

9.6 Resource 6: Participant Information Sheet



INFORMATION SHEET

NoHoW: Evidence-based ICT tools for weight loss maintenance.

Thank you for your interest in taking part in our research study.

We would like to invite you to take part in this exciting study investigating new technologies and innovative web-based approaches that may help people maintain their weight loss. Before you decide whether you would like to take part, we want you to understand why this study is being carried out and what it involves. Please take time to read the following information and to decide whether or not you would like to take part. If you have any questions or if you would like more information, please contact the research team (you'll find their contact details at the end of this sheet). You may like to discuss your participation with your family and friends before making a decision.

What is the aim of the study?

Many people can manage to lose weight, but for lots of people keeping this weight off in the long term can be difficult. Researchers already know that maintaining weight loss depends on changing different behaviours, like eating and physical activity. There are many techniques available to help people change their behaviour in the long term, but we still don't know which of these techniques work well for keeping the weight off and preventing weight regain.

To understand more about what techniques are most effective for weight loss maintenance, the University of Leeds is part of a study called NoHoW (Navigating to a Healthy Weight), which will test new information and communication technologies (ICT), based on the most recent evidence to help people maintain their weight loss. It will examine whether providing support via a web-based toolkit, digital weighing scales and a digital activity meter can influence weight loss maintenance over an 18-month period.

Do I have to take part?

No, the study is completely voluntary and the decision to take part is entirely up to you. If you do decide you would like to take part, you will be asked to complete a short online form to check if you are able to take part in this study. Even if you sign up to the study you are free to withdraw at any point, without giving any reason.

Who is organising and funding the research?

The research is organised by Professor James Stubbs and his team at the University of Leeds. The research team at the University of Leeds are working in collaboration with other centres across Europe. The research has been funded by a grant from the European Union's Horizon 2020 research and innovation programme.

Has the research been approved?

All research led by the University is reviewed by an independent group of people called a Research Ethics Committee. The project is approved by the School of Psychology Research Ethics Committee at the University of Leeds (16-0243; 26-Sept-2016).

Do I have to have lost weight to take part?

Yes. As this study involves supporting people to maintain weight loss, you must have lost at least 5% of your weight in the last 12 months to be eligible to take part. You must also have had a BMI of 25 or higher before your weight loss (don't worry, these will be calculated for you as part of the eligibility check). You must have lost weight intentionally, so you will not be able to take part if you have lost weight due to illness or surgical procedures including bariatric surgery (i.e. gastric band or bypass surgery). However, if you haven't quite lost 5% we would still like to hear from you.

Will I need access to the internet?

Yes. As this study is based on testing web-based tools you will need access to one of the following: computer, laptop, smartphone or tablet with access to the internet. This is so you can access the toolkit. You will also be given a Fitbit Aria wireless weighing scales and a Fitbit Charge 2 wrist worn activity meter which you'll be asked to use for the duration of the study. The scales and activity meter link to the internet, via Wi-Fi, so that your weight and physical activity can be relayed back to the research team. This allows us to record how your weight and activity change over the course of the study.

Can I take part?

You can take part if you:

- Are 18 years or older
- Are able to travel to the University of Leeds for up to 5 visits over 18 months.
- Have lost $\geq 5\%$ of your weight in the last 12 months.
- You had a BMI of 25 and above before you lost weight
- Are still at least 5% below your highest weight (and no more than 150kg due to the maximum weight the scales allow)
- Are able to follow written and verbal information in English.
- Have the ability to access the internet via Wi-Fi.
- Are able to use standard bathroom standing scales

If you have not quite lost 5% of your body weight and are still interested in joining the NoHoW study, we would like to keep in touch with you over the next 12 months as you might become eligible during this time. You can provide us with your contact details and consent to us contacting you when you complete the online eligibility form.

You will not be able to participate if you:

- Have lost weight due to illness or surgical procedures, including bariatric procedures.
- Are pregnant
- Are breastfeeding
- Have been recently diagnosed with an eating disorder
- Have been diagnosed with any condition that may interfere with mild to moderate physical activities-an activity which raises your heart rate, makes you breathe faster and makes you feel warmer
- Have recently been diagnosed with Type I Diabetes.
- Plan to move out of the area or undertake long-term travel for more than four weeks in the next 18 months
- Are currently involved with a research project that confounds with the aims of NoHoW (excluding local health interventions and weight management services)

Before you decide to take part,

- 1- Please take your time to read the information sheet on our website <http://http://bit.ly/2IRfN7I/>.
- 2- After looking through the information about the study, if you think you'd like to take part, please **complete the online eligibility form** on the website (https://nohow.eu.qualtrics.com/jfe/form/SV_7aFlxPo00PHIOPr).

If you are not eligible to take part, the eligibility form will immediately provide you with an answer. If you are able to take part, the NoHoW research team will give you a call to confirm some details. Then we will arrange to meet with you at the University of Leeds and answer any remaining questions you have before you formally sign up to take part in the study.

What does the study involve?

The research team would like to recruit 1600 people to take part in this study over three centres in the UK, Denmark and Portugal. You will be provided a version of the NoHoW toolkit, Fitbit Charge 2 and Aria Scales, and asked to attend 4 measurement days and an optional device training day.

The NoHoW Toolkit

You will be provided with a version of the NoHoW Toolkit (a web-based app for weight loss maintenance) that we ask you to use for the duration of the 18 months. You will be

randomized into one of four versions of the toolkit which aims to help you to maintain your weight loss. The versions of the toolkit will consist of a range and combination of helpful components, that could include general health information, tools to help you self-manage your eating and activity behaviours, your motivation, or your emotional responses to stress in relation to weight loss maintenance. Each version of the toolkit is different to help us understand what works for weight loss maintenance. There is no set time limit on how much or how long you should spend on using the toolkit.

Fitbit Charge 2 and Aria Scales

You will be provided with a free Fitbit Charge 2 and Aria weighing scales (worth £200). Fitbit devices are provided for free for research purposes. All participants will be required to weigh themselves with the Fitbit Aria scales for a *minimum of twice a week* and on the same days of the week (e.g., Monday and Thursday) throughout the study. Participants should do this first thing in the morning after going to the toilet and in the same light clothing (e.g. the same bathrobe) each day. You can of course weigh yourself more if you prefer.

You will also be required to wear a wrist-worn activity meter (Fitbit Charge 2) for the duration of the study (18 months) which will record your activity patterns and heart rate. You can keep your devices after 12 months of participation in the NoHoW study. Information will be continuously relayed back to the confidential and secure NoHoW data-hub from both devices. Also, we will request your permission to create a Fitbit account with your personal email address provided in the online eligibility form. This will be created before your first visit where this account will then be connected to the Fitbit devices and NoHoW toolkit.

Measurement days

You will be asked to attend the University of Leeds, Lifton Place, School of Psychology for four measurement days and one optional toolkit/Fitbit training day spread across 18 months (at 0, 6, 12 and 18 months). Your measurements will be taken in a fasted state. We ask that you do not eat or drink anything except for water from 10 pm the night before attending your visits at baseline, 6, 12 and 18 months. A summary of each visit is included below;

Visit 1

Your first visit will be the longest and could take between 2- 4 hours (less if you complete the questionnaire prior to coming onsite).

- Discuss and ask questions about the study.
- If you still wish to take part, you will be invited to sign a consent form giving your agreement to participate in the study for 18 months.
- We will take a range of fasted measurements including:
 - body weight,
 - height,
 - hip and waist circumference,
 - blood pressure and heart rate,
 - body composition (e.g. fat mass and fat free mass),
 - (optional) hair samples to assess long-term cortisol (a hormone related to

- stress),
- (optional) fasting blood samples via a small finger-prick to assess Full Lipid profile (e.g. cholesterol) and HbA1c (an assessment of blood sugar levels across the past 3 months)
 - (optional) Leeds Food Preference Questionnaire (approx. 10 minutes), which is a computer task that asks you to rate 16 pictures of foods on a visual scale.

You will be informed of all your results at the end of the study but we will tell you straight away if your results fall outside the expected range.

You will then be asked to complete a series of questionnaires consisting of the following:

- A one-off questionnaire to provide information about you such as date of birth, gender, employment, marital status, dependents, weight loss history, experience with mobile technologies, and eating behavior (takes approximately 30 mins)
- Questionnaires relating to physical activity, motivation, emotional state, stress, well-being, quality of life and dietary intake (takes approximately one hour).
- You will have the option to complete these questionnaires at home prior to coming onsite, which will reduce the time on-site (except for the optional Leeds Food Preference Questionnaire which will be done onsite).

After this:

- You will be randomly assigned to one of four versions of the toolkit, using a computer program.
- You will receive your Fitbit devices and training on how to use them
- You will receive your log-in details and training on how to use the toolkit.
- Arrange an additional toolkit/fitbit training day (optional).
- After the first session, complete 4 consecutive days diet recall using a quick and easy online system called INTAKE24 (training provided).

