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Motivating weight loss through a personalised avatar

Submission date
17/12/2018

Recruitment status
No longer recruiting

Registration date
08/01/2019

Overall study status
Completed

Last Edited
06/10/2022

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Population obesity is a UK health priority. Obesity increases the risk of ill health (e.g. diabetes, heart disease, cancer, depression) as well as demand for, and cost of, healthcare services. Adult obesity interventions rely mainly on individuals reducing food (calorie) intake and increasing physical activity but lack of sustained motivation and poor adherence to diet plans remain key barriers to weight loss success. Virtual reality technology is expanding rapidly. This has great potential for supporting weight loss through the use of a personalized avatar (computerized image of oneself). Experimental studies have shown that an individual's behaviour can be positively influenced by changing the appearance, experience and behaviour of an avatar. Experiments have also shown that when different potential futures are presented to an individual through an avatar, their behaviour changes to enable achievement of their preferred future option. This study aims to develop an avatar program to support weight loss. A computer program for generating self-resembling avatars will be developed through a series of design phases with feedback from service users and healthcare professionals. The final prototype will allow individuals to see their avatar gaining/losing weight and the influence this has on their health risks.

Who can participate?
Adults aged 18-65, 2. White British or South Asian ethnicity, and BMI over 30 (obese)

What does the study involve?
The avatar program is tested within a NHS weight loss clinic. Participants are randomly allocated to receive either routine care or routine care plus use of the avatar program. The avatar program is used to explain the importance of weight improvement, current health risks and explore possible weight/health futures. On appointment completion, the participant is given a website address and password to access their personalized avatar. They are encouraged to explore how increasing/decreasing weight impacts on the appearance and BMI boundary health risks of their avatar. Time spent accessing the avatar program, and activity within it, is monitored as a proxy measure for engagement with the technology. Follow-up appointments with the research nurse coincide with weight loss service appointments at 1 month and 3 months. A further appointment to meet with research nurse is made at 6 months. Data is collected on weight loss, patient feelings about weight loss and their experience of using the avatar program.

What are the possible benefits and risks of participating?
The study findings will determine whether a full clinical trial is warranted to test the impact of avatar technology on population weight loss.

Where is the study run from?
Mid Yorkshire Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
January 2019 to January 2020

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Prof. Maryann Hardy
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
39782

Study information

Scientific Title
MotiVar: Motivating weight loss through a personalised avatar

Acronym

MotiVar

Study objectives
Virtual reality technology such as the use of a personalized avatar to show potential future weights will influence an individual's behaviour and help to support weight loss.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health Research Authority, North East - Newcastle and North Tyneside 1 Research Ethics Committee, 12/09/2018, ref: 18/NE/0286

Study design
Randomised; Both; Design type: Treatment, Process of Care, Education or Self-Management, Psychological & Behavioural, Active Monitoring, Validation of investigation /therapeutic procedures

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obesity

Interventions
The intervention:
Mid Yorkshire Hospitals NHS Trust weight improvement service offers a 12-week weight loss support programme to participants within Bradford, a socially diverse area. Participants within the intervention arm will attend the weight improvement service for their initial appointment (T0). The participant will be met by the research nurse who will take digital photographs (clothed) and confirm baseline anthropomorphic measures for input into the avatar creation programme. The participant will also be asked to complete an Impact of Weight on Quality of Life-lite (IWQOL-lite) survey, EQ-5DL Euroqual measure of health status, and a weight efficacy lifestyle-short form questionnaire (WEL-SF), the tools proposed to determine baseline quality of life and weight loss self-efficacy in a full RCT if warranted. Total data collection time will be less than 15 minutes per appointment.

The participant will then attend their initial appointment with the Health Care Professional (HCP) who will use the avatar programme to explain the importance of weight improvement, current health risks and explore possible weight/health futures. On appointment completion, the participant will be given a website address and password to access their personalized avatar. They will be encouraged to explore how increasing/decreasing weight impacts on the appearance and BMI boundary health risks of their avatar. Time spent accessing the avatar programme, and activity within it, will be monitored as a proxy measure for engagement with the technology. This will be achieved bu automatic computerised background monitoring of programme access and will be exported as a spreadsheet of activity by participant unique identifier.

