

Active Advent Study

Adult Participant Information Sheet

Investigators Details:

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We would like to invite you to take part in our study. Before you decide we would like you to understand why the research is being done and what it would involve for you. We hope the information below will help you decide about whether you would like to take part in this study.

What is the purpose of the study?

Participation in regular physical activity is good for your health and can reduce your risk of developing many different diseases such as cardiovascular disease and diabetes. This study is interested in comparing two different ways of helping the public increase or maintain their physical activity during the Christmas period.

To do this, we will randomise you (like tossing a coin) into one of two groups. If you are randomised to group one you will receive ideas for Christmas themed physical activities, you can do each day during advent via email (4 weeks). If you are randomised to group two you will receive written information about the importance of physical activity for health via email.

Who is doing this research and why?

This study is being organised and co-ordinated by the Centre for Lifestyle Medicine and Behaviour at Loughborough University. It is funded via the National Institute for Health Research.

Are there any inclusion or exclusion criteria?

You just be aged 18 or over with access to email to take part. We will also assess your current levels of physical activity and determine whether you meet our inclusion criteria. You must also be living in the UK, be able to understand and communicate in English and must be able to stand and be physically active.

What will I be asked to do?

If you take part in this study, there are several things we will ask you to do:

Before the study begins:

- We will ask you to complete an expression of interest form online and we will check you are over 18 years and have an email account
- If you are eligible, we will ask you to complete some questions about yourself (age, gender, employment status, ethnicity, height and weight) and some brief questions about how much physical activity you usually do each day.

- Some people may be asked to wear an accelerometer for 7 days, which is a device that looks like a watch and measures your physical activity. We will ask you to complete a brief wear diary alongside the accelerometer to help us understand your physical activity patterns in more detail. We will ask you to post this back to us using a freepost envelope.

When the study begins:

- If you are randomised to group one, you will receive one email each day between 1st and 24th of December that will include ideas for Christmas themed physical activities.
- If you are randomised to group two, you will receive written information about the importance of physical activity for health via email at the start of the study.
- Both groups will be asked brief questions about the physical activity you have done in the previous week. This will be done three times during December.
- If you are randomised to group one, we will ask you some additional questions each week of December to understand which physical activity ideas you completed and your enjoyment of these.
- If you were asked to wear an accelerometer watch at the start of the study, we will ask you to wear it again for up to 24 days during the study and to post this back to us using a freepost envelope.

Once I take part, can I change my mind?

After you have read this information and asked any questions you may have if you are happy to participate, we will ask you to complete an Informed Consent Form. Please complete the Informed Consent Form and return it via email to g.j.biddle@lboro.ac.uk. However, if at any time you wish to withdraw from the study, please just contact the main investigator. You can withdraw at any time, for any reason and you will not be asked to explain your reasons for withdrawing. However, once the results of the study are aggregated (expected to be by 01/02/2022), it may not be possible to withdraw your individual data from the research.

Will I be asked to attend any sessions and where will these be?

You won't be asked to attend any sessions. The entire study takes place online and can be done from anywhere in the UK.

How long will it take?

The study will run from the start of November 2021 through to the end January 2022. No study task is expected to take more than 5 minutes to complete. In total, study tasks are not expected to exceed 35 minutes in total.

Are there any disadvantages or risks in participating?

We are not expecting any substantial risks from taking part in this study. If you are asked to wear an accelerometer, you may experience mild skin irritation. This is unlikely but is possible if you have particularly sensitive skin. If you do experience irritation, we recommend you change the wrist you are wearing the device on at regular intervals.

What are the possible benefits of participating?

If randomised to group one, you receive ideas for Christmas themed physical activities you can do each day during advent (between 1st and 24th of December). If randomised to group two, you will receive written information about the importance of physical activity for health at the start of December. Participating in regular physical activity may improve your health and wellbeing.

Data Protection Privacy Notice

Loughborough University will be using information/data from you in order to undertake this study and will act as the data controller for this study. This means that the University is responsible for looking after your information and using it properly.

What personal information will be collected from me and how will it be used?

Your age, gender, ethnicity, education level, postcode, employment status, height and weight will be collected during your participation for analysis. Your contact details (name, address, email, phone number) will be used to contact you in relation to Active Advent.

What is the legal basis for processing my personal information?

Personal data will be processed on the public task basis. For further details on the data protection legislation see: <https://ico.org.uk/your-data-matters/>

Under the General Data Protection Regulation (GDPR), some of the personal data which will be collected from you is categorised as “sensitive data”. The processing of this data is necessary for scientific research in accordance with safeguards. This means that study has gone through an ethical committee to ensure that the appropriate safeguards are put in place with respect to the use of your personal data.

How long will my personal information be retained?

We will keep identifiable personal information about you until 31st of March, 2022.

Will my personal information be shared with others?

Only researchers directly involved in the study will have access to study data. No identifiable participant information will be disclosed.

Will my taking part in this study be kept confidential?

If you decide to take part in this study, all personal information collected about you will be kept strictly confidential. It will be securely handled and stored at Loughborough University in accordance with your consent and the provisions of the General Data Protection Regulation (GDPR). With your permission, and where relevant to your involvement in the study, your data may be looked at by researchers from the Active Advent team at Loughborough University, the trial Sponsor (Loughborough University) or the regulatory authorities.

How will the anonymised data/results collected from me be used?

Once the study has finished, we may publish the findings in a scientific journal including direct quotations from the questionnaire responses. No individual will be identified in any publications and all quotations will be anonymous.

How long will the anonymised data/results be retained?

The anonymised results will be retained by Loughborough University for 10 years (until 31/03/2032) after the completion of the research in line with Loughborough University's Policy. The research team will seek approval from Loughborough University as the sponsor of the study before deleting the data.

I have some more questions; who should I contact?

Dr Gregory Biddle, email: g.j.biddle@lboro.ac.uk, telephone: 01509 228483

What if I am not happy with how the research was conducted?

If you are not happy with how the research was conducted, please contact the Secretary of the Ethics Review Sub-Committee, Research & Enterprise Office, Hazlerigg Building, Loughborough University, Epinal Way, Loughborough, LE11 3TU. Tel: 01509 222423. Email: researchpolicy@lboro.ac.uk

The University also has policies relating to Research Misconduct and Whistle Blowing which are available online at <https://www.lboro.ac.uk/internal/research-ethics-integrity/research-integrity/>.

If you require any further information regarding the General Data Protection Regulations, please see: <https://www.lboro.ac.uk/privacy/research-privacy/>.