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

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2. Lay summary

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 increased amount of time sitting. Here, we outline a study to test an intervention that aims to increase physical activity in the public during the Christmas holiday period. 105 participants who are physically inactive will be randomised to a comparator group (receive a healthy living leaflet) or an physical activity intervention group, that will involve receiving daily emails for ~ 4 weeks between 1st and 24th December. These emails will contain a Christmas themed physical activity idea, encouragement to complete each activity and a behavioural tip to help participants do the activity. Each idea will have three variations (Easy Elf, Average Angel and Strenuous Santa), where participants can select the difficulty of the activity they wish to complete. Participation in physical activity will be measured in both groups at the start of the study for 7 consecutive days and weekly during the ~4-week Active Advent intervention. Participants in the intervention group will be asked some questions to understand their views about trying to increase their physical activity over Christmas using the intervention ideas.

3. Introduction

Physical activity is known to be a key factor in the prevention and management of disease and ill-health [1], as well as in reducing the risk of all-cause mortality [2]. It is currently estimated that 72.5% of the global population are sufficiently active [3]. National estimates collected in the Health Survey for England, 2016, suggest 66% of males and 58% of females achieved the then recommended level of moderate-to-vigorous physical activity based on self-reported data [4]. If estimates include self-reported participation in muscle strengthening activity as well as aerobic activity, estimates for those meeting the guidelines drop dramatically, falling to 31% for males and 23% for females [4]. The estimates are even lower when including participation in activities to improve balance [4]. These statistics highlight the importance now of developing and testing novel interventions to help the public become more physically activity to ensure good health.

In many countries the Christmas period, is a time characterised by public holidays, social occasions (parties and visiting family/friends), overconsumption of festive foods and drinks and an increase in sedentary behaviours, such as sitting and screen time. In addition, in many countries the Christmas holidays are also the winter period of the year and we know physical activity levels decrease and people are more sedentary during cold(er) weather periods of the year [5]. Evidence has also shown that the population gain weight over the Christmas holiday season [6,7], at an average of 0.4-0.9 kg [8], which physical inactivity may contribute towards. Here, we aim to utilise the festive season to increase physical activity by testing a bespoke Christmas themed Active Advent physical activity intervention.

4. Aims and objectives

Primary objective

Using a randomised controlled trial methodology, to investigate the effect of a Christmas themed Active Advent physical activity intervention on self-reported moderate-to-vigorous intensity physical activity.

Secondary objectives

To investigate the effect of a Christmas themed Active Advent physical activity intervention on self-reported muscle-strengthening physical activity.

To investigate the effect of a Christmas themed Active Advent physical activity intervention on accelerometer-assessed moderate-to-vigorous intensity physical activity.

To investigate the effect of a Christmas themed Active Advent physical activity intervention on accelerometer-assessed total physical activity.

To investigate the effect of a Christmas themed daily Active Advent physical activity intervention on accelerometer-assessed sedentary behaviour.

To investigate adherence to the intervention.

To explore the engagement and enjoyment of the Active Advent physical activity intervention.

5. Methodology

Study design

The study will adopt a randomised control trial design with 2:1 randomisation of participants to the intervention or comparator group. Baseline will take place prior to 1st December, when the intervention will start and continue until 24th December. The study timeline is outlined in Figure 1.

Recruitment

Participants will be recruited through several routes including workplaces, community groups and social media. Individuals will complete a short online expression of interest form to indicate their interest in taking part which will include questions to screen individuals for the study inclusion/exclusion criteria listed below. Those eligible will be contacted to take part and randomised thereafter.

Study population

Inclusion criteria

Aged 18 years or more.

Access to email

Currently living in the UK

Completing ≤ 75 minutes of MVPA per week (self-report using Exercise Vital Signs Questionnaire [9]).

Exclusion criteria

Unable to understand and communicate in English.

Pre-existing condition that inhibits ability to stand or be physical active.

