

Your SAY

Hypoglycaemia

Participant Information Sheet

Thank you for your interest in taking part in the “Your SAY (Self-management And You): Hypoglycaemia” study.

This study is about your experiences with hypoglycaemia (also called “low blood glucose” or “low blood sugar”) and your quality of life. We are interested in how the actual episodes of hypoglycaemia as well as thoughts or fears about hypoglycaemia affect your quality of life. We want to better understand the impact of hypoglycaemia on people with diabetes and their partners, so that we can improve support for these people.

Before you decide if you would like to take part, please read through and save a copy of this Participant Information Sheet. Then, if you are happy to take part, please return to the **survey** and confirm that you have read and understood the information below.

Who is running the study?

This study is part of the Hypo-RESOLVE project (www.hypo-resolve.eu), and is led by a team of researchers from:

- The University of Southern Denmark (SDU) in Odense, Denmark – Prof Frans Pouwer, Dr Melanie Broadley, Hannah Chatwin, Manon Coolen, Mette Valdersdorf Jensen, Kevin Matlock, and Uffe Søholm
- The Australian Centre for Behavioural Research in Diabetes (ACBRD), a partnership between Diabetes Victoria and Deakin University, in Melbourne, Australia – Prof Jane Speight and Dr Christel Hendrieckx

Professor Frans Pouwer is the lead for this survey and takes responsibility for this study.

What does the study involve?

Taking part in this study involves filling out an online survey on your computer, tablet or smartphone. It takes approximately 30 minutes.

“Your SAY: Hypoglycaemia” invites you to have your say and think about *how* hypoglycemia affects your quality of life. With this study, we are trying to see whether it matters how we ask about quality of life. Some of the items may seem similar, but each questionnaire asks you to think about quality of life in a different way. Once you begin the survey, you will be asked a few questions about your age, gender, living situation, employment, and other similar questions. Then, you will be asked about your/your partner’s diabetes, your quality of life, your experiences with hypoglycaemia, your feelings about hypoglycaemia, and your emotional well-being.

Completing the survey confirms that you have read this Information Sheet and agree to take part in this study. If you are below 18 years of age, please show this Information Sheet to your parent(s) and discuss your participation with them before deciding to take part in this study.

Are there any risks?

There are no foreseeable risks associated with you taking part in this study. There will be no medical or blood tests involved. You will only be asked to answer questions on your computer, tablet, or smartphone.

While we don’t think you will be upset by the survey questions, thinking about your experiences of living with diabetes and hypoglycemia might cause some people to feel discomfort. If you do begin to feel any negative emotions, please save your place in the survey and exit. We encourage you to talk about these feelings with a family member, friend, or health professional as soon as possible. You can also visit the following links to find free emotional support in your country:

- <https://www.7cups.com>
- <https://www.befrienders.org>
- <https://www.therapyroute.com>

If filling out this survey makes you concerned about your diabetes and its management, you could talk about this with your diabetes team. You could also call the helpline for the diabetes organization where you live.

Who can I contact about this study?

Please email the Study Team if you want to talk about this survey more before deciding whether to participate, or if you have any questions or comments about the study.

Email: sduhypoteam@gmail.com

If you have any complaints about any part of the study, the way it is being conducted, or any questions about your rights as a participant, you can contact the Research Ethics Coordinator at SDU Research & Innovation Organization.

Telephone: +45 65 50 20 22

Email: sdu-rio@sdu.dk

If you have any questions about data protection and your rights as a data subject, you can contact the Data Protection Officer, Simon Kamber.

Telephone: +45 65 50 39 06

Email: dpo@sdu.dk



Who can take part?

To take part in this study, you must:

- Be aged 16 or above
- Be willing and able to complete the survey in English
- Be one of the following:
 - Diagnosed with type 1 diabetes for at least 6 months
 - Diagnosed with type 2 diabetes and using insulin for at least 6 months
 - in a relationship and living with a person who is.

Can I leave the study at any time?

You do not have to take part in this study. Choosing not to take part will not affect your relationship with SDU or other institutions in the Hypo-RESOLVE Study. If you do take part, you can stop completing the survey at any time without giving a reason. However, your answers up until that point will be saved, so we will be unable to delete your data. This is because we do not collect any of your identifying information (e.g., your name), so we are not able to find and remove your data.

Are there any benefits for me personally?

There are no specific benefits to you, but people take part in surveys like this for many reasons:

- Some people find the questions interesting. Taking part offers you a chance to think about diabetes, hypoglycaemia, your well-being, and how these affect your quality of life.
- Other people take part to help researchers to understand more about how diabetes and hypoglycemia affect people’s lives and how to help other people with diabetes.

Does the survey ask for my contact or personal details?

You do not need to give your name or contact details for this study, so no-one can identify you from your answers to the questions. Some questions may seem personal, e.g., about your age and income. These questions are included to help us describe the people who take part. When we write the report for this study, we will only talk about the average age of people who took part. Your personal information will not be used to identify you.

What will happen to my information?

This survey is hosted online via the University of Southern Denmark (SDU), using Qualtrics (an online survey software). All survey responses will be kept in a password-protected file on the SDU server. Once we have closed the survey, data will be stored in secure SDU computer files that can be used only by our research team. A copy of the data may be shared with our research colleagues at Hypo-RESOLVE partnering institutions, where the data will be stored on their password-protected computers. In accordance with EU laws, all data may be kept in anonymized form for up to 10 years after the study has ended and then deleted completely.

Your answers to the survey will be analyzed together with those from other people taking part in the “Your SAY: Hypoglycaemia” study. The overall results of the study will be published in academic journals, diabetes magazines and newsletters and presented at conferences and other research meetings.

Has this study been approved by an Ethics Committee?

Yes. Approval to conduct this study has been given by the SDU Research Ethics Committee (Case No. 21/8758) in Odense, Denmark.

www.hypo-resolve.eu/haveyoursay



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