Patient Information Form

"The CANDI-hEDS study"

Study title:

Comprehensive Assessment of Nutrition & Dietary Intervention in Hypermobile Ehlers Danlos Syndrome (hEDS/HSD): a personalised approach:

Phase I – nutritional and dietary assessment

Dear Sir/Madam,

This is an invitation to participate in the above medical study. Participation is on a voluntary basis. To come to this decision, it is important to carefully read the information below and optionally discuss it with your partner, family or acquaintances. After being satisfied you have read and understood the below information, you can register your interest to take part by clicking the link at the bottom of this document or you can email the clinical research team with any questions you may have ahead of registration.

Introduction

People with Hypermobile Ehlers Danlos Syndrome (hEDS/HSD) commonly suffer from Functional Gastrointestinal disorders (FGID), i.e. problems with the function rather than the structure of their gut. Symptoms include premature fullness and discomfort after eating regular sized meals (functional dyspepsia) or lower abdominal pain, altered bowel habit and bloating (irritable bowel syndrome) to name but a few. The most widely recognised trigger of symptoms is food, and diet is often the first lifestyle change that patients make to avoid symptoms. Yet there is little evidence regarding what dietary approaches are currently being taken by this patient group and whether they improve symptoms and quality of life.

Aim of the study

The aim of our study is to assess the existing diets and symptoms of EDS UK members and hEDS / HSD patients attending our Neurogastroenterology clinic at the Royal London Hospital.

Do I have to take part?

No. Participation is completely your choice

Study design

We invite you to register for the study using the link at the bottom of this document and enter your name and email address. Emails will then be sent to you directly containing links to electronic questionnaires which we invite you to complete in your own time. Once you have completed all the questionnaires you will be marked as having finished the study.

This study is intended to be part of a three phase approach to investigating and managing diets and nutrition in the population of patients with hEDS / HSD. This means that by taking part you may be invited to take part in subsequent phases of the study if you are happy to do so.

Electronic questionnaires

You will receive email links containing a number of questionnaires. In total they should take approximately 1.5 hours to complete. However you can answer them at your own pace and save them to return to and complete later. Electronic questionnaires must be completed within 4 weeks and you will receive reminder emails if questionnaires remain incomplete. All questions are mandatory such that we have a complete set of answers from each participant who enters our study. All data will be attached to your unique identification number and analysed on a group level rather than as per your individual name i.e. your answers will not be looked at by the researcher in the context of your name.

Study requirements

There are always some specific requirements, which study participants have to meet to be suitable to participate in a study. For this study, participants should have a diagnosis of Hypermobile Ehlers Danlos Syndrome / Hypermobility Spectrum Disorder / EDS Hypermobility Type/ Joint Hypermobility Syndrome or Type III Ehlers Danlos syndrome. The diagnosis must have been made by a clinical doctor.

You have to be over the age of 16 to take part and have access to the internet plus a suitable device for completing the electronic questionnaires.

Potential burden for participants

Participation in this study will involve no physical visits to our clinic. The burden is on the time taken to complete the questionnaires. Electronic questionnaires must be completed within X time frame upon which the study will be closing.

Participation

Before participation, you will have to sign an informed consent form electronically (tick boxes). By signing this, you confirm that you were informed about the study, that you understand the aim of the study and that your participation is on a voluntary basis. Even after you have signed this form, you will have the right to quit the study at any time. A potential withdrawal will not have any influence on your clinical health care in our clinic or any other centre.

Withdrawal from the study

If you wish to withdraw from the study after beginning the questionnaires, please email the researcher below.

Insurance and sponsoring organisation

Each participant in this study will be covered by a specific insurance, as contracted by QMUL. This insurance covers possible damage resulting from participation in this study. The sponsor of the study is Queen Mary University of London.

Benefits and risks

There is no personal benefit from participating in this study, but neither will it bring along any risks. Participating will cost you some time to complete the questionnaires during the study period. Furthermore, this study represents Phase I of a 3 part study into the investigation of nutrition and diet in this patient group. If you take part, you may have the opportunity, if you are willing, to take part in subsequent phases of the study which will involve dietary advice. However there is no obligation to take part in subsequent phases if you do not wish to do so.

This study will lead to a better understanding of the nutritional issues faced by patients with EDS and may lead to better ways of managing dietary issues.

In case of something going wrong, please get in contact with one of the researchers at the Wingate Institute via email. You can also get advice and service from the Patient Advice and Liaison Service (PALS) either in person at a drop in session or over the phone or by mail: The Royal London Hospital 0203 594 2040 / Please see link for further information on PALS

Privacy

All confidential data entered into the form will be stored separately from your questionnaire answers on a secure database using encryption. All questionnaire data will be coded in our database using a unique identification number without mentioning any information traceable to you, such as your name or email address.

We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data in case we need to check it or for future research.

We will make sure no-one can work out who you are from the reports we write.

How will we use information about you?

We will need to use information from you and your medical records for this research project.

This information will include your name/ NHS number/email address and telephone number

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 instead.

We will keep all information about you safe and secure.

Some of your information will be sent to Monash University, Australia. They must follow our rules about keeping your information safe.

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.

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.
- 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 at www.hra.nhs.uk/information-about-patients/

QMUL: data-protection@qmul.ac.uk

Results of the study

We will not communicate individual results to the participants. We hope to disseminate the results via EDS UK website and social media channels. We further hope that results will be published in a peer reviewed journal and might be disseminated in abstract form at (international) scientific meetings.

To register your interest to take part please email - wingate@qmul.ac.uk with your full name and 'CANDI-hEDS' in the subject title

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