



PARTICIPANT INFORMATION SHEET v3.0

Research Title: A Qualitative Study to Investigate the Impact of Ehlers Danlos Syndrome (EDS) on Occupation

My name is Jessica James, I am a pre-registration occupational therapy student at Cardiff University. Occupational therapists aid people to overcome the effect of physical or mental illness so they can participate in their everyday tasks, which going forward I will refer to as occupations. A person's ability to participate in their occupations is essential for occupational balance. Occupational balance is considered to be the state of integration of occupations and demands of a person's life, where the person is satisfied and happy with the balance between work, leisure and everyday occupations. In this study, I am investigating the effect EDS has on a person's ability to participate in their occupations and aim to develop an understanding of how EDS affects a person's occupational balance. I would like to invite you to take part in a research study for my dissertation.

Joining the study is entirely up to you, before you decide I would like you to understand why the research is being done and what it would involve for you. I can go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. Please take as long as you need to read through the information sheet. Please feel free to talk to others about the study if you wish.

The first part of the Participant Information Sheet tells you the purpose of the study and what will happen to you if you take part. Then more detailed information about the conduct of the study is provided.

Do ask if anything is unclear.

1. What is the purpose of this research project?

The purpose of this study is to gain an understanding of how chronic conditions such as EDS affect a person's occupations and occupational balance. People with Ehlers-Danlos Syndrome (EDS) often experience symptoms such as dislocations, pain and other internal organ issues. This research aims to discover whether these symptoms affect a person's occupations and the occupational balance of a person's life and if they do, how do they affect a person's ability to participate in their occupations and how does it affect a person's schedule and balance of occupations.

2. Why have I been invited to take part?

You have been invited because the support group you are a part of is for supporting people with Ehlers Danlos Syndrome and since the study is regarding adults with EDS, it was the easiest place to access people who could provide useful information in investigating the effect of EDS on occupation within adults with EDS.

3. Do I have to take part?

No, your participation in this research project is entirely voluntary and it is up to you to decide whether to take part.

4. What will taking part involve?

An interview online over Zoom meetings, which will take around 45-60 minutes; however, may take more or less time depending on the person. After this, no further action is needed.

5. Will I be paid for taking part?

No. You should understand that any data you give will be as a gift and you will not benefit financially in the future should this research project lead to the development of a new treatment/method/test/assessment.

6. What are the possible benefits of taking part?

There will be no direct advantages or benefits to you from taking part, but your contribution will help us understand how EDS affects occupation and occupational balance.

7. What are the possible risks of taking part?

Due to the sensitive nature of the topic, emotional stress may be experienced. However, you do not have to answer any question that makes you uncomfortable and information will be given in the debrief sheet at the end of the interview for places that can aid with any psychological symptoms or specific EDS issues. Risks to confidentiality will be reduced by ensuring only the research team has access to personal data and data is password protected and each interview data will be anonymised during the transcription phase to protect your confidentiality. Participants can withdraw by contacting the researcher by email by the 7th February 2021. After the 7th February, data analysis will begin, and information will be anonymised so cannot be withdrawn.

8. Will my taking part in this research project be kept confidential?

All information collected from (or about) you during the research project will be kept confidential and any personal information you provide will be managed in accordance with data protection legislation. Please see 'What will happen to my Personal Data?' (below) for further information. However, if you disclose information of intent to harm yourself or others or intent to commit a crime then the researcher will be required to cease the interview report this to their supervisor so further action can be taken.

9. What will happen to my Personal Data?

Cardiff University is the Data Controller and is committed to respecting and protecting your personal data in accordance with your expectations and Data Protection legislation. Further information about Data Protection, including:



- your rights
- the legal basis under which Cardiff University processes your personal data for research
- Cardiff University's Data Protection Policy
- how to contact the Cardiff University Data Protection Officer
- how to contact the Information Commissioner's Office may be found at <https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection>

All participants that need printed copies of the above-mentioned documentation and privacy notices are readily available through contacting the student researcher.

Your personal data will be processed from September 2020 to April 2021, the duration of the study. Prior to submitting the study to the University in March 2021, the research team will anonymise all the personal data it has collected from, or about, you in connection with this research project, with the exception of your consent form. This data will be anonymised in the data analysis phase (7th February) and all participants will be given pseudonyms. Your consent form will be retained for 5 years and may be accessed by members of the research team and, where necessary, by members of the University's governance and audit teams or by regulatory authorities. Anonymised information will be kept for a minimum of 5 years but may be published in support of the research project and/or retained indefinitely, where it is likely to have continuing value for research purposes.

Personal data will be kept on a password-protected laptop that only the research team has access to. It is not possible to withdraw after any anonymised data that has already been published or in some cases, where identifiers are irreversibly removed during the course of a research project, from the point at which it has been anonymised.

10. What happens to the data at the end of the research project?

Data from the research project will be shared within the University as part of my dissertation and hopefully, shared outside the University through publication in scientific journals. Any personal data will be removed from the data before sharing takes place.

11. What will happen to the results of the research project?

The results of this study will be submitted during April 2021 as part of my dissertation. It is my hope to publish the results of this research project in academic journals and present findings at conferences. Participants will not be identified in any report, publication or presentation. Verbatim quotes may be used from the interview; however, no identifying information will be included, pseudonyms will be used.

12. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions



School of
Healthcare Sciences
Ysgol y Gwyddorau
Gofal Iechyd

Contact Details:

Jessica James

Email Address: JamesJE4@cardiff.ac.uk

If you remain unhappy and wish to complain formally, you can do this by contacting the School of Healthcare Sciences Director of Research Governance (Dr Kate Button buttonk@cardiff.ac.uk 02920687734).

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, you may have grounds for legal action, but you may have to pay for it.

13. Who is organising and funding this research project?

The research is organised by Jessica James in Cardiff University as part of her occupational therapy degree and Ruth Squire, the academic supervisor for the project.

14. Who has reviewed this research project?

This research project has been reviewed and given a favourable opinion by the Occupational Therapy School Research Ethics Committee, Cardiff University.

15. Further information and contact details

Should you have any questions relating to this research project, you may contact us during normal working hours:

Name: Jessica James

Role: Student Researcher

Email Address: JamesJE4@cardiff.ac.uk

Name: Ruth Squire

Role: Academic Supervisor

Email Address: SquireRE@cardiff.ac.uk

Thank you for considering taking part in this research project. If you decide to participate, you will be given a copy of the Participant Information Sheet and a signed consent form to keep for your records.