Visit 2 – Training Day (Optional)

Your second visit will be an optional 1-2 hour training day scheduled within approximately two weeks after your first visit. You will have the opportunity to discuss any questions that might have emerged concerning using the toolkit, the set-up of the Fitbit Charge 2, the Fitbit Aria Scales at home and completing the 4-day diet recall.

Visits 3 -5

You will be asked to attend the University of Leeds again at:

- 6 months (3rd visit)
- 12 Months (4th Visit)
- 18 Months (5th Visit)

Each visit will last up to 2 hours. A researcher will take many of the same fasted measurements made at visit 1, including body weight, hip and waist circumference, blood pressure and body composition. **We won't be requesting the optional blood and hair**

samples at month 6 (3rd visit) or month 18 (5th visit). Even if you choose to provide blood and hair samples at the start of the study, you can change your mind at any point. You will also be asked to complete questionnaires relating to physical activity, motivation, emotional state, stress, well-being, and quality of life. You will have the option to complete these questionnaires at home prior to coming onsite to save time during the visit (except for the optional Leeds Food Preference Questionnaire which will be done onsite) You will also be asked to complete 4 consecutive days 24 hour diet recall using INTAKE24 after each visit.

Following your final visit you will be provided with a study data sheet which will outline all of the measures taken from you throughout the duration of the study.

Additional measures throughout the 18 months

At a number of time points (month 1, 3, 6 and 12) throughout the study, you will be asked to complete some short online questionnaires about your experience of the toolkit.

You may also be asked at a later stage of the study, to take part in an informal focus group where you will have the opportunity to share your experiences about the study and toolkit. You will be provided with further information at a later stage and asked to sign a separate consent form if you agree to participate.

Can I keep my Fitbit Charge 2 and Aria Scales?

If you remain in the study and attend the 12 month visit, you'll be able to keep your devices as a small "thank you" for taking part in this important research.

If you withdraw from the study before completing your 12 month visit, we would be grateful if you could return the activity meter and digital weighing scales to the University of Leeds in order to give a potential participant a chance to take part in the study. We would ensure that the tools will be reset, so any information or data will be deleted.

Do I have to provide blood samples?

Donation of blood for this study is voluntary and you should not feel under any pressure to give a sample. You do not have to agree to this or to explain why you might choose not to donate. We will be collecting blood samples from a small finger prick at your first visit and then 12 months later if you provide consent. Even if you choose to provide blood samples at the start of study, you can change your mind at any point. Any personal information provided by you in connection with the blood tests will be held in strict confidence.

For reasons of safety, you should not provide a blood sample if:

- You know, or think that you might be infected with Hepatitis B or Hepatitis C.
- You know, or think that you might be infected with HIV
- You have a sexual partner who is infected with Hepatitis or HIV
- You are unwell at that time.
- You are anaemic or receiving treatment for anaemia or iron deficiency

However, we still would appreciate your valuable participation if you wish to complete the other measures (body weight, height, hip and waist circumference, blood pressure, body composition and optional hair samples) and questionnaires.

Do I have to provide hair samples?

No. You do not have to agree to this and again you would not need to explain your reasons. If you opt into providing a hair sample, we would collect the hair samples to assess the cortisol content, which acts as a biomarker of long-term stress. We would collect a sample initially on your first visit and then 12 months later. Even, if you choose to provide a hair sample at the start of study, you can change your mind at any point. If you're happy to provide a sample, during your visit to the research centre we would take a thin tuft of hair, place a clip around the hair 1-2cm from the scalp and then cut hair as close to the scalp as possible. We would also ask how many times a week you wash your hair and if you have dyed your hair within the past 6 months. Any personal information provided by you in connection with the donation will be held in confidence.

What are the possible benefits of taking part?

While the aim of the Toolkit is to support you with maintaining weight loss, we can't promise that your participation will benefit you directly although we do hope that you will find it interesting taking part in the research. At the end of the trial, all participants will receive an e-book of all toolkit components, regardless of which arm you were randomized to. We endeavour to learn from this research to help people control their weight in the longer-term. Your participation in this study will help the team to find out how useful our approach is in helping maintain weight loss and may be beneficial to others in the future.

What are the possible disadvantages or risks of taking part?

There are no expected disadvantages involved in taking part in in this study however, we will ask you to travel to the University of Leeds site up to five times throughout the 18 month duration of the study to complete some questionnaires and measures. Each visit will take between 2 and 4 hours and we will provide breaks at any time. If you would like to participate in the focus group, this will take additional time (approximately up to 1.5 hours). It is not anticipated that you will find the topic of the discussions distressing; however, you are free to stop at any time and contact Dr. Sarah Scott at s.e.scott@leeds.ac.uk.

