A Christmas themed physical activity intervention to increase participation in physical activity during Advent: pilot randomised controlled trial

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ABSTRACT

OBJECTIVES

To examine the recruitment, retention, and preliminary effects of a Christmas themed physical activity intervention designed to increase participation in physical activity and decrease sedentary behaviour in inactive adults.

DESIGN

Pilot randomised controlled trial.

SETTING

Recruitment from social medial platforms, workplaces, and community groups in the UK.

PARTICIPANTS

107 inactive adults (who did not meet the UK guidelines for physical activity) aged 18-75 years.

INTERVENTIONS

The intervention consisted of an email sent to participants each day of Advent (1-24 December 2021), which contained a Christmas themed physical activity idea to be completed that day. Each physical activity idea was presented in three intensity formats, including Easy Elf (light intensity), Moderate Mrs Claus (moderate intensity), and Strenuous Santa (vigorous intensity). The comparator group received a leaflet about healthy living on the 1 December.

MAIN OUTCOME MEASURES

Participants were randomly assigned (2:1) to either the intervention or control and were masked to group allocation before randomisation. Primary outcomes were recruitment rate, retention, and weekly minutes of participation in self-reported moderate-to-vigorous intensity physical activity by use of the exercise vital signs questionnaire. Primary analysis compared change in minutes of moderate-to-vigorous intensity physical activity from baseline to weeks one, two, and three during the Active Advent intervention. Secondary outcomes were participation in muscle strengthening based physical activity (days per week), accelerometer measured moderate-to-vigorous intensity physical activity, light intensity physical activity, total physical activity, and sedentary time (minutes per day), and enjoyment of and adherence to the intervention.

RESULTS

323 individuals expressed interest in participating in the trial and 107 were randomly assigned to the intervention (n=71) or the comparator (n=36) group. The recruitment target (n=105) was reached within 19 days of starting recruitment. 23 (21%) of 107 participants were lost to follow-up. On average, the groups reported participation in similar minutes of moderate-to-vigorous intensity physical activity in weeks one and two. At week three, the adjusted mean difference between groups was 20.6 minutes of participation in moderate-to-vigorous intensity physical activity per week (95% confidence interval −29.7 to 70.9) in favour of the intervention group. Accelerometer data showed that the intervention group spent fewer minutes sedentary per day than comparators (mean difference −58.6 (−113.5 to −3.8)). Overall, 42 (70%) of 60 participants in the intervention group reported that they liked the intervention and 41 (69%) of 59 reported that they completed the Active Advent intervention ideas each day.

CONCLUSIONS

The public were interested to participate in a Christmas themed physical activity intervention during Advent, which might increase physical activity and reduce time sedentary. Enjoyment of, and adherence to the intervention shows the potential benefit that Christmas themed physical activity campaigns/initiatives might have for improving public health.

TRIAL REGISTRATION

ISRCTN12415556.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Participation in physical activity is an important behaviour in the management and prevention of non-communicable diseases; yet, large proportions of the population do not meet current physical activity guidelines

Despite multiple iterations of national and international guidelines, physical activity levels remain low in many countries, highlighting the need for innovative interventions

The Christmas period is known to be a time where the public are less physically active and more sedentary, which might contribute to weight gain during this period

WHAT THIS STUDY ADDS

The public are interested to engage in a Christmas themed physical activity intervention during Advent

A Christmas themed physical activity intervention during Advent showed promise for increasing physical activity and reducing sedentary time among inactive adults

The Active Advent intervention was enjoyed by participants, showing that the public would welcome public health campaigns to help them to be more physically active and less sedentary at Christmas

Introduction

Physical activity is known to be a key factor in the prevention and management of non-communicable diseases[1 2] and in reducing the risk of all-cause

mortality.[3] Based on self-reported data, about 60% of adults meet the recommended level of participation in moderate-to-vigorous physical activity; however, these estimates reduce greatly to around 25% when participation in muscle strengthening activity is included.[4] Despite multiple iterations of national and international guidelines for physical activity, activity levels have remained low. These statistics highlight the importance of testing innovative interventions that can be delivered at scale to help the public to become more physically active and to ensure optimal health.

