. Other information will be kept securely for up to 10 years in line with University of Glasgow policies. We will inform your GP, with your consent, that you are taking part in the study. We will only pass information about you to anyone outside the study if we have concerns about your or anyone else's safety. You have the option of agreeing to the research team sharing your research data with other researchers. This would involve us storing your research data anonymously with the UK Data Archive (an internationally acknowledged centre of expertise who store research data for use by researchers and scientists). Other genuine researchers may then access this data to help answer future research questions. All information stored adheres to the Data Protection Act 1998. You will never be identifiable from the research data. **Please note that you do not have to agree to us sharing your data to be able to take part in the study.**

Expenses and payments
We cannot pay you directly to take part in this study but to thank you for your time helping with the study we will give you £20 vouchers at each data collection point.

What will happen to the results of the research study?
A report of the research results will be sent to the funder and will be published on their website. Results will be published in scientific journals and presented at scientific meetings. You will not be identified in any report, publication or presentation. Once the research study is complete the results will be posted on the study website. If you would like the results sent to you please contact the Trial Manager. We will also send you newsletters at regular intervals during the study to update you on progress.

Who is organising and funding the research?
This study is being organised by the Social and Public Health Sciences Unit at the University of Glasgow. The research is being paid for by the National Institute of Health Research Public Health Research Programme.

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the NHS Research Ethics Committee for the West of Scotland.

Contact for further information:
Trial Manager, Lynsay Matthews
Tel: 0141 353 7633
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THANK YOU FOR CONSIDERING TAKING PART IN THIS STUDY.