

Snacktivity™ to help people increase their physical activity

We are inviting people from across different settings and communities to take part in a study that is testing a new approach to helping people become more physically active called SnacktivityTM. This approach encourages people to do short 'snacks' of physical activity throughout the day to improve their health and well-being.



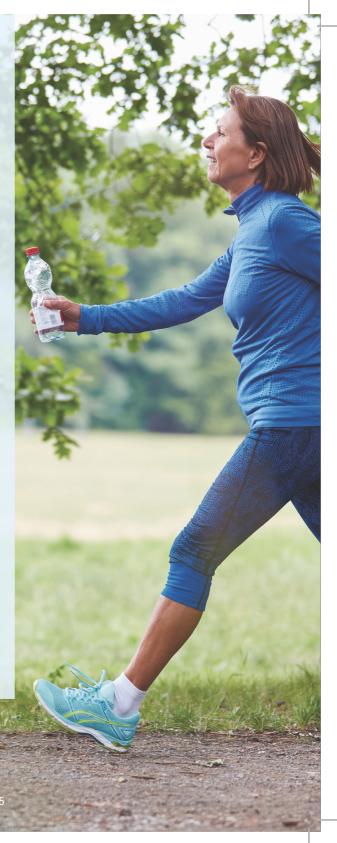


Before you decide if you would like to take part, please read this information sheet-it explains why the research is being done and what it means for you if you take part. If you have any questions, please contact the study team (details below). We have also created a short video to help explain the study which you can watch here birmingham.ac.uk/snacktivity or by scanning the QR code above.

What is the Snacktivity™ study about?

People have become less physically active and spend a lot of time sitting. Being physically active reduces your risk of developing illnesses such as heart disease, cancer, type 2 diabetes and can even improve your mood. This study aims to explore whether the Snacktivity™ approach helps people to become more active and is aimed at everyone regardless of their age, fitness, ability or disability.

Snacktivity™ focuses on encouraging people to do short 'snacks' of physical activity throughout the day. An 'activity snack' lasts between 2-5 minutes and can easily be fitted into daily life e.g., using the stairs instead of a lift, taking an extra short walk and leg raises while watching the television.



What will happen if I agree to take part?

At the start of the study

- You will be asked to complete a brief questionnaire about your physical activity to check if you are eligible to take part.
- If you are eligible, you will be asked to sign an online form to check that you understand and consent to take part. All participants will be posted a physical activity wrist monitor to wear for nine days, which will record how much activity you usually do each day. You will then be asked to return this in a free postage envelope.
- You will be asked to complete a short online questionnaire (10 mins) which asks questions such as your age and gender, general health, and any contacts you have had with health services recently. You will also be asked to upload a picture of your weight with you standing on home weighing scales so that we can see if the study changes your weight.
- We will then allocate you to one of two groups at random (like tossing a coin):

 Snacktivity group: This group will be asked to incorporate their choice of activity snacks into the day, given access to a new Snacktivity™ mobile phone app and wear a Fitbit watch for twelve months to help track your physical activity and support you with Snacktivity ™. Comparison group: This group will receive some educational information

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wider community (e.g. social media and

community events)

If you are recruited via an NHS Trust/ setting and have an appointment e.g. GP practice

 At your next appointment, the health professional will allocate extra time to discuss the Snacktivity™ study and ways you could increase your physical activity. With your consent, the health professional may audio record your conversation about physical activity (optional).

If you are recruited via a non-NHS setting e.g. social media, a community support group

 A researcher will call you to discuss how you could increase your physical activity.
 With your permission, the researcher may audio record your conversation.

After three months

After three months, everyone will be sent a wrist monitor in the post to wear for nine days to record your physical activity movements again. You will be asked to complete the short online questionnaire again. This includes uploading a picture of your current weight on home scales.

After twelve months (end of the study) After twelve months, everyone will be sent a wrist monitor in the post to wear for nine days which will record your physical activity movements for the final time. You will also be asked to complete a short questionnaire for the final time. This includes uploading a picture of your current weight on home scales.

How long will the study take?

You will be involved in the study for around 12 months.

What are the possible benefits of taking part?

We hope the study will help you to be more physically active and it may improve your health. You will receive $2 \times £30$ shopping vouchers in total (£30 when you complete the three month follow-up and £30 when you complete the twelve month follow-up).

If you are in the Snacktivity™ group you will be given to keep a Fitbit watch and access to a Snacktivity™ mobile phone app that helps you monitor your Snacktivity™/physical activity.

By agreeing to participate you will provide researchers with important information that may help others to become more physically active to improve their health. We will also be checking to see whether participation in the study helps to reduce costs for the NHS.

What are the possible disadvantages and risks of taking part?

We do not expect any risks or disadvantages from taking part in this study.

How do I take part?

If you are interested in taking part in the study you can complete the eligibility screening form online redcap.link/snacktivity wp4 screening or complete and return the paper form included (if applicable) to the Birmingham Clinical Trials Unit using the freepost envelope provided or contact the research team on:

E: <u>snacktivity@trials.bham.ac.uk</u> or T: 0121 414 6046

What if I do not want to take part?

It is entirely up to you to decide if you want to take part. However, if you do take part, you are free to withdraw at any time, without giving a reason and it will not affect your medical care in any way. You can withdraw from the study at any time by contacting the study team using the contact details below. If you are allocated to the SnacktivityTM.



group and withdraw from the study before completing the 12 month follow up, you will be asked to return the Fitbit watch.

