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Evidence-based information and communications technology tools for weight loss maintenance

Submission date
16/12/2016

Recruitment status
No longer recruiting

Registration date
22/12/2016

Overall study status
Completed

Last Edited
30/10/2023

Condition category
Not Applicable

✓ Prospectively registered
✓ Protocol added
? SAP not yet added
✓ Results added
? Raw data not yet added
✓ Study completed

Plain English Summary
Background and study aims
Obesity is a key economic and healthcare challenge for Europe. Most adults try to lose weight but fail to maintain it. Effective programmes for weight loss are widely available, but most people re-gain their lost weight. The most promising behaviour change techniques for maintaining weight loss maintenance are self-monitoring, goal setting, action control, building self-efficacy and intrinsic motivation. Stress management and emotion regulation skills can also prevent relapse and weight regain. Information communication technology (ICT) offers attractive tools for teaching and supporting these techniques, some of which are currently delivered face-to-face. ICT delivery includes tracking technologies, weighing scales and activity sensors, online tools and smartphone apps, multimedia resources and internet-based support. A broad choice of tools is most likely to be acceptable to users, who can pick and choose their own preferred technologies. This study tests whether ICT-based delivery of the most promising behavior change techniques is effective for maintaining weight loss.

Who can participate?
Adults aged 18 or older who have lost at least 5% of their body weight intentionally in the last 12 months, and started with a BMI of 25 or more

What does the study involve?
Participants are invited to attend five sessions across 18 months. Additionally, at a number of time points (month 1, 3, 6, 12 and 18) throughout the study, participants are also asked to complete some short online questionnaires about their experience of the toolkit.
The first visit takes place at the research centre at the University of Leeds and takes up to 4 hours. Participants are asked to give a range of measurements including body weight, height, hip and waist circumference, and health markers including optional blood pressure, body composition, and optional hair samples. Participants also have the option to provide fasting blood samples via a small finger-prick, which will help to assess important health markers but this is voluntary. Participants are also asked to fill out a one-off questionnaire. This includes information such as date of birth, gender, and personal characteristics (e.g. weight loss history,

experience with mobile technologies, and some questions about your typical eating behaviour). Participants are also asked to complete questionnaires relating to physical activity, motivation, emotional state, stress, well-being, quality of life, and diet. Participants are then randomly allocated to one of four groups. These groups are offered one of four different versions of the toolkit that might provide general health information, tools to help participants self-manage their eating and activity behaviours, their motivation, or their emotional responses to stress. Participants in each of these groups are required to weigh themselves a minimum of twice a week and on the same days of the week (e.g., Monday and Thursday) throughout the study with the Fitbit Aria weighing scales. Participants are also required to wear a wrist-worn activity meter (Fitbit Charge 2) for the duration of the study. Participants are provided with these devices free of charge. At the end of the day, there is a short training session to get participants set up with their tools (Fitbit Charge 2 and Aria weighing scales). A few days after their visit participants are also asked to complete an online 4-day food diary. Participants are then asked to visit the University of Leeds one week later for a shorter second visit (2 hours) for training on how to use the different components of the Toolkit (i.e. the NoHoW web-based app, the Fitbit Charge 2 and Aria scales). The third, fourth and fifth visits take place at 6, 12 and 18 months after the first visit and last up to 4 hours each. A researcher takes many of the same measurements made at visit 1 including body weight, height, hip and waist circumference, blood pressure and body composition. Participants are asked to complete questionnaires relating to physical activity, motivation, emotional state, stress, well-being, quality of life, and diet.

What are the possible benefits and risks of participating?
The potential benefits are increased knowledge and skills for weight loss maintenance in the long-term. Participants receive a £30 reward and are able to keep the Fitbit Charge HR and Aria scales for free. There are no expected disadvantages involved in taking part in this study.

Where is the study run from?
1. University of Leeds (UK)
2. The Parker Institute (Denmark)
3. University of Lisbon (Portugal)

When is the study starting and how long is it expected to run for?
March 2015 to February 2020

Who is funding the study?
European Union’s Horizon 2020 research and innovation programme (Belgium)

Who is the main contact?
Prof. James Stubbs
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Study website
http://nohow.eu

Contact information

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Protocol/serial number
Nil known

Study information

Scientific Title
A 2 x 2 randomised controlled trial to evaluate the effectiveness of evidence-based information and communications technology behaviour change tools for weight loss maintenance in overweight/obese adults after clinically significant weight loss

