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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

### 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

### Primary study design
Interventional

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

### 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
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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