Who is organising and funding the research?

The study was developed by
Loughborough University (LU), with the
Universities of Birmingham (UoB),
Leicester (UoL), Edinburgh and East
Anglia. The study is sponsored by
Birmingham Community Healthcare NHS
Foundation Trust and coordinated by the
Birmingham Clinical Trials Unit. The
research is funded by the National Institute
for Health and Social Care Research
(Department of Health and Social Care).

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your interests. This study has been reviewed and given a favourable opinion by Surrey Research Ethics Committee - 24/LO/0186

Will my taking part in this study be kept confidential?

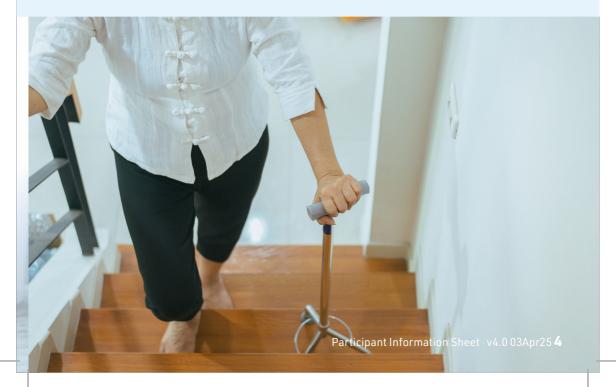
If you decide to take part in this study, all information collected about you will be kept strictly confidential. It will be securely handled and stored at the UoB, LU and UoL in accordance with your consent and the provisions of the General Data Protection Regulation (GDPR). With your permission, and where relevant to your involvement in the study, your data may be looked at by University researchers., the study Sponsor or the regulatory authorities. Your GP/health professional will be informed of your participation in the study.

If you would like further information please contact:

E: snacktivity@trials.bham.ac.uk or T: 0121 414 6046.

Chief Investigator is Professor Amanda Daley, Loughborough University, Leicestershire,

E: a.daley@lboro.ac.uk



Additional Information and Data Privacy Notice

What happens if I have a complaint about the study?

If you have a concern about any aspect of this study, you should ask to speak to the study team at the University of Birmingham Clinical Trials Unit who will do their best to answer your questions. The contact details for the study team are at the bottom of page 5 of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting National Health Service complaints mechanisms, this is usually the Patient Advisory and Liaison Service (PALS).

NHS PALS Service at Birmingham Community Healthcare Foundation NHS Trust: E: complaints.bchc@nhs.net or T: 0121 466 7038

What if something goes wrong during my participation in the study?

In the event that something does go wrong and you are harmed during the study, and this is due to someone's negligence then you may have grounds for legal action for compensation against Birmingham Community Healthcare NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).



What will happen to the results of the research study?

Once the study has finished, we may publish the findings in a journal.

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

We will need to use information from you for this research project. The Birmingham Clinical Trials Unit, Loughborough University and University of Leicester will process personal data. This information will include your name, date of birth (DOB), gender, home address, ethnicity, marital status, employment status, household income and your healthcare professional's contact details e.g. your GP surgery (if applicable). People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number (participant ID number) instead and we will keep all information about you safe and secure.

If you are randomised to the Snacktivity group, your first name, last name, age, and gender will be preloaded onto the SnackApp by the research team. A Fitbit profile will also need to be created for you using your participant ID number, DOB and gender. Your daily physical activity data will be collected from the study app (SnackApp) and stored to help us understand your physical activity patterns. This information and details about how you use the app will be stored by the phone and sent wirelessly to a dedicated encrypted server that is based in the UK (London) and are Google servers managed by Cuttlefish Multimedia. All data will be stored centrally in a secure database and your personal information will be stored separately from any of the other data. A copy of your completed consent form will be sent to your GP to inform them of your participation in the study. Short message service (SMS) text messages will be sent to you via FireText, an Online SMS platform which will be programmed into our trial database. In order for us to use the service we will need to provide your name and mobile phone number to FireText to allow them to send the message to you, your data is held in line with GDPR.

Once we have finished the trial, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information at:

- www.hra.nhs.uk/informationabout-patients/
- by asking one of the research team: snacktivity@trials.bham.ac.uk
- by sending an email to the co-sponsors data protection officers: dp@lboro.ac.uk or bchc.dpo@nhs.net

If you would like further information about how health researchers use information from participants please visit www.hra.nhs. uk/patientdataandresearch

What is the legal basis for processing my personal information?

As defined by General Data Protection Regulation (GDPR), some of the personal data which will be collected from you is categorised as "sensitive data" (e.g. your name and contact details). The processing of these data is necessary for scientific research in accordance with safeguards. This means that the study has been through an ethical committee to ensure that the appropriate safequards are put in place with respect to the use of your personal data. Personal data will be processed on the public task basis. Individuals' rights to erasure and data portability do not apply if you are processing on the basis of public task. However, individuals do have a right to object.

How long will my personal data be retained?

Your data will be retained by the study team and LU for 25 years after the completion of the research in line with the study office and Loughborough University's Policy. The research team will seek approval from BCHC and LU as co-sponsors of the study before the deletion of data. Your anonymised data may be used in other ethically approved health studies.



Further information

If you require any further information regarding the General Data Protection Regulations, please see: www.birmingham.ac.uk/research/bctu/data-protection.aspx. If you have any further questions about the research or how we use your information, please contact the Data Protection Officer dataprotection@contacts.bham.ac.uk or the study team using the contact information above.









