ISRCTN12415556 https://doi.org/10.1186/ISRCTN12415556

A trial to investigate the impact of a Christmas-themed physical activity intervention during advent on participation in physical activity and sedentary behaviour: Active Advent

Submission date
29/09/2021

Recruitment status
No longer recruiting

Registration date
11/11/2021

Overall study status
Completed

Last Edited
20/12/2022

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Many people do not do enough aerobic-based physical activity and only 1% of the UK population do sufficient amounts of muscle-strengthening physical activity. Given the health benefits of participation in all types of physical activity, it is important to develop novel interventions to increase people's physical activity levels. The Christmas holiday period is a high-risk time for physical inactivity and an increased amount of time spent sitting. The aim of this study is to test an intervention that aims to increase physical activity in the public during the Christmas holiday period.

Who can participate?
Adults aged 18 years or over, who have access to emails, currently live in the UK and report participating in no more than 75 minutes per week of moderate-to-vigorous intensity physical activity.

What does the study involve?
Participants are randomly allocated to one of two groups. Those allocated to group one will receive one email each day between 1st and 24th of December that will include ideas for Christmas-themed physical activities. Those allocated to group two will receive written information about the importance of physical activity for health via email at the start of December.

What are the possible benefits and risks of participating?
Participating in regular physical activity may improve health and well-being. This study involves very little risk to participants. Wearing an accelerometer can cause mild skin irritation. To prevent this, participants will be encouraged to remove the accelerometer daily to clean the skin underneath the device, and to switch wrists if necessary.

Where is the study run from?
Loughborough University (UK)

When is the study starting and how long is it expected to run for?
June 2021 to January 2022

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

Who is the main contact?
Dr Gregory Biddle, g.j.biddle@lboro.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Gregory Biddle

ORCID ID
http://orcid.org/0000-0002-4394-0655

Contact details
Sir John Beckwith Building
Loughborough University
Loughborough
United Kingdom
LE11 3TU
+44 (0)1509 228483
g.j.biddle@lboro.ac.uk

Type(s)
Public

Contact name
Dr Gregory Biddle

Contact details
Sir John Beckwith Building
Loughborough University
Loughborough
United Kingdom
LE11 3TU
+44 (0)1509 228483
g.j.biddle@lboro.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
6057

Study information

Scientific Title
A pilot randomised controlled trial to investigate the effects of a Christmas-themed physical activity intervention during advent on participation in physical activity and sedentary behaviour: Active Advent

Acronym
Active Advent

Study objectives
The Active Advent intervention will increase self-reported moderate-to-vigorous physical activity more than the comparator group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/11/2021, Loughborough University Human Participants Sub-Committee (Hazlerigg Building, Research & Enterprise Office, Loughborough University, Loughborough, LE11 3TU, UK, +44 (0)1509 222423, LEON@lboro.ac.uk), ref: 6057

Study design
Pilot randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Inactive adults

Interventions
Unequal randomisation will be used to ensure a 2:1 ratio in favour of the intervention group. Randomisation will be done sequentially.

The intervention will consist of a daily physical activity idea over each of the 24 days of advent which will be sent to participants via email (or via SMS) each day. Each activity idea will be divided into three levels of difficulty, and from which participants can select: Easy Elf (low intensity), Moderate Mince Pie (moderate intensity and Strenuous Santa (vigorous intensity). Participants are free to change the difficulty of their activity each day. The duration of each Active Advent physical activity idea will vary and will be determined by the activity type and anticipated intensity (for example, a Strenuous Santa activity may be shorter than an Easy Elf activity due to the higher intensity).

Participants randomised to the comparator group will receive a healthy living leaflet. This will be sent once on or around 1st of December.

Intervention Type
Behavioural

Primary outcome measure
Moderate-to-vigorous intensity physical activity measured using the exercise vital signs questionnaire at baseline, week 1, week 2 and week 3 of the intervention period

Secondary outcome measures
1. Muscle-strengthening physical activity measured using the exercise vital signs questionnaire at baseline, week 1, week 2 and week 3 of the intervention period
2. Moderate-to-vigorous intensity physical activity measured with an accelerometer at baseline and towards the end of the intervention period
3. Total physical activity measured with an accelerometer at baseline and towards the end of the intervention period
4. Sedentary behaviour measured with an accelerometer at baseline and towards the end of the intervention period
5. Adherence to the intervention measured with an online survey at week 1, week 2 and week 3 and at the end of the intervention period
6. Enjoyment of the intervention measured with an online survey at week 1, week 2 and week 3 and at the end of the intervention period

Overall study start date
01/06/2021

Completion date
31/01/2022

Eligibility

Key inclusion criteria

1. Aged 18 years or over
2. Access to email
3. Currently living in the UK
4. Completing ≤75 minutes of moderatetovigorous physical activity (MVPA) per week

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
105

Total final enrolment
107

Key exclusion criteria
1. Unable to understand and communicate in English
2. Pre-existing condition that inhibits their ability to stand or be physically active

Date of first enrolment
01/11/2021

Date of final enrolment
30/11/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Loughborough University
The Centre for Lifestyle Medicine and Behaviour
School for Sport, Exercise and Health Science
National Centre for Sport and Exercise Medicine
Loughborough
United Kingdom
LE11 3TU

Sponsor information

Organisation
Loughborough University

Sponsor details
Research & Enterprise Office
Loughborough
England
United Kingdom
LE11 3TU
+44 (0)1509 222222
Researchpolicy@lboro.ac.uk

Sponsor type
University/education

Website
http://www.lboro.ac.uk/

ROR
https://ror.org/04vg4w365

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Once the study is completed, the researchers plan to publish the findings in a peer-reviewed journal. Participants will not be identified in any way in the study publications. The results may also be presented at scientific conferences and or meetings. A summary of the study findings will be posted on a Loughborough University website within 12 months after the end of the study.

Intention to publish date

01/12/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available. Anonymous data will be stored securely at Loughborough University for up to 10 years after the end of the study, at which time it will be deleted. Identifiable data will be deleted at the end of the study.

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	version 1.1		07/10/2021	No	Yes
Protocol file	version 1.1		07/10/2021	No	No
Results article		19/12/2022	20/12/2022	Yes	No