

Participant Information Sheet



The Prediction of Childhood Overweight/Obesity Based on Parental Lifestyle and Genetic Parameters

INFORMATION SHEET FOR THE TRIAL GROUP

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Participant Information Sheet Part A

You are invited to take part in a PhD study assessing the effect lifestyle and genetic factors have on obesity, specifically childhood obesity. Before you decide to take part you need to understand why the research is being carried out and what exactly it will involve. Please take the time to read the following information sheet carefully and to ask any questions that you may have. Talk to others about the study if you wish and do not hesitate to ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Background and purpose of the study

Excess bodyweight is one of the most important risk factors contributing to disease burden worldwide, affecting over two billion adults and 10% of children. Currently in the UK close to a third of children aged 2-15 years are overweight or obese. These individuals are more susceptible to heart disease, diabetes, musculoskeletal disorders, several cancers, depression, social anxiety and eating disorders. The National Health Service spent an estimated £5.1 billion on overweight-related disease in 2014-2015. This value is said to be a mere fraction of the expenses that will be associated when the future outlook of childhood overweight is considered. This study aims to collect information and use this to build a predictive tool based on lifestyle and genetic factors to help future generations.

Who is organising and funding this research?

This study is funded by St Mary's University, Twickenham.

The researchers in the study will not be paid for including you in this study.

What will happen to the results of the research study?

The results of this study will be used to increase the knowledge base of childhood obesity.

You will be offered the opportunity to be informed of the results of any of the measurements taken throughout the study. This will include whether you have any lifestyle factors that have been associated with overweight and obesity in research and

whether or not you carry specific genes that have been associated with overweight and obesity in research; both of which can play a part individually and combined.

At any point throughout the study or after completion the researcher is able to provide feedback on any questions you may have regarding them.

Participation in the study will not be disclosed to any other destination of the finished study; your data will be anonymous.

Participant Information Sheet Part B

Why have I been invited?

You have been invited to take part because you are aged 16+ and fit the inclusion criteria below:

- Participants must be the biological parent/s of a 0-16 year old child.
- The child in question must not have a history of any chronic disease.

Can I refuse to take part?

Participation is not a requirement, it is up to you to decide whether you would like to participate or not. If you agree to take part, you will be asked to sign a consent form. **After signing the consent form you are still free to withdraw at any time, even without providing a reason.**

What will happen to me if I decide to take part?

If you decide to take part in the study you will be provided with a questionnaire and saliva collection vial (and instructions). The questionnaire can be either provided online or a hardcopy with a return envelope, dependent on participant request. The questionnaire will need to be completed and 2mm of saliva will need to be provided and returned to St Mary's University, Twickenham (address provided on return envelope).

This is the end of your direct involvement of the trial.

What will my questionnaire answers and saliva be used for?

The data collected in this study will be anonymised and coded. The questionnaire is used to assess specific lifestyle factors that have been related to overweight and obesity in previous research. The saliva samples will provide the researcher with genetic information relating to specific genes that have been associated to overweight and obesity in previous research.

What will the results of this study tell me?

The results of this study will inform you if you are a carrier of selected overweight/obesity associated genes and will provide you with lifestyle information regarding overweight/obesity. If you are a carrier of such genes this does not necessarily mean your child will be overweight or obese. You will be provided with information/literature on your genetic results on completion of the trial. If you wish for any further information regarding genetics do not hesitate to ask the researcher at any point.

The benefits of participation

Participation in this study will contribute to our understanding of why certain people are overweight and/or obese.

Will my participation be kept confidential and what will happen to the data?

Yes. Ethical and legal practice will be followed and all information about you will be handled in confidence. The data of this study will be anonymised and coded. The electronic and recorded data will be stored on University computers, which are password protected. Paper data will be stored in a locked environment. Only researchers involved in this study and regulatory authorities will have access to the data. All information collected during the course of the research will be kept strictly confidential according to the Data Protection Act 1998. All human tissue samples collected will be in line with the Human Tissue Act 2004.

How much time will need to be given up in order to participate?

The questionnaire and saliva sample should take no longer than 15 minutes to complete. Participants are advised to have a brief read of the questionnaire before attempting to answer the questions, so they can collect any information they may not have at hand.

Who has reviewed this study?

All research undergone at St Mary's University, Twickenham is looked at by St Mary's Research Ethics Committee to protect your safety, rights, wellbeing and dignity.

Final Statement

Agreement to participate in this research should not compromise your legal rights if something goes wrong.

YOU WILL BE GIVEN A COPY OF THIS FORM TO KEEP TOGETHER WITH A COPY OF YOUR CONSENT FORM.