

**Participant Information Sheet**

**Title of Study:** Living with type 2 diabetes and cardiovascular disease. A qualitative investigation of individual experiences

You are being invited to take part in a research study.You do not have to take part if you do not want to. Please read this information, which will help you decide.

1. **What is the purpose of the study?**

The aim of the study is to gain a better understanding of the experiences, attitudes, and views of people who are living with both Type 2 Diabetes (T2D) and heart problems. In particular, we would like to know more about what is important to you when managing your conditions.

1. **Why have I been invited to participate?**

You have been identified as someone who has Type 2 diabetes (T2D) and heart problems. If you are unsure, please ask the researcher.

1. **Do I have to take part?**

No. You can ask questions about the research before deciding whether to take part. If you do not want to take part that is OK. We will ask you to sign a consent form and will give you a copy for you to keep. Your consent will be audio recorded if you decide to take part in the study via MS teams. 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. You may withdraw from the study by contacting Jessica Brown at J.Brown@2022.ljmu.ac.uk. Alternatively, please contact the supervisor of the study, Dr Lisa Newson at L.M.Newson@ljmu.ac.uk.

1. **What will happen to me if I take part?**

If you decide to take part, you will be invited to a group discussion with approximately 4 other people with similar health conditions to yourself and one of our experienced researchers. The researcher will present a short presentation of the findings from a previous study that interviewed 27 individuals with T2D and heart problems. The researcher will ask if the results resonate with the group and further ask you to discuss your feelings and experiences.

Sometimes discussing your health can be uncomfortable to talk about, however, you won’t be pushed to discuss anything you don’t want to speak about. The discussion will take place face to face in a private location or on online on MS teams depending on which is most convenient to you. It will last between 60 minutes. You will be offered regular breaks as necessary.

Following your group talk with a researcher there will also be an option to be a part of the co creation of an intervention aimed at improving your experiences of living with T2D and heart issues. This will be similar to the focus group and involve talking with a few others on your opinions of intervention design (e.g. booklet vs video etc) and delivery (e.g. in person vs online). This part will be optional, and you will be asked to tick whether you would like to take part on the consent form.

1. **Will I be recorded and how will the recorded media be used?**

The audio recording is essential to your participation, and you should be comfortable with the recording process. The audio recordings of your activities made during this study will be used only for analysis. We will ask to record the discussion, so we can listen again afterwards. What you have said will be typed out, and any identifiable information will be removed. Once this has been done, the recording will be destroyed.

1. **Are there any potential risks in taking part?**

Questions included in this study require participants to reflect on their wellbeing. If you feel worried or in low mood, there are several sources of advice or help which are free and readily available to you and which may provide useful. These include:

* Diabetes UK confidential helpline for support or advice: 0345 123 2399
* Diabetes and heart disease information https://www.diabetes.org.uk/guide-to-diabetes/complications/cardiovascular\_disease
* Diabetes.co.uk forum for discussions about managing diabetes <https://www.diabetes.co.uk/forum/>
* British Heart Foundation support group and communities <https://www.bhf.org.uk/informationsupport/support/support-groups-and-online-communities>

1. **Are there any benefits in taking part?**

Studies on participants who take part in investigations on topics that cover difficult subjects have found that being a part of them is an overall positive experience. Furthermore, the reason for doing this research is to understand and hopefully improve health and wellbeing related outcomes for patients in the future. Taking part means that you will have helped make this happen.

1. **Payments, reimbursements of expenses or any other benefit or incentive for taking part**

There will be no payment or any benefit or incentive for taking part in this study. Unfortunately, we cannot reimburse any expenses you may incur.

1. **What will happen to information provided?**

The information you provide as part of the study is the study data. Any study data from which you can be identified (e.g. from identifiers such as your name, date of birth, audio recording etc.), is known as personal data. Your participation in this study will involve the collection/use of personal data.

We will keep personal data safe and secure. People who do not need to know who you are will not be able to see your name or contact details. The personal data collected will include:

* Contact details. With your agreement, we would like to store your contact details so that you may be contacted about future opportunities to participate in research studies
* A record of consent (which will include your name)
* Study data. We will use a code/pseudonym so that you cannot be directly identified from the data. Study data will include audio recordings (which include your voice and/or image). Interview recordings will be deleted once the interview transcript has been verified as accurate and an evaluation has determined that it has no further research value.

Following the Liverpool John Moores University code of practice Study data / records of consent / contact details (if consent provided to store contact details for participation in future research) will be stored for a minimum of 5 years. Furthermore, with your consent all interview transcripts will go into an archive so that people in the future will be able to understand the lives of those living with long term conditions.

Your participation in this research will be recorded in MS Teams and your personal data will be processed by Microsoft. The recordings will be removed from the above third-party platform and stored on LJMU managed file storage as soon as possible following the completion of data collection.

Although every reasonable effort has been taken, confidentiality during actual internet communication procedures cannot be guaranteed.

Before your personal data is transferred to secure storage there is the possibility that the investigator could lose control of authorised access. We will take steps to mitigate the risk of your personal data being viewed by someone outside of the study team. You should not participate if this risk is not acceptable to you.

If you decide to take part in the focus group, we will not tell anyone that you have taken, although there is of course a possibility that another member of the group might recognise you. All members of the focus group will be asked to respect the confidentiality of their fellow participants.

We will write our reports in a way that no-one can work out that you took part in the study. Please note that confidentiality may not be guaranteed; for example, due to the limited size of the participant sample, the position of the participant or information included in reports, participants might be indirectly identifiable in transcripts and reports. The investigator will work with the participant in an attempt to minimise and manage the potential for indirect identification of participants. We would like your permission to use direct quotations but without identifying you in any research outputs.

In certain exceptional circumstances where you may present the researcher information relating to poor medical practice and be under a significant risk of harm or need urgent medical attention or advice, the investigator may need to report this to your GP or appropriate authority. This would usually be discussed with you first.

Other examples of those exceptional circumstances when confidential information may have to be disclosed are:

* The investigator believes you are at serious risk of harm, either from yourself or others
* You pose a serious risk of harm to, or threaten or abuse others
* As a statutory requirement e.g. reporting certain infectious diseases
* Under a court order requiring the University to divulge information
* We are passed information relating to an act of terrorism

1. **What will happen to the results of the study?**

Once results are analysed participants will be able to see a summary of the results. The results will be made available on a webpage or link for participants to find out about the study. If you do not have access to the internet the results can be collected from the researcher at a secure location at a suitable at your local GP surgery or at Liverpool John Moores University. The researchers also intend to publish the results in a PhD thesis and appropriate journal article. This study also has the capacity to possibly provide a novel framework that suggests practical steps for healthcare professionals to improve current usual care for those with comorbidities. Furthermore, gaining a better understanding of what psychological support looks like for those more than one long term condition can help identify and improve psychological interventions that will support self-management and improve outcomes of their long- term conditions.

1. **Who has reviewed this study?**

This study has been reviewed and received ethics clearance through the HSC REC A and NHS Research Ethics Committee.

1. **Who is organising and who isfunding/commissioning the study?**

The investigation has been competitively awarded through a PhD studentship at Liverpool John Moores University.

1. **Whom do I contact if I have a concern about the study or I wish to complain?**

If you have a concern about any aspect of this study, please contact *Jessica Brown* at *J.Brown@2022.ljmu.ac.uk.* Alternatively, please contact the supervisor of the study, *Dr Lisa Newson* at *L.M.Newson@ljmu.ac.uk* and we will do our best to answer your query. You should expect a reply within 10 working days. If you remain unhappy or wish to make a formal complaint, please contact the Chair of the Research Ethics Committee at Liverpool John Moores University who will seek to resolve the matter as soon as possible:

Chair, Liverpool John Moores University Research Ethics Committee; Email: [FullReviewUREC@ljmu.ac.uk](mailto:FullReviewUREC@ljmu.ac.uk); Tel: 0151 231 2121; Research Innovation Services, Liverpool John Moores University, Exchange Station, Liverpool L2 2QP

If you are a patient of the Healthier South Wirral Primary Care Network and wish to raise a concern please do so by visiting the website and visit the ‘Contact Us’ page - <https://healthiersouthwirralpcn.co.uk/contact-us/> or if your query is urgent please contact your practice directly.

1. **Data Protection**

Liverpool John Moores University (LJMU) is the data controller with respect to your personal data. LJMU Data Protection Officer can be contacted at DPO@ljmu.ac.uk.

LJMU takes your privacy very seriously. This privacy notice explains how we use your personal information and your rights regarding that information. The information we hold and process will be used for management and administrative purposes only, to enable us to manage our relationship with you effectively and lawfully whilst you are working with us and after your duties have been completed. Your personal data will be processed in accordance with the Data Protection Act 2018 and the General Data Protection Regulation 2016/679 (GDPR).

If you take part in this research, we will need to know your name and contact details so that you can be contacted about attending the focus group and if decided to ‘opt in’ to be contacted again about future studies. Investigators will always make sure that as few people as possible can see this sort of information that can show who you are.

The University will collect and process your personal data for the purpose of research. Data Protection laws allow us to use personal data for research with appropriate safeguards in place. The lawful basis is Article 6(1)(e) – processing that is necessary for the performance of public tasks that are in the public interest and Article 9(2)(j) – processing that is necessary for scientific research purposes.

To communicate our research to the public and the academic community your anonymised data is likely to form part of a research publication or conference presentation or public talk. The privacy of your personal data is paramount and will not be disclosed unless there is a justified purpose for doing so.

We are committed to being transparent about how we collect and use your data and to meeting our data protection obligations. Information about your rights with respect to your personal data is available from:

* <https://www.ljmu.ac.uk/legal/privacy-and-cookies/external-stakeholders-privacy-policy/research-participants-privacy-notice>
* https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/transparency-wording-for-all-sponsors/.
* [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
* our leaflet available from [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)
* by asking one of the study team or contacting us using the information below

1. **Contact details**

Principal Investigator: *Jessica Brown*

Supervisor Name: *Dr Lisa Newson*

LJMU Email address: *l.m.newson@ljmu.ac.uk*