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Personalised goals using mobile technology to reduce sedentary behaviour in people living with obesity

Submission date
18/10/2020

Recruitment status
No longer recruiting

Registration date
21/10/2020

Overall study status
Completed

Last Edited
22/10/2020

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
In Ireland, the frequency of people living with is nearly double that of the global average, standing at 23%. Obesity is one of Irelands biggest public health challenges to date. The primary and most dangerous hazards associated with obesity include increased cardiovascular disease (CVD) risk, increased mortality, increased multi-morbidities, decreased quality of life and increased risk of mental health issues. Sedentary behaviour is linked closely to the development /maintenance of obesity. Personalised goals have been found to be effective in increasing physical activity in a number of studies. The purpose of this study is to examine whether weekly personalized goals, review and feedback can significantly reduce sedentary behaviour, reduce BMI and improve psychological outcomes in people living with obesity.

Who can participate?
People who are enrolled on the CLANN programme run by the Croi Heart and Stroke Charity in University College Hospital, Galway.

What does the study involve?
Participants will either be assigned to a control or intervention group for the duration of the study. All participants will participate in the base CLANN programme. In addition, the intervention group will receive weekly personalized sedentary behaviour goals. All participants will be asked to fill in questionnaires at the first visit and will be followed up over a 10-week period after which the same measures will be applied for follow-up data.

What are the possible benefits and risks of participating?
It is expected that this programme will increase the quality of life and health of participants. The risk to the safety of engaging in increased physical exercise is expected to be minimal compared with the risks associated with day to day life. The intervention involves advice given by health professionals on diet and physical activity and will be appropriate for the participants' ability and integrated into their current lifestyle.

Where is the study run from?
The Croi Heart and Stroke Charity Building in Galway (Ireland)

When is the study starting and how long is it expected to run for?
From March 2017 to August 2017

Who is funding the study?
Investigator-initiated and funded

Who is the main contact?
Dr Jane Walsh
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CLANN2018

Study information

Scientific Title
Personalised goals using mobile technology to reduce sedentary behaviour in people living with obesity

Acronym
CLANN

Study objectives
To investigate whether weekly personalized goals, review, and feedback significantly reduce sedentary behaviour compared with standard advice/treatment in people living with obesity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 16/12/2016, the Galway University Hospitals Clinical Research Ethics Committee (Room 59, 1st Floor, HR Building, Merlin Park, Hospital, Galway, EC5, Ireland; +353 (0)91 757631; colette.collins@hse.ie), ref: C.A.1652
2. Approved 15/02/2017, the School Research Ethics Committee (SREC), National University of Ireland Galway

Study design
Single-centre interventional randomized controlled trial with a 2x2 mixed analysis of variance design

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Obesity, under consideration for bariatric surgery

Interventions
The study is employing a 2 groups (intervention and control) x 2 time-points (baseline, 10-week follow-up) mixed Analysis of Variance design to investigate the impact of a personalised goal-

setting versus standard care on primary and secondary health outcomes in a group of patients enrolled in the CLANN Programme (https://croi.ie/about/our-programmes-services/croi-clann/) designed to reduce weight in patients living with obesity.

Baseline measures for all variable are assessed after which participants are randomly assigned, using simple randomisation, to either intervention or control condition.

Standard Care (control group): Standard care group will attend the CLANN programme for 10 weeks. The CLANN programme is a lifestyle intervention, run by the cardiac foundation Croì, which patients are referred to by their bariatric consultant. The programme consists of eight 2.5 hour sessions whereby the attendees have a brief check-up with their nurse and complete an exercise class, and then receive an educational seminar. The seminars include healthy eating, food labels, benefits of physical activity, psychological issues of obesity and maintaining change. No sedentary behaviour goals are given as part of the programme. On the penultimate week of CLANN, the control group's sedentary behaviour and psychosocial variables will be measured again.

Intervention group: This group will participate in the same CLANN programme as the standard care group. However, they also receive weekly personalised goals to decrease their sedentary behaviour. These will be based on their baseline numbers. Sedentary behaviour is calculated as the amount of time spent sitting or lying, minus eight hours for sleep. Personalised goals are obtained by subtracting 10% from remaining sedentary time. Goals are increased/reduced incrementally by 10%. Participants in the personalised goals condition will wear the activPAL device again on week five to obtain goals based on updated objective data. Participants receive their weekly goals at the beginning of each CLANN session.

Intervention Type
Behavioural

Primary outcome(s)
1. Sedentary behaviour assessed using the activPAL device at baseline and 10 weeks. The activPALTM is an accelerometer providing measures on the sitting/lying time and the number of up/down transitions in the time period.

Key secondary outcome(s))
1. Body Mass Index (BMI) calculated from measurements of weight and height at baseline and 10 weeks
2. Distress was measured using the Kessler Psychological Distress Scale (K10) at baseline and 10 weeks
3. Anxiety measured using the Overall Anxiety Severity and Impairment Scale (OASIS) at baseline and 10 weeks
4. Self-efficacy was measured using the General Self-Efficacy (GSE) scale at baseline and 10 weeks

Completion date
30/08/2017

Eligibility

Key inclusion criteria

1. Age ≥18 years
2. Competent in the English language
3. Enrolled in the Croi CLANN Programme at University College Hospital Galway

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/03/2017

Date of final enrolment
15/06/2017

Locations

Countries of recruitment
Ireland

Study participating centre
Croi Heart and Stroke Charity
Croí House
Moyola Lane
Newcastle
Galway
Ireland
H91 FF68

Study participating centre
School of Psychology
NUI Galway
Galway

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H91 EV56

Sponsor information

Organisation
National University of Ireland, Galway

ROR
https://ror.org/03bea9k73

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as the research team at present do not have the mechanism to fully and confidently deidentify the large amount of data gathered. The data will be held on a secure virtual server at NUIG, and questionnaire data collected at baseline and follow-up will be stored in a secure locker in NUI Galway School of Psychology for 7 years in accordance with the data protection act.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes