

Child Health Unit, Department of Primary Care and Public Health Charing Cross Campus Reynolds Building St Dunstan's Road London W6 8RPI



ADULT/PARENT/GUARDIAN INFORMATION SHEET

Health & Activity of Pupils in the Primary Years (HAPPY) study

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

Please contact us if anything is unclear or if you would like more information. Our contact details are provided at the end of this information sheet. Thank you for reading this.

What is the purpose of this study?

Research has shown that school environments are important settings that can provide children with opportunities to be physically active. Increased physical activity can help to improve children's overall health and wellbeing. We are investigating the opportunities that schools provide that may encourage children to be active, to find out how active children are during the school day.

Why have I been invited?

Schools across London have been invited to take part in this study. The school your child attends was invited to take part in our study and they agreed to participate in this important research. We would like to invite you and your child to take part in this study to find out more about how much activity children do whilst they are at school.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part, both you and your child will need to agree to participate. You will be given this information sheet to keep and be asked to sign a consent form. If you agree to participate, you are still free to withdraw at any time without giving a reason. If you decide to withdraw from the study after we have collected data from you and your child, you will need to let us know in writing to remove and delete your data from the study. All the data that we use for analysis and for reporting is anonymised, neither you, your child nor the school will be identifiable.

What will happen to me if I take part?

There are minimal risks from taking part in this research. The research will be ongoing for the next year but you will only be contacted to take part at one time point (i.e., one visit to your child at the school).

What do I have to do?

Your participation: Through the school, we will send you a questionnaire to complete which will ask a few questions about your general health, qualifications, employment, household, and a few questions about your child's health and behaviour. The questionnaire should take around 10 minutes to complete and can be completed online if you prefer (a secure link to the online version will be printed on the questionnaire that you receive). The questionnaire will have an ID number so that the responses you

provide cannot be linked back to you by anyone outside the research team. The questionnaires will be stored in lockable filing cabinets at Imperial College London with restricted access to the study team only.

Your child's participation: The HAPPY study researchers will visit the school to take height and weight measures of your child. <u>Please let us know if your child has any important health issues that may affect their everyday activity, such as a pacemaker.</u> The measures are quick (less than 5 minutes). Your child will also be given a questionnaire to take home to complete (please help them to complete this), and is also available to complete online using a secure link printed on their questionnaire. This will ask your child about their health and wellbeing, the activities they do at school and whether they enjoy these) and should take around 10 minutes to complete. As with your questionnaire, only an ID number will appear, and the questionnaires will be stored in lockable filing cabinets at Imperial College London with restricted access to the study team only.

Activity watch: When the study team visit your child's school, they will give your child an activity watch to wear. This activity watch collects information about your child's movement and activity (i.e., step counts). It is important that the watch is worn continuously for 7 days and is NOT removed during that period. It needs to be worn at all times and during all activities – it can be worn during a bath/shower (it is water resistant) and whilst sleeping. After the wear period, we will ask you to return the monitor and completed questionnaires back to the school and we will collect these from the school. We'd like your child to try their best to wear the activity watch for the full 7-days, but if it becomes uncomfortable or if they really don't like wearing it, they should take it off. Please help your child take it off and keep it somewhere safe until it needs to be returned with the questionnaires.

School participation: As part of the study, your child's class teacher will be asked to complete a very short questionnaire about your child's educational performance.

We may seek opportunities to take photos of the children being assessed (i.e., wearing the activity watch, standing on the height scale) such as the picture seen here to promote the study (this picture was taken by a school and shared with us). You can choose whether you would like your child to be part of these photo opportunities by indicating this on the parent consent form.



What are the possible disadvantages and risks of taking part?

There are no disadvantages or risks to you or your child from participating in this research.

What are the possible benefits of taking part?

The study may not help you directly, but your participation will help us to understand how school environments can help children to be active which will benefit their health. **YOUR CHILD WILL RECEIVE A £5 AMAZON VOUCHER** as a thank you when we have all the data (height/weight measures, yours and your child's questionnaires, and the activity watch back after the 7-day wear period).

All the data that we collect from you and your child will be kept in <u>strict confidence</u>. You and your child will be given an ID number which means that nobody outside the research team will be able to identify you from your responses.

What if something goes wrong?

Our measures are straightforward (simple height and weight measure of your child) and it is unlikely that anything will go wrong. If the activity watch is lost or damaged there are no consequences for you or the school, but please let the study team know straight away.

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Principal Investigator (happy.study@imperial.ac.uk). If you are still not satisfied with the response, you may contact the Imperial College Research Governance and Integrity Team (rgitcoordinator@imperial.ac.uk)

What will happen to the results of the study?

We will publish the results from the study in scientific journals, and present the findings at conferences, seminars and to relevant organisations. <u>None of the results will include any details that identify you, your child, or your child's school</u>. We will also share the results through newsletters, social media, and on our study website which you and the school can access at your convenience.

Who is organising and funding the research?

This research is funded by the National Institute for Health and Care Research (NIHR), School for Public Health Research (SPHR), and being undertaken by Imperial College London. The study is being led by Professor Sonia Saxena in the Department of Primary Care and Public Health. The research is a collaboration with experts from the Universities of Cambridge, Birmingham, Durham and Exeter.

Who has reviewed the study?

The study was given favourable opinion by Imperial College Research Ethics Committee (ICREC) and approval by Professor Azeem Majeed, Head of the Department of Primary Care and Public Health.

Contact for further information

If you have any questions about the study, or would like to know more before deciding to participate, please contact the HAPPY study team at <u>happystudy@imperial.ac.uk</u> Alternatively, please write to us at: HAPPY study team, Child Health Unit, Department of Primary Care and Public Health, Imperial College London, Charing Cross Campus, Reynolds Building, St Dunstan's Road, London, W6 8RP.

The HAPPY study core team are:

Principal Investigator: Professor Sonia Saxena Research Team: Dr Bina Ram, Ms Nancy Gullett, & the Clinical Research Network team.

They study is part of a wider collaboration team with partners at Cambridge, Durham, Birmingham, and Exeter Universities.

Thank you for reading this information leaflet. We hope you consider taking part in this important research!

FURTHER INFORMATION

How will we use Information about you?

Research Study Title: Health & Activity of Pupils in the Primary school Years (HAPPY) study (6800895).

Imperial College London is the sponsor for this study and will act as the Data Controller for this study. This means that we are responsible for looking after your information and using it appropriately. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

The study is expected to finish in September 2025.

For more information / confirmation regarding the end date please contact the study team, see 'WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED' for contact information.

We will need to use information (including personal data and data created as part of the study) from you for this research project.

This information will include your name, contact details, and data collected as part of the study. People within the College and study team (see section 'Sharing your information with others') will use this information to do the research or to check your records (see information to be collected) to make sure that the research is being done properly and the information held (such as contact details) is accurate.

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 unique study number instead.

We will keep all information about you safe and secure.

Once we have finished the study, 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.

LEGAL BASIS

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

Imperial College London - "performance of a task carried out in the public interest"; Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the <u>UK Policy Framework for Health</u> and <u>Social Care Research</u>

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), Imperial College London) rely on "scientific or historical research purposes or statistical purposes.

INTERNATIONAL TRANSFERS

There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA) or to other countries outside the EEA. Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a UK adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguards how your personal data is processed.

SHARING YOUR INFORMATION WITH OTHERS

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

This research is a collaboration with experts from the Universities of Cambridge, Birmingham, Durham and Exeter. Data sharing with collaborators will be by written request to the Principal Investigator. Any data that is shared will be pseudonymised. Collaborators will not have access to any personal data at any point.

- Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.
 - The following Research Collaborators / Partners in the study
 - Third Party University data will only be shared if necessary for research and reporting and with explicit consent from the Principal Investigator (PI). Any data shared will not include personal information that will identify you.
 - Third Party Company data will only be shared if necessary for research and reporting and with explicit consent from the PI. Any data shared will not include personal information that will identify you.
 - Third Party Government department data will only be shared if necessary for research and reporting and with explicit consent from the PI. Any data shared will not include personal information that will identify you.

POTENTIAL USE OF STUDY DATA FOR FUTURE RESEARCH

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the <u>UK Policy Framework for Health and Social Care Research</u>.

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

COMMERCIALISATION

Data from the study may also be provided to commercial organisations or non-commercial organisations for the purposes of undertaking the current study, future research studies or commercial purposes such as development by a company of a new test, product or treatment. We will ensure your name and any identifying details will NOT be given to these third parties, instead you will be identified by a unique study number with any sample analysis having the potential to generate 'personal data'.

Aggregated (combined) or anonymised data sets (all identifying information is removed) may also be created using your data (in a way which does not identify you individually) and be used for such research or commercial purposes where the purposes align to relevant legislation (including the GDPR) and wider aims of the study. Your data will not be shared with a commercial organisation for marketing purposes.

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 because some research using your data may have already taken place and this cannot be undone.

- We need to manage your records in specific ways for the research to be reliable. This means that we may not be able to let you see or change the data we hold about you if this could affect the wider study or the accuracy of data collected.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED

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

- by asking one of the research team
- by sending an email to happystudy@imperial.ac.uk
- by referring to our website

COMPLAINT

If you wish to raise a complaint about how we have handled your personal data, please contact the research team first by sending an email to happystudy@imperial.ac.uk, or by ringing us on 020 7594 0879.

Following our response, if you are not satisfied please contact Imperial College London's Data Protection Officer via email at <u>dpo@imperial.ac.uk</u>, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO)- via <u>www.ico.org.uk</u>. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.