Participant Information Sheet

Study Title: A qualitative study of the feasibility of diabetes technology in Wolfram syndrome

Investigators: Dr. Josephine Elliott, Dr Felicity Boardman, Professor Tim Barrett, Dr Renuka Dias

Introduction

You are invited to take part in a research study. Before you decide whether or not you want to take part, you need to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully. Talk to others about the study if you wish.

(Part 1 tells you about the study and what will happen if you take part. Part 2 gives you more detailed information about the conduct of the study).

Please ask us if there is anything that is not clear or if you would like more information.

PART 1

What is the study about?

Wolfram syndrome is a very rare condition, characterised by diabetes insipidus, insulin-dependent diabetes and optic atrophy. In recent years, technology for helping to manage type 1 diabetes mellitus has rapidly advanced and led to improvement in glucose control for patients with type 1 diabetes, however, there is little information published about whether Wolfram-associated insulin-dependent diabetes has also benefited from new technology for diabetes, such as glucose sensors and insulin pumps. This study is therefore about asking patients with Wolfram syndrome how they manage their Wolfram-associated insulin-dependent diabetes and specifically whether they have found any diabetes technology useful in improving their glucose control and/or quality of life.

Data collection will be in two forms, an online survey and an interview to explore your views and experiences on managing your (or your child's) Wolfram-associated insulin-dependent diabetes. You can choose to do both the survey and interview, or just the survey. The survey is online via

Microsoft forms and is designed to take about 10 minutes. Interviews will take place via video-call on Microsoft Teams about aim to last about 30-60 minutes. Participants can choose to have their camera turned off throughout the call. All data gathered from surveys and interviews will be anonymised before sharing the results of the study.

The data from these interviews will be analysed to look for common and/or important themes. These themes will tell us the sorts of things people living with Wolfram syndrome think are important in relation to their insulin-dependent diabetes and how we can better support them in their diabetes care.

Understanding more about what patients find useful or challenging in their diabetes management will help us to better support our patients. If technology such as glucose sensors are found to be useful, we can also use this data to advocate for funding for patients to be able to access glucose sensors.

Why have I been asked to take part?

You are being asked to participate as you either have Wolfram syndrome yourself and are 18 years old or older, or you are the carer or family member of someone who has a diagnosis of Wolfram syndrome and is under 18 years old or does not have the capacity to complete the survey/interview themselves. If you are under 18 years old, you can still take part but will need your parent or guardian to complete the online survey on your behalf (via the parent/carers' survey link) and, if you would like to take part in the interviews, you will need a parent or guardian to sign the consent form to take part and your parent or guardian will need to be present during the interview.

Do I have to take part?

It's entirely up to you to decide. If you choose to participate in the interview, you will be asked to sign a consent form to confirm that you have agreed to take part prior to the interview starting.

For both the survey and interview, you will be free to withdraw at any time until 1st June 2026, without giving a reason and this will not affect your usual healthcare in anyway.

What will happen to me if I take part?

If you choose to participate in the online survey, we will ask you to tick a box at the start to confirm that you have read this participant information sheet and agree to take part. This survey will be anonymous unless you choose to share your name and phone number to be contacted for an interview.

If you would like to take part in the survey, please complete the online google docs survey through the relevant below link.

For patients 18 years old or older:
https://forms.cloud.microsoft/e/N2gRygaxVh

For parents/carers:
https://forms.cloud.microsoft/e/LVfg1PZeAH

The interviews will happen online via a Microsoft Teams video-call at a time convenient for you. Before the interview takes place, you will be required to sign a consent form stating your agreement to participate in the research. The interview will be recorded and last approximately 30 to 60 minutes. After the interview is complete, it will be typed up word-for-word (transcribed) and you will be given the opportunity to check over the resulting text (transcript) to make sure it is accurate, but this is not essential. If you would like to check your transcript, we can adjust the font, contrast and spacing of the transcript, or the transcript can be read to you by a member of our research team, if required. You may choose to have a relative, friend, interpreter or carer to assist you with transcript checking if you'd like to do this or use text to speech technology.

What are the possible disadvantages risks, and/or discomforts of taking part in this study?

Some people might find talking to a researcher about their experiences with Wolfram syndrome and their views about their diabetes management distressing, even if they did not expect to. If you feel distressed during your interview, please tell the researcher and your interview can be paused, or you may want to end the interview. You may also direct the interview to topic areas that you are happy to discuss and skip over those that you are not. Should you feel that the interview brings up issues related to Wolfram syndrome that are difficult for you, please discuss these with the clinician who manages your care, or alternatively, your GP (who will both have been informed that you are taking part in this study).

What are the possible benefits of taking part in this study?

This research will contribute to an understanding of the experiences of people living with Wolfram syndrome and how they feel about managing their insulin-dependent diabetes. Understanding what helps people with Wolfram syndrome to manage your diabetes will help us to better support patients as their clinicians, including advocating for glucose sensors and/or insulin pumps, if these are felt to be useful to patients.

Expenses and payments

There will be no costs incurred for taking part. There are no financial incentives to participate in an interview.

Will my taking part be kept confidential?

Yes. We will follow strict ethical and legal practice and all information about you will be handled in confidence. Further details are included in Part 2.

This concludes Part 1.

If the information in Part 1 has interested you and you are considering participating, please read the information in Part 2 before making a decision.

PART 2

Who is organising and funding the study?

This research is being organised by a researcher at University of Birmingham, Dr Josephine Elliott. There is no specific funding for this project.

This project has been approved by the University of Birmingham research ethics board.

What will happen if I don't want to carry on being part of the study?

Participation in this study is entirely voluntary. Refusal to participate will not affect you in any way. If you decide to take part in the study, you will need to sign a consent form, which states that you have given your consent to participate.

If you agree to participate, you may nevertheless withdraw from the study at any time until 1st June 2026 without affecting you in any way.

You have the right to withdraw from the study completely and decline any further contact by study staff after you withdraw.

Withdrawal from the study will not in any way affect any support you receive from your clinical team.

Will my taking part be kept confidential?

We will collect personal information of the name and age of the person with Wolfram syndrome taking part in the study, their medical history, their diabetes management, and an email address or phone number to contact you during the study.

Your data will be treated as strictly confidential in line with the Data Protection Act, 1998. Your name and contact details for the interview will be kept securely in an encrypted folder, and these personal details will be destroyed immediately after the interviews are transcribed and hence anonymised.

Your interview recording will be stored in a University of Birmingham secure password-protected server. Once the study has ended, all names and identifiers will be removed or disguised to protect your identity, and your transcript will be stored on a password protected file. All audio recordings and patient details of the interviews will be destroyed after transcription.

What will happen to the results of the study?

The results of this study will be shared via the Wolfram syndrome UK newsletter, published in academic journals, presented at academic and patient conferences and a report on the results will also be sent to all participants who wish to receive one. All patient and family/carer details will be anonymised prior to dissemination of results.

What will happen when the study ends?

Once the study has ended, your contact details and name will be destroyed. However, the anonymised transcripts (with all names and identifying information removed) will be archived on the Birmingham Environment for Academic Research (BEAR) secure server for up to 10 years, so that, in the future, other researchers may analyse the data. You will have the option to refuse the archiving of your interview transcript.

What if I want more information about the study?

If you have any questions about any aspect of the study or your participation in it that are not answered by this participant information sheet, please contact:

wolfram.diabetes.research@gmail.com

You can learn more about patient support for Wolfram syndrome at the Wolfram syndrome UK charity website:

https://wolframsyndrome.co.uk

Thank you for taking the time to read this participation information leaflet.