The toolkit might encourage you to increase your physical activity. You will need to consult your GP before undertaking any additional exercise particularly if you have any underlying health issues or existing health issues that might be made worse by moderate physical activity.

The Fitbit Charge 2 is designed to be worn day and night and so there are some clear guidelines for caring for your Fitbit to avoid the unlikely event of skin irritation that can occur with misuse. These guidelines will be provided to you during your Fitbit training session.

Will my information be kept confidential?

All information collected will be kept strictly confidential in accordance with the Data Protection Act (1998).

You will be given a unique study number and your personal contact details will be stored separately from any other information you provide. This way your personal identity and the information you provide in the study cannot be connected by anyone outside the study

team. Personal data will be held in a secure location, and hard copies of information will be kept in locked cabinets, electronic copies of information will be kept in password-protected files, shared drives, and computers to which only members of the research team will have access. It will be stored securely for 20 years (the length of time we need to keep research information for) then it will be destroyed. All of the results of the study that are analysed and published will be fully anonymised so that neither you nor your individual results will be identified.

Occasionally, blood pressure or blood test results may fall out of the usual range which may be due to conditions such as high blood pressure, pre-diabetes, diabetes and high cholesterol. In these cases, we will share the results of your measurements (blood pressure, blood test) with yourself and, with your consent, your GP. If you do decide to participate in the focus group, anything that is discussed will be treated with the strictest confidence.

While your information is kept strictly confidential, if researchers feel that there is a reason to be concerned for the safeguarding or well-being of yourself or others (e.g. self-report of suicidal thoughts) researchers have a duty of care to notify the appropriate authorities (e.g. a GP).

What will happen if I don't want to carry on with the study?

You are free to withdraw from the NoHoW study at any time without giving a reason. If no longer meet the inclusion criteria throughout the duration of the study we may ask you to withdraw from the trial. You can decide if you are happy for us to use the information from the questionnaires and measure that you may have provided before you leave the study. If you choose to withdraw your data, please contact the research team no later than four weeks after your last data collection point initially at baseline and 6, 12 or 18 months, as the data may be inaccessible in the locked, anonymised database after this time. Your data will be collected at each visit at baseline, 6, 12 and 18 months. When you contact the research team, you will need to cite your unique Study ID which will be provided to you at the start of the study. The information collected from the questionnaire and measures at each point will be stored anonymously in separate databases. Four weeks after each data collection point, the databases containing the new information should be inaccessible ready for the team to start analysing the data. Your data cannot be removed after this time point. Once you have withdrawn from the study you will no longer be able to access the NoHoW Toolkit.

What if there is a problem?

If you have a concern about this study, please contact the Co-Investigator, Dr. Sarah Scott, by telephone on (0113) 3430622 or e-mail at nohow@leeds.ac.uk. If your concern cannot be resolved or should you wish to make a complaint regarding the study, we will put you in touch with the Principal Investigator (Professor James Stubbs).

What will happen when the study is complete?

Once all the data have been collected and analysed, the results will be written up and will be shared with a wide range of audiences, including other researchers, health professionals and the general public. The results will be written up for publication in academic journals and will be and communicated through various channels including the project website, social media and press releases. Your personal contact details will be stored separately

from any other information you provide. This way your personal identity will be anonymous and you cannot be identified personally from the results of the study.

We endeavour to learn from this research to help people maintain the weight that they have lost. It is anticipated that we will develop a service for weight loss maintenance with our commercial partner Slimming World, which will be based on the effective components of the intervention and will be available to the public.

What do I do now if I want to participate?

If you have decided that you would like to take part, you can go to our website <http://http://bit.ly/2IRfN7I/> and fill in the **online eligibility form**. If you are able to take part, a member of the research team will contact you to go through the details of the study and check some of the information we require and then arrange a visit to the research centre at the University of Leeds. You will once again have the opportunity to discuss the study in detail and what you can expect if you decide to take part. If you have decided that you do not want to take part in the study, you don't have to do anything.

What if I have any questions?

If you need more information please feel free to contact Dr. Sarah Scott by telephone on (0113) 3430622 or e-mail at nohow@leeds.ac.uk. Alternatively, you can contact the Principal Investigator Professor James Stubbs at r.j.stubbs@leed.ac.uk. If you would like more information please visit our website <http://http://bit.ly/2IRfN7I/> and our main project website <http://nohow.eu/>.

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