Recognising the context in which health interventions are implemented is likely to affect their success. The Christmas period is a time characterised by public holidays, social occasions, overconsumption of festive foods and drinks, along with a decrease in physical activity and an increase in sedentary behaviours, such as sitting and screen time.[5] In many countries, the Christmas holidays are also the winter period of the year and we know that physical activity decreases and people are more sedentary during colder weather.[6] Physical inactivity also contributes to weight gain and evidence has shown that the population gain around 0.4-0.9 kg of weight over the Christmas holiday season.[7-9] The Christmas holidays are a high risk period for physical inactivity and weight gain, therefore, we aimed to test the recruitment, retention, and preliminary effects of a Christmas themed physical activity intervention during Advent designed to increase participation in physical activity and decrease sedentary time in adults.

Methods

Trial design

The study was a pilot randomised controlled trial with a 2:1 randomisation favouring the intervention group. Recruitment and baseline data collection took place between 11 and 30 November 2021. The last assessment of follow-up data took place on 18 January 2022. This study is reported according to the CONSORT statement for pilot randomised controlled trials and was preregistered at the ISRCTN registry.

Participants and randomisation

Participants were recruited through social media (Twitter, Facebook, and Instagram), a range of workplaces (eg, Loughborough University and local councils), and local community groups (eg, sports, leisure, and hobby groups). Individuals interested in taking part completed a short online expression of interest form, which included questions to screen for the study inclusion and exclusion criteria. Participants were eligible if they were aged 18-75 years, had access to email, lived in the UK, self-reported completing less than 150 minutes of moderate-to-vigorous intensity physical activity per week, and were considered physically able to participate (determined by the American College of Sports Medicine exercise preparticipation health screening questionnaire for exercise professionals[10]). All participants provided written informed consent before completing the baseline measures and thereafter were randomly assigned a group.

A 2:1 randomisation ratio was adopted so that the Active Advent intervention could be experienced and evaluated by more participants in the time available to conduct the study. The random allocation sequence was generated by an independent member of the research team who had no other involvement in the study. We randomly assigned participants using a computer-generated list, which was concealed from the other members of the research team. Participants were randomised to the Active Advent intervention or the comparator group. Participants were masked to the specific details of each of the trial groups before randomisation. The study groups were only referred to as physical activity groups one and two, with brief descriptions of each to ensure participants did not know which group was the intervention or comparator.

Intervention and control

The intervention group received the Active Advent intervention between the 1 and 24 December 2021 (three weeks and three days). Participants received an email each day that contained a Christmas themed physical activity idea to be completed that day. Each physical activity idea was divided into three levels of physical activity intensity, and participants selected which level was most suitable for them: Easy Elf (light intensity), Moderate Mrs Claus (moderate intensity), or Strenuous Santa (vigorous intensity). Participants were free to choose the intensity level of their physical activity each day as they wished. The duration of each physical activity idea varied and was determined by the activity type and intensity. For example, a Strenuous Santa physical activity idea might have been shorter in duration than the Easy Elf activity on a given day because the activity might have required participants to be physically active at a higher intensity (fig 1). Supplementary file S1 provides an overview of each Active Advent activity, as well as two examples of the intervention emails received by participants in the intervention group. The intervention was developed in line with the COM-B model, with a particular emphasis on increasing competence, opportunity, and motivation to be physically active.[11] Each activity was designed by the research team, who made pragmatic decisions in determining the intensity of the activities based on previous work[12] and their expertise. Each activity was accompanied with a detailed description of how to complete it correctly and safely (supplementary file S1). For safety and competency, some of the more complex activities were accompanied with a brief video showing how to complete them (supplementary file S2).

The comparator group received a healthy living leaflet based on public health guidance after randomisation on 1 December (supplementary file S3).

