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Snacktivity to promote physical activity WP4

Submission date 18/03/2024	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol
Registration date 22/03/2024	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 18/08/2025	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
There is strong evidence that being active and sitting less is important for health. Guidance states that adults should, over a week, complete at least 150 minutes of moderate to vigorous-intensity physical activity (30 minutes per/day) in periods of 10 minutes or more. However, few people manage this which puts their health at risk. This is concerning and new ways are needed to help people to be active daily. The reason why so few people are meeting the current physical activity guidance may be because they have to make big changes to their lifestyle, which can be too difficult. An alternative is an idea we have called Snacktivity. Rather than encouraging people to do 30 minutes of physical activity each day in one go, or in 10-minute periods, Snacktivity focuses on encouraging people to do small physical activity ‘snacks’, throughout the day so they achieve 150 minutes of activity per/week. The aim of this study is to evaluate the effectiveness and cost-effectiveness of the Snacktivity™ intervention in both NHS and non-NHS settings.

Who can participate?
Adults who are aged 18 years and over who do not complete 150 minutes or more of MVPA per week as per the national guidelines.

What does the study involve?
Participants will be randomly allocated to receive standard advice about physical activity (large changes) or encouragement to achieve their physical activity by Snacktivity (small changes). The researchers will promote Snacktivity in the intervention group by giving participants a physical activity monitor to help track their Snacktivity and overall physical activity, and access to an App called SnackApp that prompts people to participate in Snacktivity. The researchers will measure physical activity at the start of the study and after 3 and 12 months.
A physical activity ‘snack’ typically lasts between 2 to 5-mins. This could be walk-talk conversations, walking coffee breaks, using stairs rather than the lift, pacing whilst using the telephone, or parking the car a little further away and walking to a destination. An important benefit of Snacktivity over current physical activity guidance is that Snacktivity encourages breaking up sitting time throughout the day. Snacktivity may also help develop people’s confidence to try to become regularly physically active, and small changes are easier for people to initiate and then maintain, than large changes.

What are the possible benefits and risks of participating?
It is hoped that the intervention will encourage participants to be more physically active which may improve their health. The researchers do not expect any risks from taking part in this study.

Where is the study run from?
1. Loughborough University (UK)
2. University of Birmingham Clinical Trials Unit (UK)
3. University of Leicester (UK)

When is the study starting and how long is it expected to run for?
August 2018 to October 2026

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

Who is the main contact?
Prof. Amanda Daley, a.daley@lboro.ac.uk

Study website
https://www.snacktivity.co.uk/

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
336675

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 60376, IRAS 336675, BCHCTrustwide336675.P

Study information

Scientific Title
A multi-centre, open-label, two-arm, parallel group, individually randomised trial, with an internal pilot and economic evaluation, to test the superiority of Snacktivity compared with usual care

Study objectives
The aim of the study is to evaluate the effectiveness and cost-effectiveness of the Snacktivity™ intervention in both NHS and non-NHS settings.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/03/2024, London - Surrey Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)207 104 8088, +44 (0)207 104 8131; surrey.rec@hra.nhs.uk), ref: 24/LO/0186

Study design
Randomized; Interventional; Design type: Treatment, Physical

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Physical activity

Interventions
The trial is a multi-centre, randomized, open-label, two-arm, individually randomised, parallel-group, superiority trial with an internal pilot and economic evaluation. The trial aims to recruit 724 inactive adults who are aged 18 years and over. The internal pilot will last 6 months from the date the trial is opened to recruitment. Data collected during this phase will inform whether progression to completion of the trial should proceed.

The internal pilot aims to assess:
1. Recruitment: Aim to recruit ≥30% of the total sample size (≥218/724 participants) in 6 months (this equates to 36-37 participants per month);
2. Adherence to Snacktivity™: Defined as a participant achieving a minimum of four bouts of MVPA lasting ≥2 minutes (i.e., activity snacks) on average each day over 12 weeks as per the feasibility trial. This criterion will be based on those who would be expected to have reached 12 weeks follow-up after the trial has been open for 6 months, which we estimate to be approximately 100-120 participants (i.e. 50-60 participants in the Snacktivity intervention group).

A traffic light system has been designed that will determine progression.

Participants will be recruited from NHS Trusts/settings and non-NHS settings.

NHS Trusts/settings will search their databases using search protocols developed by the lead Clinical Research Network and invite participants based on eligibility at this pre-screening stage. Potential participants who are over the age of 18 years and have an NHS consultation booked during the recruitment phase of the trial will be invited to take part. The date of the consultation should be at least three weeks prior to the date of invitation to allow enough time for screening, consent and baseline data collection to be completed before the participant sees the HCP.

Alternatively, treating clinicians/HCPs can raise the topic of the Snacktivity trial in routine consultations and ask the patient if they would be interested in participating in the trial and offer the invitation pack (if the patient has an additional consultation booked at least three weeks away).
If an NHS Trust/setting routinely uses or wishes to use SMS text messages to send patients details of their scheduled appointments and/or to notify them about this trial, a trial invite link will be added to these text messages.

Potential participants can also be invited to take part in the trial via non-NHS settings including via social media platforms (including via NIHR Be Part of Research), third-sector organisations, public health organisations and others.

Potential participants identified via online platforms, social media, posters or text messages for example, will be invited to take part in the trial using an electronic trial link (or QR code). The link, when clicked, will direct the potential participant to an online survey, hosted on the studies REDCap database. Embedded within the survey will be a link to an electronic version of the participant information sheet (PIS), a summary PIS and a short video explaining the trial for potential participants to view before deciding if they would like to take part in the trial or not. If interested, the potential participant will then be directed to complete the expression of interest form, eligibility questions (inclusion and exclusion) and the Physical Activity Vital Sign (PAVS) questionnaire. Based on the answers provided, the survey will indicate to the participants if they are eligible or ineligible to join the trial. If eligible, and the potential participant is still willing to participate, they will be asked to complete the consent form online.

Potential participants identified via searches of NHS Trust/settings electronic patient records or during consultations for example can be sent trial invitation packs in the post. These can either be sent with their consultation appointment letter (or a reminder of their upcoming appointment) or independently.

The invitation packs will contain the trial invitation letter, PIS, screening form and a prepaid return envelope. The trial invitation letter will include the electronic trial link (as a web address, as described above in case the potential participant would like to complete the screening form online), otherwise they can complete the paper forms and post them back to the trial office. A QR code will also be added to the invitation letter, which once scanned, will direct the potential participant to view the electronic version of the main PIS, summary PIS and the short video explaining the trial. Paper forms received in the post will be entered into the REDCap database by the trial team. All participants who return a screening form will be contacted to confirm if they are eligible or ineligible to join the trial. Eligible participants will either be sent a link (via email or text message) to complete the consent form online or the trial team will call the participant and complete it online on their behalf over the telephone.

Once eligible participants complete the informed consent form, they will be asked to complete the baseline questionnaire, which includes uploading a picture of them standing on home weighing scales clearly showing their current weight. They will also be sent an accelerometer in the post to wear for 9 days.

Upon return of the accelerometer and confirmation that it contains valid activity data (minimum of 4 valid days) participants will be randomised to either:
1. The Snacktivity intervention, access to the SnackApp and an infographic detailing the current guidance for physical activity or
2. Usual care (an infographic detailing the current guidance for physical activity with no other support offered).

The Snacktivity intervention aims to promote the importance of regular physical activity through Snacktivity, the usefulness of Snacktivity, encouraging regular self-monitoring of Snacktivity to achieve sustained Snacktivity, goal setting for daily Snacktivity, as well as action planning and implementation strategies for Snacktivity.

There are two main components within the Snacktivity intervention: HCPs or researchers raising and encouraging Snacktivity with participants in their consultations/telephone calls, and the promotion of technology to support behaviour change and sustained engagement in Snacktivity (via the phone app: SnackApp and physical activity tracker device).

All those randomised to the usual care group will receive the current guidance for physical activity.

All participants will be followed up at 3 and 12 months and will be asked to complete a questionnaire (including sending a picture of their current weight) and wear an accelerometer for 9 days at each time point.

Where possible and with the consent of participants, the delivery of the usual care information and Snacktivity intervention will be audio-recorded to assess fidelity and intervention contamination (aim for around 25% of consultations to be audio-recorded).

Intervention Type
Behavioural

Primary outcome measure
Average weekly moderate to vigorous physical activity (MVPA) measured using the Axivity (AX3) device at 12 months

Secondary outcome measures
1. The proportion of participants meeting the guidance amount of 150 minutes of MVPA per week measured using the using the Axivity (AX3) device at baseline, 3 and 12 months
2. Average total minutes (sum of light, moderate and vigorous) of physical activity per day measured using the Axivity (AX3) device at baseline, 3 and 12 months
3. Average number of minutes of light, moderate and vigorous physical activity per day measured using the Axivity (AX3) device at baseline, 3 and 12 months
4. Average minutes of MVPA accumulated in bouts lasting ≥2, ≥5 and ≥ 10 minutes per day measured using the Axivity (AX3) device at baseline, 3 and 12 months
5. Average number of MVPA bouts lasting ≥2, ≥5 and ≥ 10 minutes per day measured using the Axivity (AX3) device at baseline, 3 and 12 months
6. Average magnitude of dynamic wrist acceleration per day (as a proxy for the total volume of activity) measured using the Axivity (AX3) device at baseline, 3 and 12 months
7. Average intensity gradient per day (no unit for this variable) measured using the Axivity (AX3) device at baseline, 3 and 12 months
8. Average minutes of sedentary time per day measured using the Axivity (AX3) device at baseline, 3 and 12 months
9. Average time (minutes) spent in prolonged sedentary behaviour per day measured using the Axivity (AX3) device at baseline, 3 and 12 months
10. Average number of prolonged sedentary bouts per day measured using the Axivity (AX3) device at baseline, 3 and 12 months
11. Average sleep duration (mins/day) and average efficiency (quality) (%/day) measured using the Axivity (AX3) device at baseline, 3 and 12 months

The researchers will also assess:
1. Weight (objective [or self-reported if the participant is unable to provide objective weight]) at baseline, 3 and 12 months
2. Depression/anxiety measured using the Hospital Anxiety and Depression Scale (HADS)) at baseline, 3 and 12 months
3. Quality of life measured using the EQ-5D-5L questionnaire at baseline, 3 and 12 months
4. Self-reported sedentary behaviours measured using the Workforce Sitting Questionnaire (WSQ) and International Physical Activity Questionnaire (IPAQ) (sitting question only) at baseline, 3 and 12 months

5. Self-efficacy for physical activity measured using the Self-Efficacy for Exercise Questionnaire at baseline, 3 and 12 months
6. Enjoyment of physical activity measured using the Physical Activity Enjoyment Scale (PACES) at baseline, 3 and 12 months
7. Habitual physical activity measured using the Self-Report Habit Index (intervention group only) at baseline, 3 and 12 months
8. Participation in Snacktivity™ measured using the Fitbit™ data (to assess intervention adherence) (intervention group only), data collected daily
9. Cost-effectiveness measured using the ICEpop CAPability measure for Adults (ICECAP-A) and a health care resource use questionnaire at baseline, 3 and 12 months

Overall study start date
01/08/2018

Completion date
30/10/2026

Eligibility

Key inclusion criteria
1. Completes <150 minutes per week of moderate to vigorous physical activity (MVPA) as assessed by the Physical Activity Vital Sign (PAVS) Questionnaire
2. Able to provide informed written consent
3. Aged >=18 years (all routes of recruitment)
4. Own a mobile phone capable of hosting apps (Apple iOS 13.0+ and Android 4.3+)
5. Agreement for their healthcare professional (HCP) to be notified of their involvement in the trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 900; UK Sample Size: 900

Key exclusion criteria
1. Unable to understand English sufficiently to complete the trial assessments
2. Women known to be pregnant or breastfeeding
3. Inpatient, bedbound or unable to complete physical activity

Date of first enrolment
27/05/2024

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Not provided at time of registration
United Kingdom
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Sponsor information

Organisation
Birmingham Community Healthcare NHS Trust

Sponsor details
Research and Innovation
First Floor
3, Priestley Wharf
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bchc.researchinnovation@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.bhamcommunity.nhs.uk/

ROR
https://ror.org/04r10g051

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0618-20008

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/03/2027

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