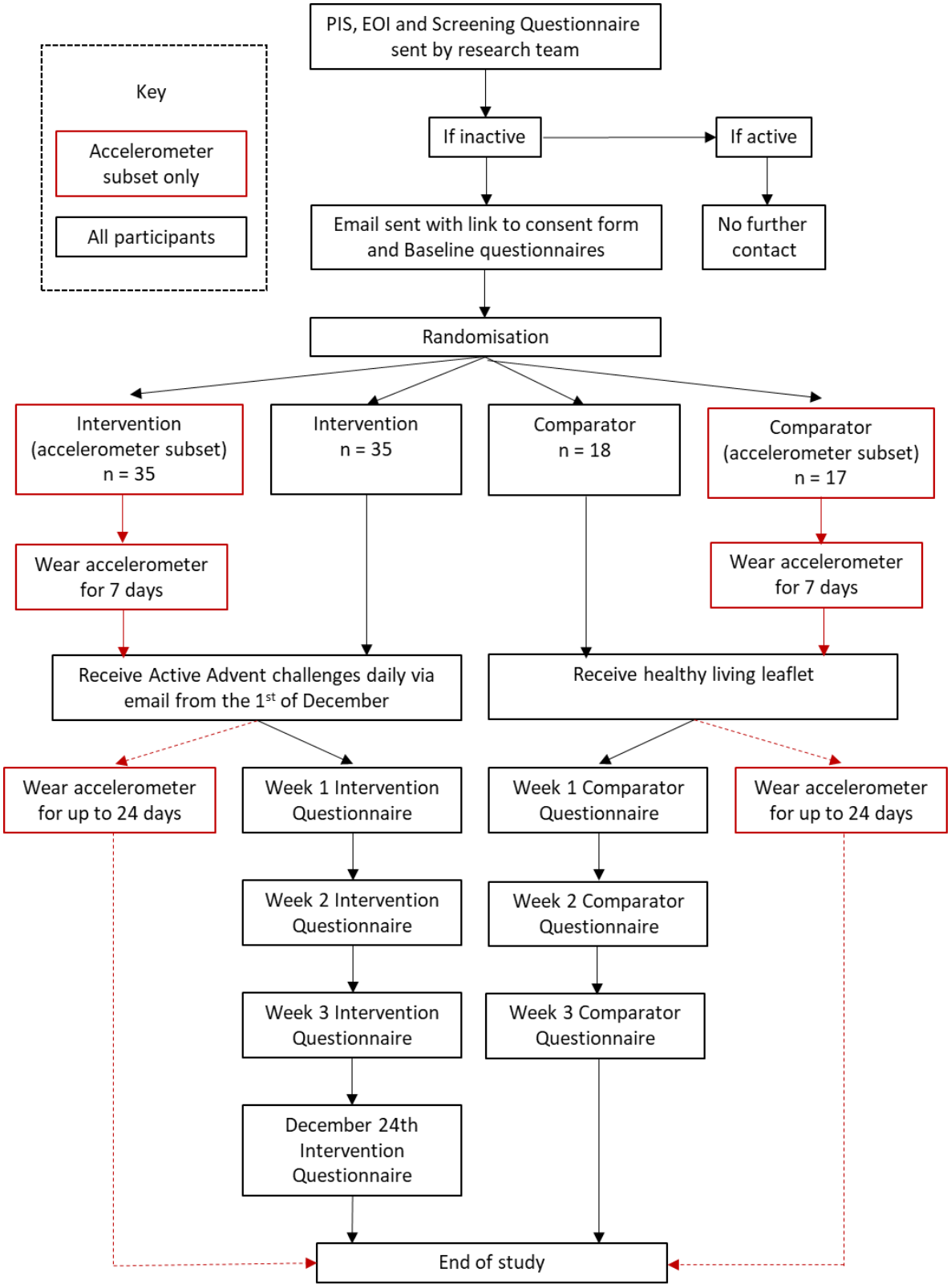

Figure 1. Participant flow diagram

Intervention

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). See Appendix 1 for some examples of the physical activity ideas.

Comparator

Participants randomised to the comparator group will receive a healthy living leaflet used in a previous Christmas based study [9]. This will be sent once on or around 1st of December.

Data collection

Baseline

Demographic data will be collected via an online survey at baseline. These data will include age, sex, ethnicity, home postcode, height, weight, education level, employment status and occupation type. We will also ask if any other individual in the household is participating in the study. Physical activity will be collected via self-report (a modified version of the physical activity vital signs questionnaire) in all participants. The exercise vital signs questionnaire is a three-item questionnaire that assesses individuals' participation in moderate-to-vigorous physical activity and muscle strengthening physical activity over a typical week. Device measured physical activity will be assessed in a 50% subset (both groups) using an accelerometer. Participants will complete a wear log alongside the accelerometer that identifies periods of time spent sleeping and time when the device has been removed. Accelerometers will either be sent in the post or delivered by a member of the study team (depending on the location of the participant).

During the intervention

All participants will report their physical activity each week using a modified version of the physical activity vital signs questionnaire (see Appendix 2) accessed via a Qualtrics online survey link at the end of each week during the intervention period. The Qualtrics online survey link for the intervention group will include some additional questions about their adherence to/enjoyment of the activity ideas. In addition, the 50% subset in both groups will be asked to wear an accelerometer again, this time for up to 24 days towards the end of the intervention period.

For the intervention group (only), data on engagement, enjoyment and adherence of the Active Advent intervention will also be collected weekly throughout the intervention period using Qualtrics online survey links (see Appendix 3 for these questions). This link will be included in the emails sent to the intervention group at the end of each week where their physical activity is collected (see above).

Sample Size

Using a 2:1 randomisation we aim to recruit at least 105 participants, 70 allocated to the intervention group 35 the comparator groups respectively. We expect 20% loss to follow up resulting in data from 56 and 28 participants in each arm respectively. Participants from the same household will be randomised to the same group.

Analysis plan

Analyses will be performed after the last participant has completed the follow-up data collection. The flow of participants will be illustrated in a flow diagram according to the Consolidation Standard of Reporting Trials (CONSORT). Differences in demographics and physical activity at baseline between participants who were lost to follow-up and those who completed the study will be assessed.

The primary analysis will be performed using an intention-to-treat protocol. Differences between group (intervention and comparator) in self-reported moderate-to-vigorous intensity physical activity during the intervention (adjusting for baseline) will be assessed. The secondary outcomes will be assessed in a similar way to that described for the primary outcome.

The process data (adherence and enjoyment of the intervention will be presented as summarised data.

6. Data management

All data collected will be anonymised and stored on the Loughborough University secure encrypted server (OneDrive). The study data file will be password protected. Only researchers directly involved in the study will have access to this study data. All study data will be stored for 10 years and thereafter it will be deleted. The research data may be shared with external investigators and will be disseminated at academic conferences and in academic journals. No identifiable participant information will be disclosed. Loughborough University are the data controllers.

7. Ethical considerations and informed consent

All data will be handled in accordance with the latest data protection legislation and anonymised for the purposes of data analysis and reporting. No sensitive data will be collected as part of the study. All participants who agree to take part will be required to provided informed consent and will be informed of their right to withdraw from the study at any time.

Potential risks

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. Other risks associated with other study related activities are in line with normal everyday risk.

Potential benefits

All participants will receive a £10 high street voucher for completing follow up. Other benefits may include improvements in health and wellbeing due to increased levels of physical activity.

8. Dissemination

Once the study is completed, we 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.

9. COVID-19 Adjustments

Due to the ever-evolving situation regarding the COIVD-19 pandemic, adjustments may be made to the study if required. These changes will not impact the scientific integrity or the regulatory requirements of the study.

10. References

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Appendix 1: Examples of Active Advent Activities

Each activity will have three different intensity levels; Easy Elf (light), Moderate Mrs Claus (Moderate), Strenuous Santa (Vigorous).

- Christmas 'postman' – walk around your neighbourhood… you can deliver your Christmas cards!
- 'Star' jumps
- Christmas 'jumper'
- Deck the halls – yoga poses mimicking putting up decorations.
- Walking through the snow – lunges mimicking wading through snow.
- Rocking around the Christmas tree – go to your local woods and walk jog or run around.
- 'Dasher' the reindeer – sprints outside or on the spot.
- Ho ho hopping
- Christmas eve stair climbing – up and down mimicking going to bed ready for Christmas day.
- 12 days of Christmas – 12 exercise circuit
- 10 lords are leaping – skipping
- 6 geese are laying - squats

Appendix 2 – a modified version of the Exercise Vital Signs Questionnaire

How many days last week did you engage in moderate-to-vigorous physical activity (like a brisk walk)?

_____ days

On average, how many minutes do you engage in physical activity at this level?

_____ minutes

How many days a week do you perform muscle strengthening exercise, such as bodyweight exercises or resistance training?

_____ days

Appendix 3 – questions on adherence to the intervention and enjoyment of the intervention

The following is an example of the questions that will be sent. The dates will change depending on the week in which the questions are sent.

On which of the following days did you complete the Active Advent physical activity challenge?

1st of December

2nd of December

3rd of December

4th of December

5th of December

6th of December

7th of December

If you did complete the challenge on the following days, which difficult level did you choose?

	Easy Elf	Moderate Mice Pie	Strenuous Santa
1st of December			
2nd of December			
3rd of December			
4th of December			
5th of December			
6th of December			
7th of December			

Please rate your enjoyment of the activities you have completed over the past week

Disliked a lot

Disliked somewhat

Neither liked nor disliked

Liked somewhat

Liked a lot