Future appointments:
Follow-up appointments with the research nurse will coincide with weight loss service appointments at 1 month (T1) (immediate effect) and 3 month (T2) (programme completion - short term effect). A further appointment to meet with research nurse will be made at 6 months (T3) (3 month post-programme completion - moderate term progress).

At each of these appointments, the research nurse will repeat the baseline measurements (digital photographs and anthropomorphic measurements) and input data into the avatar programme. The participant will also be asked to complete the IWQOL-lite, WEL-SF and EQ-5DL surveys. Weight loss will be displayed as a change in avatar health risks and appearance. The sensitivity of avatar appearance to weight change will be dependent upon agreed weight loss programme goal and participant preferred avatar appearance on reaching goal weight. Incremental changes in avatar appearances from realistic to goal appearance will be automatically calculated and weight loss progress represented by both changing avatar appearance and weight loss achievement progress bar. At points T0-T2, progressive avatar data will be available to the HCP for use during the weight improvement service appointment. After each appointment, the participant will be able to access their updated personalised avatar online to explore changes in potential weight/health futures and, over time, their weight change history. HCPs using the avatar programme will attend training on its operation prior to study commencement. They will be informed of study purpose and asked to use the avatar programme as part of the participant interaction to assist in explaining health risks and allow participants to observe personalised weight/health futures. Participating HCPs will also be invited to take part in a focus group to discuss their experiences of using the avatar technology 3-6 months post study commencement.

Routine care:
Participants recruited into the routine care (control) arm will receive the same number of appointments with the weight improvement service as those provided to the intervention group. They will be met by the research nurse at time intervals T0-T3 as per intervention arm. At each appointment they will be weighed and asked to complete the IWQOL-lite, WEL-SF and EQ-5D surveys before meeting the HCP as per intervention group.

Randomisation:
A parallel group approach will be undertaken with participants assigned to routine care, or routine care plus avatar, and treated according to group assignment. A minimisation method for randomisation will be adopted to ensure balance between study arms with respect to key demographic variables (e.g. gender). A dynamic randomisation algorithm will allocate each person to a group once consent has been received. The allocation algorithm takes account of previous assignments to achieve balance.

Recruitment:
Potential participants will be identified by the clinical team on GP referral to the weight improvement programme (Mid Yorkshire Hospitals NHS Trust) and sent an information pack including invitation letter, information sheet, researcher permission to contact form and postage paid envelope. Names of potential participants will be documented by the NHS research administrator assigned to this project. The research nurse/researcher will confirm with the administrator on a weekly basis those patients who have returned the permission to contact forms.

One week after the information pack has been posted, the NHS research nurse assigned to this project will telephone those patients who have not responded to ensure receipt of pack, establish patient interest in participating in study, and obtain verbal consent for research nurse /researcher to make contact to discuss study at a time convenient to the patient.

The research nurse/researcher will telephone those patients interested in participating to describe the study further and assess willingness to participate. Patients who are willing to participate and meet the inclusion criteria will be sent a consent form to complete and return at their initial weight improvement service appointment. Reasons for ineligibility and number of patients declining participation, including reasons where possible, will be recorded.

A sub sample of purposively selected patients within the avatar intervention arm (based on age, gender and socio-economic status as defined by postcode of home address and comparison with the Office of National Statistics Multiple Indices of Deprivation) will be invited to take part in a focus group discussion to share their experiences of using the avatar programme. Up to 2 focus groups, each of 6-8 persons, will be held approximately 3-6 months post study commencement.

Data collection:
Baseline and follow-up data for patients who meet the inclusion criteria and consent to participate in the study will be collected as described within intervention and routine care sections above. All assessments will be distributed and co-ordinated by the research nurse. A private room within the clinical environment will be available for data collection purposes.

