

# Snacktivity-C™ intervention to promote physical activity for young people during cancer treatment

<b>Submission date</b> 18/05/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/05/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/07/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Regular physical activity may help young people with cancer to manage treatment-related side effects such as fatigue, as well as improve their quality of life. However, evidence shows that young people with cancer spend small amounts of time participating in physical activity. When trying to be physically active, young people with cancer face multiple challenges such as fatigue, feeling unwell, and time and transport restrictions. Physical activity interventions that help participants to overcome such challenges are required. The Snacktivity-C™ intervention was developed specifically for young people with cancer using the Snacktivity™ approach. Snacktivity™ promotes the idea that completing small but frequent bouts of physical activity throughout the day, called physical activity 'snacks', can help people to accumulate more physical activity throughout their week. This study aims to assess the feasibility and acceptability of the Snacktivity-C™ intervention for young people undergoing cancer treatment.

### Who can participate?

Young people aged 13 to 24 years who are receiving treatment for cancer.

### What does the study involve?

Participants will be randomly allocated to either the intervention or comparator group for 8 weeks. The intervention group will receive the Snacktivity-C™ physical activity intervention where they will be encouraged to complete activity 'snacks' (lasting 2-5 minutes) regularly throughout their day. Activity 'snacks' include activities such as using stairs rather than the lift, keeping moving whilst the kettle boils, squatting during advert breaks when watching TV, or lunging whilst getting ready in the morning. Participants in the intervention group will receive a physical activity tracker, and access to an app called the Snacktivity-C™ SnackApp so that they can monitor their physical activity. The comparator group will receive written advice on physical activity during cancer treatment.

What are the possible benefits and risks of participating?

It is hoped that the Snacktivity-C™ intervention will encourage participants to be more physically active which may improve their health and well-being. The researchers do not expect any risks from taking part in this study.

Where is the study run from?

Loughborough University (UK)

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

August 2022 to July 2024

Who is funding the study?

National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?

Miss Ellie Langworthy, e.j.langworthy@lboro.ac.uk

## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

320158

**Protocol serial number**

CPMS 55590, IRAS 320158

## Study information

## **Scientific Title**

A randomised controlled trial to investigate the feasibility and acceptability of a Snacktivity-C™ physical activity intervention for young people during cancer treatment

## **Acronym**

ACTION

## **Study objectives**

The aim of the ACTION study is to undertake a randomised feasibility trial with nested qualitative interviews to assess the feasibility and acceptability of the Snacktivity-C™ intervention for young people during cancer treatment.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 24/04/2023, West Midlands – South Birmingham Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)207 104 8345; southbirmingham.rec@hra.nhs.uk), ref: 23/WM/0064

## **Study design**

Randomized; Interventional; Design type: Prevention, Psychological & Behavioural, Physical

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Cancer

## **Interventions**

Participants will be randomised to the intervention or comparator group using 2:1 randomisation. Randomisation will be completed by a staff member independent to the trial using an online software tool called sealed envelope. Participants will be randomised with stratification according to age category (13-17 years or 18-24 years). The staff member will inform the lead researcher of what group the participant has been assigned to.

Participants will be randomised to either the intervention (n = 26) or comparator (n = 13) group for 8 weeks. Participants in the intervention group will receive the Snacktivity-C™ intervention where they will be encouraged to complete short bouts of physical activity, called activity 'snacks'. They will also be provided with a physical activity tracker and access to a mobile app (Snacktivity-C™ SnackApp) to allow them to monitor their physical activity. Participants in the comparator group will receive written guidance about physical activity during cancer treatment. Physical activity, fatigue, and quality of life will all be measured at the start of the study and 8 weeks later for both the intervention and comparator groups.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

The feasibility and acceptability of the Snacktivity-C™ physical activity intervention according to pre-specified progression criteria for the following outcomes:

1. Proportion of participants who on average completed a minimum of 4 bouts of moderate to vigorous intensity physical activity (MVPA) lasting  $\geq 2$  min each day over 8 weeks, measured using a physical activity tracker
2. Proportion of participants who accumulated a total weekly average of at least 90 mins of total physical activity (all intensities), measured using a physical activity tracker
3. Proportion of participants who reported the intervention helped increase their physical activity behaviours, measured using a single-item questionnaire
4. Number of participants recruited in 6 months compared to target sample size

Timepoint(s): End of trial

## **Key secondary outcome(s)**

1. Total physical activity measured using a research-grade wrist-worn accelerometer at baseline and 8-week follow up
2. Moderate-vigorous physical activity measured using a research-grade wrist-worn accelerometer at baseline and 8-week follow up
3. Steps measured using a research-grade wrist-worn accelerometer at baseline and 8-week follow up
4. Total physical activity measured using the International Physical Activity Questionnaire (IPAQ) at baseline and 8-week follow up
5. Sedentary time measured using a research-grade wrist-worn accelerometer at baseline and 8-week follow up
6. Fatigue measured using the PedsQL Multidimensional Fatigue Scale at baseline and 8-week follow up
7. Quality of life measured using the PedsQL Cancer Module at baseline and 8-week follow up

Process outcomes:

1. Exercise self-efficacy measured using the Self-Efficacy for Exercise (SEE) scale at baseline and 8-week follow up
2. Outcome expectations measured using Outcome Expectations for Exercise Scale at baseline and 8-week follow up
3. Time spent on the SnackApp measured using app data during the intervention period (intervention group only)
4. Participant's experiences of the Snacktivity-C™ intervention, measured using semi-structured interviews post-follow-up (intervention group only)

## **Completion date**

31/07/2024

## **Eligibility**

### **Key inclusion criteria**

1. Between 13 and 24 years
2. Receiving at least one of the following treatments for cancer: chemotherapy, radiotherapy, immunotherapy, targeted drug therapy, hormonal therapy)
3. Able to speak and read standard English
4. Have a least one parent or guardian who can speak and read standard English
5. Able to provide informed written consent (and/or assent for those under 16 years)

6. Access to smartphone with Bluetooth capable of hosting mobile applications (Apple iOS 10.0+ and Android OS 4.0+)
7. Living in England, Scotland or Northern Ireland
8. Not already participating in physical activity or lifestyle behavioural change research

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

13 years

**Upper age limit**

24 years

**Sex**

All

**Total final enrolment**

31

**Key exclusion criteria**

1. Undergoing surgery only
2. Unable or unwilling to provide consent (and/or assent for those under 16 years)
3. Terminal cancer diagnosis
4. Cannot speak and read standard English
5. Do not have access to a smartphone with Bluetooth or the capability of hosting mobile applications (Apple iOS 10.0+ and Android OS 4.0+)
6. Living outside of England, Scotland or Northern Ireland
7. Already participating in physical activity or lifestyle behavioural change research

**Date of first enrolment**

19/06/2023

**Date of final enrolment**

31/05/2024

**Locations****Countries of recruitment**

United Kingdom

**Study participating centre**

Not provided at time of registration

United Kingdom

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## Sponsor information

### Organisation

Loughborough University

### ROR

<https://ror.org/04vg4w365>

## Funder(s)

### Funder type

Government

### Funder Name

NIHR Academy; Grant Codes: NIHR300026

## Results and Publications

### Individual participant data (IPD) sharing plan

The data generated during the current study will be added to the Loughborough University repository (<https://repository.lboro.ac.uk/>) after the findings are published.

### IPD sharing plan summary

Stored in publicly available repository

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			20/09/2023	No	No