Acronym
NoHoW

Study hypothesis
1. That participants will be more effective at maintaining weight loss in the long-term when receiving a toolkit that combines content for self-regulation and motivation compared to only self weighing.
2. That participants will be more effective at maintaining weight loss in the long-term when receiving a toolkit that combines content emotion-regulation components compared to only self weighing.
3. That there is an additive effect of combining self-regulation and emotion regulation at improving maintenance of weight loss compared to only self weighing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The University of Leeds, School of Psychology Research Ethics Committee, 27/10/2016, ref: 16-0275

Study design
International multi-centre 2 x 2 four-arm randomised controlled trial with adaptive stratified sampling using minimisation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Participant information sheet can be found on the recruitment website at http://uk.nohow.eu

Condition
Overweight and obese adults who have achieved clinically significant weight loss (5%)

Interventions
The NoHoW study is an International multi-centre 2 x 2 four-arm randomised controlled trial with adaptive stratified sampling using minimisation. It will run across 18 months, which will include a 6-month active intervention and a 12-month follow up.

Participants attend five sessions across 18 months. Additionally, at a number of time points (month 1, 3, 6, 12 and 18) throughout the study, participants are also asked to complete online questionnaires about their experience of the toolkit.

The first visit takes place at the research centre at the University of Leeds and takes up to 4 hours. Participants are able to discuss the study in detail and are invited to sign a consent form giving your agreement to participate in the study. All data will be anonymised. Participants are then asked to give a range of measurements including body weight, height, hip and waist circumference, and health markers including optional blood pressure, body composition, and optional hair samples. Participants also have the option to provide fasting bloods samples via a small finger-prick, which will help to assess important health markers but this is voluntary. Participants are also asked to fill out a one off questionnaire. This includes information such as date of birth, gender, and personal characteristics (e.g. weight loss history, experience with mobile technologies, and some questions about your typical eating behaviour). Participants are also asked to complete questionnaires relating to physical activity, motivation, emotional state, stress, well-being, quality of life, and diet.

Participants are then randomly allocated to one of four groups. These groups are offered different versions of the toolkit that might provide general health information, tools to help participants self-manage their eating and activity behaviours, their motivation, or their emotional responses to stress. The four groups are:
1. Self-weighing, only access to generic toolkit content
2. Self-weighing and toolkit content focused on self-regulation and motivation components, including feedback on weight trajectories
3. Self-weighing and toolkit content focused on emotional regulation, including feedback on weight trajectories
4. Self-weighing and toolkit expanded to focus on both self-regulation + motivation + emotional components, including feedback on weight trajectories

Participants in each of these groups are required to weigh themselves a minimum of twice a week and on the same days of the week (e.g., Monday and Thursday) throughout the study with the Fitbit Aria weighing scales. Participants are also required to wear a wrist-worn activity meter (Fitbit Charge 2) for the duration of the study. Participants are provided with these devices free of charge. At the end of the day, there is a short training session to get participants set up with their tools (Fitbit Charge 2 and Aria weighing scales). A few days after their visit participants are also asked to complete an online 4-day food diary.

Participants are then asked to visit the University of Leeds one week later for a shorter second visit (2 hours) for training on how to use the different components of the Toolkit (i.e. the NoHoW web-based app, the Fitbit Charge 2 and Aria scales).

The third, fourth and fifth visits take place at 6, 12 and 18 months after the first visit and last up to 4 hours each. A researcher takes many of the same measurements made at visit 1 including body weight, height, hip and waist circumference, blood pressure and body composition. Participants are asked to complete questionnaires relating to physical activity, motivation, emotional state, stress, well-being, quality of life, and dietary intake.

Intervention Type
Behavioural

Primary outcome measure
Weight (kg) is measured using the SECA 704 at 0, 6, 12 and 18 months