Outcomes

The primary outcomes of interest were the recruitment rate, percentage lost to follow-up, and minutes of

Fig 1 | Intervention content summary: the Active Advent calendar

participation in self-reported moderate-to-vigorous intensity physical activity per week measured using the exercise vital signs questionnaire.[13] The exercise vital signs questionnaire has been shown to be a valid tool for assessing physical activity when compared with accelerometery.[13]

As a secondary outcome, participants reported how many days they performed muscle-strengthening exercises per week, also assessed using the exercise vital signs questionnaire. Additional secondary outcomes were measured via accelerometer and averaged (mean) per day across all valid days during the intervention period: sedentary time, light intensity physical activity, moderate-to-vigorous intensity physical activity and total physical activity.[14] Additional process outcomes asked participants in the intervention group to rate their enjoyment of the activity ideas and to report their adherence to the intervention by recounting which activity at which intensity they completed each day (Easy Elf, Moderate Mrs Claus, or Strenuous Santa) on a weekly basis (week one, week two, and week three) and for the 22-24 December. Adverse events were not formally collected. We had no reason to expect that this trial would lead to an excess of adverse events as the promotion of physical activity is already part of standard care and has been shown to be low risk, as per the NHS guidelines.[15] However, participants were asked to report any issues when completing the Active Advent intervention to the research team.

Assessment of outcomes

Primary and secondary outcomes were assessed at baseline and at weeks one, two, and three during the intervention period. We collected all outcomes (except the accelerometer measured physical behaviours) using an online questionnaire hosted on Qualtrics, a specialist online survey software. The questionnaire asked participants in the intervention group to state which activity ideas they had completed in the previous week and at which intensity (Easy Elf, Moderate Mrs Claus, or Strenuous Santa). For the last three days of the intervention (22, 23, and 24 December) the intervention group received the same

Table 1 | Baseline characteristics. Data are number of participants (%), unless otherwise specified

Characteristic	Intervention (n=71)	Comparator (n=36)	Total (n=107)
Age (years):			
Mean (SD)	45.7 (12.2)	47.5 (14.3)	46.9 (12.9)
IQR	34.0-55.5	34.5-59.5	34.0-57.3
Range	19-73	25-75	19-75
Missing	6 (8)	0	6 (6)
Gender:			
Male	10 (15)	2 (6)	12 (12)
Female	55 (85)	34 (94)	89 (88)
Missing	6 (8)	0	6 (6)
Employed:	56 (86)	32 (89)	88 (87)
Full time employment	32 (45)	20 (56)	52 (49)
Part time employment	16 (23)	10 (28)	26 (24)
Self employed	5 (7)	1 (3)	6 (6)
Unemployed	2 (3)	0	2 (2)
Full time parent/homemaker	3 (4	0	3 (3)
Retired	4 (6)	4 (11)	8 (8)
Student/pupil	0	1 (3)	1 (1)
Missing	6 (8)	0	6 (6)
Ethnicity:			
White	55 (85)	34 (94)	89 (88)
Ethnicity other than white	10 (15)	2 (6)	12 (12)
Missing	6 (8)	0	6 (6)
IMD level:			
1 (least deprived)	2 (3)	2 (6)	4 (4)
2	4 (6)	1 (3)	5 (5)
3	16 (24)	3 (9)	19 (19)
4	11 (17)	9 (27)	20 (20)
5 (most deprived)	33 (50)	18 (55)	51 (52)
Missing	5 (7)	3 (8)	8 (7)
Body mass index:			
<18	1 (2)	0 (0)	1 (1)
18-24.9	29 (46)	14 (39)	43 (43)
25-29.9	17 (27)	10 (28)	27 (27)
≥30	16 (25)	12 (33)	28 (28)
Missing	8 (11)	0	8 (7)
Moderate-to-vigorous intensity physical activity (min/week):	75.6 (43.7)	81.8 (40.7)	77.7 (42.7)
Missing	0	0	0
Muscle strengthening activity (days):	0.38 (0.74)	0.39 (0.69)	0.38 (0.72)
Missing	0	0	0

IMD=Index of Multiple Deprivation by fifths; SD=standard deviation; IQR=interquartile range.

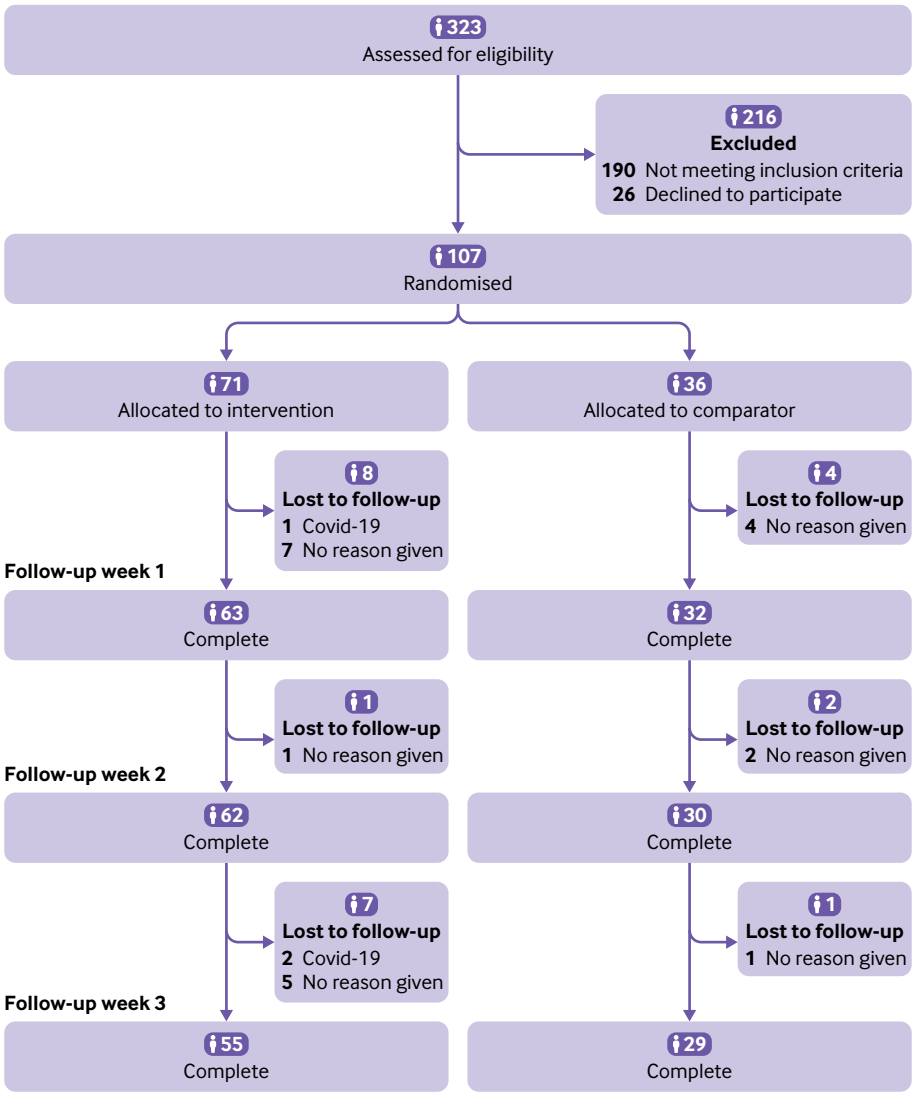

Fig 2 | CONSORT flow diagram

questionnaire asking only in relation to these three days.

About half of participants in both groups (37 in the intervention and 20 in the comparator group) were asked to wear an accelerometer on their non-dominant wrist 24 hours a day for the duration of the study (ie, 24 days of Advent). Participants wore the ActiGraph Link GT9X device (AG; ActiGraph, Pensacola,FL, USA). AG were initialised to record data at a sampling frequency of 30 Hz using ActiLife software (version 6.13.4, full edition, ActiGraph, FL, USA). Thirty Hertz was used to maximise the battery life of the AG to ensure as much as possible of the intervention period was monitored. All AG devices were initialised, data were downloaded using ActiLife, and processed and analysed identically with R package GGIR version 2.6.0.[16] Participants were excluded if their accelerometer files showed: after calibration error greater than 0.01 g (10 mg), fewer than three days of valid wear (defined as >16 h per day),[17] or wear data were not available for each 15 minute period of the 24 h cycle.[18]

Sample size

We aimed to recruit at least 105 participants; 70 allocated to the intervention group, 35 the comparator groups. Based on previous research, we expected a 20% loss to follow-up in each group.[19] This randomised controlled trial was a pilot so no formal sample size calculation was conducted, however, previous evidence has recommended sample sizes of between 24 and 70 participants for such a study design.[20 21]

Statistical analysis

All analyses were conducted using IBM SPSS Statistic 27. Participants' characteristics were recorded by means (standard deviation) or frequencies (%). Repeated measures linear mixed models were used to compare moderate-to-vigorous intensity physical activity and muscle strengthening activity between the groups at one, two, and three weeks follow-up. We considered the group, alone and in combination with time, as fixed effects, with baseline measurement as a covariate, time (one, two, and three weeks) as a

Table 2 | Self-reported moderate-to-vigorous intensity physical activity and muscle strengthening activity over the intervention period

Outcome and group	Baseline (mean (SD))	Week one		Week two		Week three	
		Mean (SD)	Adjusted* mean difference between groups (95% CI)	Mean (SD)	Adjusted* mean difference between groups (95% CI)	Mean (SD)	Adjusted* mean difference between groups (95% CI)
Moderate-to-vigorous intensity physical activity (min/week)							
Intervention	75.6 (43.7)	105.9 (100.3)	−12.8 (−60.9 to 35.4)	123.2 (108.7)	−2.0 (−51.2 to 47.1)	130.4 (159.3)	20.6 (−29.7 to 70.9)
No of participants	71	63	—	62	—	55	—
Comparator	81.8 (40.7)	125.0 (130.3)	—	136.3 (118.1)	—	120.7 (107.6)	—
No of participants	36	32	—	30	—	29	—
Muscle strengthening activity (days)							
Intervention	0.38 (0.7)	1.2 (1.8)	0.54 (−0.2 to 1.2)	1.2 (2.0)	0.60 (−0.1 to 1.3)	1.2 (2.0)	0.60 (−0.1 to 1.3)
No of participants	71	63	—	62	—	55	—
Comparator	0.39 (0.7)	0.59 (1.1)	—	0.57 (1.0)	—	0.55 (0.9)	—
No of participants	36	32	—	30	—	29	—

CI=confidence interval; SD=standard deviation.
*Adjusted for baseline.

repeated factor, and participants as a random factor. The study was not powered to detect differences between the groups; therefore, our focus was on the confidence intervals calculated from the models and not P values. Accelerometer measured physical activity behaviour data were analysed by use of a generalised estimating equation model with an independent correlation structure. Data related to the enjoyment of the intervention and adherence to the Active Advent intervention were summarised using descriptive measures by mean (standard deviation) and frequency (%). These measures were calculated per day for adherence and per week for enjoyment, as well as mean scores across the 24 day intervention period.

Patient and public involvement

Discussions with members of the public inspired this study, however, no direct work with patient and public groups was involved in this study due to limited resources.

Results

We randomly assigned 107 inactive adults to the intervention group (n=71) or to the comparator group (n=36) and most were women (89 (88%) of 107 participants), of white ethnicity (89 (88%) of 107 participants), and employed (88 (87%) of 107 participants) (table 1). Most participants were in full time employment (53%). The mean age of participants was 46 years (standard deviation 12.9), and 56% were overweight or living with obesity. Figure 2 illustrates the flow of participants through the study. No safety concerns were reported by participants throughout the intervention period.

Recruitment and retention

A total of 323 individuals expressed interest in participating in the study during the recruitment period. The recruitment target was reached within 19 days of starting recruitment. A mean of 6 participants consented per day. Data were missing for 23 (21%) of 107 participants for self-reported moderate-to-vigorous intensity physical activity at week three (end of intervention phase). Characteristics of those who did and did not complete follow-up were similar (supplementary table 1). Of these 23 participants, 16 were from the intervention group and seven were from the comparator group. Only three participants, all of whom were in the intervention group, stated the reasons for their withdrawal, which was due to contracting covid-19.

Self-reported physical activity

On average, the intervention and comparator groups reported similar minutes of participation in moderate-to-vigorous intensity physical activity in week one and two. At week three, the adjusted mean difference between groups was 20.6 minutes of participation in moderate-to-vigorous intensity physical activity per week (95% confidence interval −29.7 to 70.9) and

Table 3 | Accelerometer measured sedentary time, light intensity physical activity, moderate-to-vigorous intensity physical activity and total physical activity between trial groups. All data reported as mean (95% confidence intervals)

Outcome	Intervention (n=28)	Comparator (n=16)	Mean difference
Sedentary time (min/day)	676.5 (638.9 to 714.2)	735.2 (695.3 to 775.1)	−58.6 (−113.5 to −3.8)
Light intensity physical activity (min/day)	224.1 (200.3 to 248.0)	202.0 (175.5 to 228.4)	22.2 (−13.5 to 57.8)
Moderate-to-vigorous intensity physical activity (min/day)	70.1 (54.9 to 85.3)	55.6 (44.5 to 66.7)	14.5 (−4.3 to 33.3)
Total physical activity (min/day)	294.2 (262.1 to 326.4)	257.6 (222.0 to 293.1)	36.7 (−11.3 to 84.6)
Waking wear time (min/day)	970.7 (943.2 to 998.3)	992.7 (968.9 to 1016.6)	−22.0 (−58.5 to 14.5)

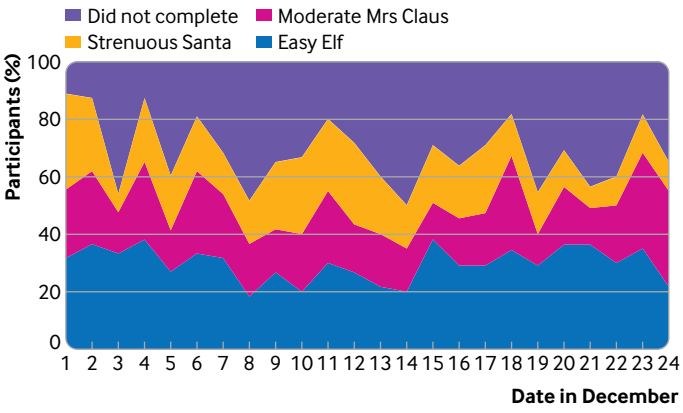

Fig 3 | Adherence to the intervention

0.6 days per week (−0.1 to 1.3) of participation in muscle-strength based physical activity in favour of the intervention group (table 2).

Accelerometer measured physical activity

Accelerometer data showed that the intervention group participated in similar, although marginally more, minutes per day of moderate-to-vigorous intensity physical activity, light intensity physical activity, and total physical activity (all intensities of physical activity combined), than did participants in the comparator group over the intervention period (table 3). On average, people in the intervention group spent fewer minutes sedentary per day during the intervention than did people in the comparator group.

Adherence to the intervention

On average, 41 (69%) of the 59 participants in the intervention group reported that they completed the Active Advent activities each day. Of these, 18 (30%) completed Easy Elf, 12 (21%) completed Moderate Mrs Claus, and 11 (18%) completed Strenuous Santa. Figure 3 shows daily adherence to the intervention where adherence remained constant throughout.

Enjoyment of the intervention

In total, 42 (70%) of 60 participants reported that they liked or enjoyed the intervention "somewhat" or "a lot." Only three (5%) of 60 participants disliked the intervention. Enjoyment of the Christmas themed physical activity ideas was consistent throughout the intervention period, ranging from 45 (72%) of 63 participants (like somewhat/a lot) in week one, to 44 (73%) of 60 in week two, and 37 (67%) of 55 in week three (fig 4).

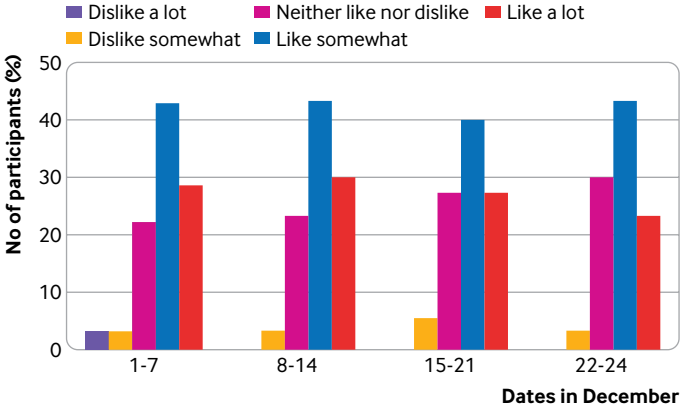

Fig 4 | Enjoyment of the intervention by week in December

Discussion

Principal findings

Recruitment to the trial was successful, achieving the stated target within three weeks. Although recruitment met the predefined target, more women than men were recruited, which is typical for lifestyle behavioural trials.[22] Retention was successful, with only 21% of participants not completing follow-up. This figure is consistent with other lifestyle and behavioural trials, which typically account for retention levels above 80%.[19 23 24] However, considering data were being collected during the Christmas period, at a time when the public are busier than usual, participant retention of 79% was encouraging. Nonetheless, future trials should consider additional methods to reduce loss to follow-up. These data highlight that the public are interested in taking part in Christmas themed physical activity events.

On average, the groups reported similar minutes of participation in moderate-to-vigorous intensity physical activity during weeks one and two, although by week three, the intervention group reported participating in more minutes per week (about 21 minutes) than the comparator group. When accelerometer measured, on average, the intervention group participated in 15 minutes more moderate-to-vigorous intensity physical activity per day than comparators (over the three-week intervention period), marginally less than when assessed by self-report at week three. Although the accelerometery findings indicated that the intervention group participated in only about 15 minutes more of moderate-to-vigorous intensity physical activity than comparators, it is important to highlight that this measurement is only an indication of the difference between groups and is not a statement of efficacy of the intervention. If a future trial were able to replicate this difference, the results would represent an important finding because even small increases in moderate-to-vigorous intensity physical activity are important for reducing all cause mortality.[25] Furthermore, a small increase of only 14 minutes per week of moderate-to-vigorous intensity physical activity (about 2 minutes per day) has been shown to reduce all cause mortality by 11%.[26] The intervention group also reported completing muscle strengthening physical activity more times per week than comparators at the three week follow-up. Furthermore, the intervention group spent less time (about 59 minutes per day) sedentary than did the comparator group (based on accelerometer data). The association of sedentary time and all cause mortality has been shown to be non-linear, however, the magnitude of this difference (about 1 hour)has also

been associated with a lower risk of all cause mortality (reduction in hazard ratio of 0.5).[26] Nonetheless, both groups levels of sedentary time during the intervention period have been associated with an increased risk of all cause mortality,[26] showing the need for further reductions. Overall, the intervention group adhered well to the Active Advent intervention with around two thirds of participants completing the daily physical activity challenges. Enjoyment of the intervention was high throughout the intervention. These results highlight that public health interventions, such as Active Advent, can be useful in nudging the public to be physically active, at a time when they need support the most.[5] Although adherence and enjoyment were high, future studies might consider how to improve these further, paying particular attention to specific physical activities and how these activities can be made more attractive or achievable.

Strengths and limitations

This study has several methodological strengths. The intervention was novel and designed to be easily scaled up, and evidence suggests that the intervention might have the potential to change health behaviours. We recruited adults from various socioeconomic backgrounds who were not achieving a sufficient amount of physical activity. Therefore, the Active Advent physical activity ideas were created to be inclusive and tailored by offering three intensity levels so that the activities could be accessible to a wide range of the population. Adherence to the intervention was good with 69% of participants completing the physical activity challenges each day. Loss to follow-up was 21% and the characteristics of those who did and did not complete follow-up were similar. Given that the study was done over the Christmas period where the public are very busy preparing for the holiday season, our findings are encouraging, particularly because the intervention is inexpensive, with minimal costs to implement across the population. The use of accelerometers alongside the inclusion of self-reported data is a particular strength because device based measurements can reduce social desirability and recall bias leading to more accurate data.[27] Participants were also masked to the specific purpose of each group before randomisation. No reported safety concerns indicate that the intervention is likely to be safe. In a larger trial, the formal recording of adverse events should be included, playing particular attention to the risk of muscular injuries and falls.

The study also has several limitations. This study was designed as a pilot trial seeking to understand whether a brief intervention had the ability to increase physical activity and decrease sedentary behaviours over three weeks of Advent and was not powered to report on intervention effectiveness. Conducting Christmas based interventions is logistically very challenging because the study needs to be advertised in November, and all participants need to be screened, consented, and have baseline assessments completed within a few days or weeks, so that the intervention period can commence in December. Although lost to follow-up (21%) was acceptable, limited data are available regarding the reasons for this loss and we therefore have little information about the steps that can be taken in future trials to reduce this percentage further. Accelerometer measured data were collected in only 50% of participants in each group, although selection for wearing the device was at random thereby reducing the possibility of bias. The intervention generated relatively small changes in behaviour and although the intervention was brief, these changes still have the potential to impact health if maintained.[26 28] Further research might wish to consider determining the effectiveness of the intervention, as our findings have indicated that the intervention might be worthwhile. Participants were only followed up until 24 December and whether the intervention helped participants maintain any changes that they had made is not known. This question would be interesting for further research. Although participants with a broad range of sociodemographic characteristics were recruited, more women than men participated. Future research should consider ways to recruit more men into lifestyle behavioural intervention trials to better reflect the population.

Conclusion

The public were interested to engage in a Christmas themed physical activity intervention, which also reduced sedentary time and showed promise for increasing participation in physical activity. Enjoyment of, and adherence to the intervention shows that the public would welcome public health campaigns to help them become more physically active and less sedentary during the Christmas holiday season.

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Contributors: GB conceived the study with input from AD, JS, KG, and CM. GB wrote the protocol with contributions from AD and JS. GB, AP, and AD lead recruitment of participants. GB wrote the first version of the manuscript with input from co-authors. GB and AR conducted the statistical analyses, with support from AD. JS processed the accelerometery data. JT conducted randomisation. All authors contributed to the interpretation of the results and reviewed and approved the final manuscript. GB is the guarantor. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/disclosure-of-interest/ and declare: support from the NIHR for the submitted work; AD is supported by a National Institute for Health Research (NIHR) Research Professorship award; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval: This study was approved by Loughborough University, Human Participants Sub-Committee I (reference number 6057). All participants provided informed consent before taking part.

Data sharing: Data from the Active Advent study or the study materials are available from the corresponding author at g.j.biddle@lboro.ac.uk. All individual participant data will be available on request one year after publication of trial outcomes. The study protocol is available on request. All requests for data access will need to specify the planned use of data and will require approval from the trial investigator team and the sponsor before release.

The guarantor (GB) affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained. The manuscript follows the CONSORT guidelines for the reporting of clinical trials.

Dissemination to participants and related patient and public communities: The results of the study will be disseminated through a newsletter to all participants, along with a link to the published article.

Provenance and peer review: Not commissioned; externally peer reviewed.

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Web appendix: Online appendix