Post study evaluation:
Evaluation of study materials, data measures and data collection processes, including experiences of using and interacting with the avatar programme, will be sought through separate focus groups for patients and HCPs. The purpose of the focus groups is to inform the design of a full RCT if warranted.

Data analysis:
All quantitative data will be entered into a password protected database. To assess data quality, 2% of all data fields will be re-entered to check for errors/omissions. Where data errors /omissions exceed 5%, data will be re-inputted and re-checked for consistency. Data will be subjected to basic descriptive statistical tests including calculation of means, standard deviations and frequencies.

Digital audio recordings of focus groups will be transcribed verbatim and analysed using a framework analysis approach. This is a systematic matrix-based approach to collating, reviewing and understanding qualitative data. Analysis will focus on their experiences of using and interacting with the avatar programme. NVivo11 data analysis software will be used to assist with data coding, cross-referencing, storage and retrieval.

Intervention Type
Behavioural

Primary outcome(s)
Weight loss: body weight (kg) and calculated BMI (kg/m2) assessed at T0-T3 (0, 3 and 6 months). Between-arm variation in actual weight loss will be determined and tested in a full RCT if warranted.

Key secondary outcome(s))

1. Uptake and continuation rates: uptake (participation) will be evaluated by comparing actual recruitment with number of eligible people expressing interest in the study (timepoint: on invitation to participate in study). Reasons for declining participation will be ascertained where possible. Attendance at time intervals T0-T2 will be used as a proxy for continuation with the weight improvement programme. Details of study attrition will be recorded at times T0 – T2.
2. Quality of life and self-efficacy, assessed using IWQOL-lite, EQ-5D-5L and WEL-SF surveys. Between-arm variation may suggest quality of life and self-efficacy differentials to be tested in a full RCT. Assessment will take place at T0-T3
3. Access to online avatar programme: patient access to avatar programme (including regularity and activity within it) will be monitored as a background computer function of the avatar programme as a proxy for level of interest in avatar technology (T0-T3)
4. Adverse events: no risk to patients as a consequence of study participation is anticipated although stress/anxiety from visualising self as an avatar cannot be excluded. The researcher will seek patient self-reports of adverse events at each attendance and report these to the research team for action as appropriate (T0-T3). If concerns pertain to health and wellbeing, the medical team within the weight loss clinic will be informed and details of concern logged with project team and Trust R&D. Where concern relates to study process, the chief investigator and Trust R&D will be informed. With patient permission, their GP will be informed of their involvement in the study.
5. Refinement of avatar programme design based on focus group feedback from patients and HCPs. This information will inform design of intervention to be adopted in a full RCT if warranted (timepoint: following focus group)
6. Estimates of key aspects of trial including:
6.1. Number of eligible participants; recruitment, retention and attrition rates; satisfaction with data collection processes and timings
6.2. Sample size estimation based on primary outcome measure (weight loss/intervention effect size) and informed by secondary outcome measures
6.3. The utility of objective (independent interaction with avatar programme) and subjective (self-report) methods to assess weight loss motivation and engagement with weight improvement programme (timepoint: end of study evaluation)

Completion date
27/01/2020

Eligibility

Key inclusion criteria
1. Adults aged 18-65 years
2. White British or South Asian ethnicity
3. BMI >30
4. Referred from GP
5. No known co-morbidities that may influence dietary intake or weight loss achievement (e.g. type I diabetes; current medication with known weight gain side effect)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Pregnant women
2. Children; Elderly (> 65 years)
3. BMI > 45
4. Persons from other Ethnic groups - multi-ethnic inclusion will increase the complexity of the avatar programme design making it cost prohibitive within this feasibility study. Should outcomes support a full RCT, avatar design programme will be expanded to reflect variations in population ethnicity and demographics

Date of first enrolment
04/02/2018

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Mid Yorkshire Hospitals NHS Trust
Aberford Road
Wakefield
United Kingdom
WF1 4EE

Sponsor information

Organisation
Mid Yorkshire Hospitals NHS Trust

ROR
https://ror.org/05g23q746

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-1215-20016

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/10/2022	06/10/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes