

The clustering of lifestyle behaviours in a multi-ethnic population: A questionnaire study

PARTICIPANT INFORMATION SHEET

You are being invited to take part in a research study but before you decide whether to take part, it is important that you understand why the research is being carried out and what it will involve. This document is designed to help you decide whether you would like to participate. If anything is unclear or you would like more information, please contact a member of the research team whose details are included at the end of this information sheet.

What is the purpose of the study?

We know that people with particular lifestyle behaviours, including level of physical activity and diet, can be linked with a higher chance of developing long term conditions including high blood pressure, diabetes and heart disease. We would like to ask people across the East Midlands (Lincolnshire, Northamptonshire, Derbyshire, Nottinghamshire, Leicestershire and Rutland) about some of their lifestyle behaviours to find out the extent to which they may raise the chances of disease, both now and in the future. We would also like to know the effects that living/working in different geographical areas may affect lifestyle habits and risk of disease.

Who are we looking for?

We would like adults 18 years old and above, either with or without long term health conditions to take part.

What happens if I decide to take part?

If you decide to take part, the study involves filling in one questionnaire which will take approximately 10 minutes to complete.

Who is organising and funding the research?

The study is being organised and coordinated by the University of Leicester and it is being led by Professor Kamlesh Khunti at the Leicester Diabetes Centre.

Do I have to take part?

It is your right to decide whether or not you would like to take part in this study. Your future medical care will not be affected whether you take part or not.

What are the possible benefits of taking part?

You will not directly benefit from taking part in the study. However in addition to helping advance medical and scientific knowledge, if you are happy for us to do so, you may be invited for future research opportunities which may include health education programmes or new treatment options or to take part in focus groups to discuss your experiences of certain health conditions.

Are there any risks in participating?

The main risk posed is the burden of time to complete the questionnaire, to minimise this burden the questionnaire has been kept as short as possible. There is an additional risk that you may be distressed by questions asked within the questionnaire booklet, however the questionnaire has been designed to avoid intrusive or distressing questions where possible, and you are free to withdraw from participation at any time should you feel distressed.

Will my GP be informed?

As your data will not be linked to your health records, your GP will not be notified by us.

Will my taking part in this study be kept confidential?

University of Leicester is the sponsor for this study. If you agree we will be using information from you in order to undertake 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 properly. Leicester Diabetes Centre will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Leicester Diabetes Centre will collect information from you for this research study if you consent to this. Leicester Diabetes Centre will keep your name, and contact details confidential and will not pass this information to the sponsor. Leicester Diabetes Centre will use this information as needed, to contact you about the research study and to oversee the quality of the study. Certain individuals from University of Leicester and regulatory organisations may look at your research records to check the accuracy of the research study. University of Leicester will only receive information without any identifying information.

The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

When you agree to take part in a research study, the information about your health and care may be provided in an anonymised form to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

You can find out more about how we use your information by contacting the study team.

If I take part, can I change my mind?

You can change your mind about the following for any reason and will not be asked to explain your reasons:

1. Allowing us to use the information you provided on the questionnaire
- A. If you contact us to withdraw your questionnaire data from the research before we have analysed it, then we can remove your information, but only if you provided your personal details when you completed the questionnaire.
2. Allowing us to contact you about future research
- A. You can withdraw consent to being contacted about future research at any time.

What will happen to the results of the study?

The research will be coded (for anonymity) and analysed by the research team before being reported in research reports. The results may also be presented in appropriate scientific journals and conferences but you will not be identified by name in any publications. You will not be directly informed of the results of the study.

What if I am harmed by the study?

It is very unlikely that you would be harmed by taking part in this type of research study. However, if you wish to complain or have any concerns about the way you have been approached or treated in connection with the study, you should ask to speak to the study team who will do their best to answer your questions. If you remain unhappy and wish to address your concerns or complaints on a formal basis, you should contact Patient Advice and Liaison Service (PALS)

Tel: 0808 1788337

Email: pals@uhl-tr.nhs.uk

Address: Level 1, Balmoral Building, LRI, Infirmary Square, Leicester, LE1 5WW

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against University of Leicester 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 do I do if I decide to volunteer?

Please read this participant information sheet before deciding whether or not to take part. Once you have decided that you would like to take part and if you are completing the paper version consent form and questionnaire remove the participant information sheet and keep for your reference. Turn over and complete the consent form and questionnaire. Once completed, put the consent form and questionnaire in the box which you will find on the reception desk in your clinic/surgery. You can take the questionnaire home to fill in and bring it back to the clinic/ surgery when convenient.

If you still have any questions about the study, please feel free to contact the study team:

Tel: 0116 258 8047

Email: lifestylestudy@uhl-tr.nhs.uk

Address: Leicester Diabetes Centre, Leicester General Hospital, Gwendolen Road, Leicester, LE5 4PW

Once you have finished reading this participant information sheet please decide whether or not to take part.

Once you have decided (that you would like to take part) please remove the participant information sheet and keep for your own records/your reference.

Please complete the consent form and questionnaire and place in the "THE MULTI-ETHNIC LIFESTYLE STUDY" BOX which you will find on the reception desk in your clinic/surgery.