Secondary outcome measures

Secondary outcome measures will be collected at 0, 6, 12 and 18 months:
1. Proportion of subjects maintaining >0, 5 and 10% weight loss, and drop-out rate
2. Body composition (e.g. fat free mass and fat mass) is measured using the Impedimed SFB7
3. Health biomarkers, including blood pressure and resting heart rate (Using the OMRON M10). Full lipid profile and HbA1c by finger prick method (using the Alere Afinion Analyser) and hair cortisol to measure stress according to a protocol outlines by Van Uum et al. (2008). Please note that the blood and hair samples will only be collected at 0 and 12 months.
4. Intervention impact on physical activity and sleep quantity and quality (e.g. daily minutes of light moderate and vigorous activity, number of steps and distance walked, heart rate throughout the day)]. Objective physical activity and sleep patterns will be analysed using the Fitbit Charge HR 2 throughout the 18 month trial. Self-reported physical activity will also be collected by the IPAQ and Activity Choice Index.
5. Dietary intake at 0, 6, 12 and 18 months through 24 hour recalls on four consecutive days within 7-days of each time point using INTAKE24.
6. Eating Behaviour (Three factor eating inventory, Controllability and automaticity of eating behaviour, Eating in the absence of hunger scale, Intuitive eating scale).
7. Impact of the interventions on well-being and quality of life (Warwick and Edinburgh Wellbeing Scale, EQ5D)
8. Moderators and mediators of behaviour change, including:
8.1. Self-regulation and motivation (Action planning and coping scales, Basic Psychological Needs and Frustration Scale, Goal content maintenance for weight loss maintenance, BREQ-3, Regulation of eating behaviour scale, Self-efficacy for exercise and easting scales)
8.2. Emotion regulation (including weight focused self-criticism scale, weight focused external shame scale, Body image acceptance and action questionnaire, Engaged living scale, Five dimensions of mindfulness, Difficulties in emotion regulation scale, Mindful attention awareness scale)
8.3. Stress Management (Perceived stress scale and depression, Anxiety and stress scale)
9. Process evaluation to investigate and feedback recruitment/reach to maximise recruitment effectiveness, reasons for engagement, continuation and drop out (through questionnaires), user experience and acceptability of the intervention arms (convenience, ease of use, outcomes for themselves and wider social networks) and unintended consequences. Questionnaires will be distributed to all participants at 0, 1, 3, 6, 12 and 18 months. Focus groups will be conducted after 6 months toolkit usage.

Overall study start date
01/03/2015

Overall study end date
28/02/2020

Eligibility

Participant inclusion criteria
1. Providing written informed consent for study participation prior to any study specific procedures
2. Aged 18 years or older (no upper limit)
3. Initial Body Mass Index (prior to weight loss) of ≥25 kg/m2
4. Written verification of at least 5% of weight loss in the last 12 months by either a physician, health professional, weight loss counsellor or friend
5. Access to a smartphone, tablet or computer with Internet access and WiFi at home to receive

reminder messages regarding weight recordings, mobile health intervention modules and intervention assessments
5. Ability to use a standing scale for weight measurements

Participant type(s)
All

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1600

Participant exclusion criteria
1. Inability to give informed consent
2. Individuals who have lost weight due to illness or surgical procedures, including bariatric procedures
3. Pregnant or planning to become pregnant in the next 18 months
4. Mothers who are breastfeeding
5. Current involvement in other research intervention studies or randomised controlled trials (excluding local health interventions and weight management services)
6. Inability to follow written material or telephone conversations in the English, Danish or Portuguese language (depending on the centre) that would preclude completion of study questionnaires and use the NoHoW TK
7. Diagnosis of anorexia nervosa, bulimia nervosa, purging disorder, or screen positive for symptoms of any of these disorders of eating at baseline

Recruitment start date
20/03/2017

Recruitment end date
31/03/2018

Locations

Countries of recruitment
Denmark

England

Portugal

United Kingdom

Study participating centre
University of Leeds
School of Psychology
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Study participating centre
The Parker Institute
Copenhagen University Hospitals
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Study participating centre
University of Lisbon
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Sponsor information

Organisation
The University of Leeds

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Sponsor type

University/education

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Other

Funder Name
Horizon 2020

Alternative Name(s)
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
Planned publications in high-impact peer reviewed journals to be published from 2017 and after the trial end date (2020).

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository - The Danish Data archives (DDA, Dansk Data Arkiv), available via https://www.sa.dk/en/services/danish-data-archive.
The process is between the application and the project's steering committee. To apply for permission to use the data, search for the project via http://dda.dk/simple-search
Following the project (and having achieved intellectual property and publication goals), this data will be made available in DDI (data documentation initiative) formats (as applicable) on the Danish Data archives (DDA, Dansk Data Arkiv), where it can be accessed by bona-fide researchers in the future. Consent was obtained for anonymised participant data to be disseminated and stored for 20 years.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	sleep study results	16/07/2020	17/07/2020	Yes	No
Protocol article	protocol	30/09/2019	15/01/2021	Yes	No
Other publications	secondary analysis on association between weight variability and cardiometabolic health markers	02/08/2020	18/01/2021	Yes	No
Other publications	Usage and effects of web intervention modules	14/04/2022	19/04/2022	Yes	No
Other publications	User experience of NoHow Toolkit	10/01/2022	19/04/2022	Yes	No
Other publications	Testing motivational and self-regulatory mechanisms of action on device-measured physical activity in the context of a weight loss maintenance digital intervention: A secondary analysis of the NoHoW trial	01/01/2023	05/09/2023	Yes	No
Results article	Primary and secondary analysis	27/10/2023	30/10/2023	Yes	No