

Participant information for participation in the observational study

The effects of an online-based glucose stabilization health promotion programme via mobile app on cognitive performance and health-related quality of life.

Dear participant!

We invite you to participate in the above-mentioned observational study. You will be informed about this in a detailed conversation via video phone call.

Your participation in this study is voluntary. You may withdraw from the study at any time without giving any reason. Refusal to participate or early withdrawal from this study will not adversely affect your medical care. All questionnaires are available in English.

Observational studies are studies that usually record and analyze only data that occur in the course of normal patient care. In some cases, additional non-incriminating tests or interviews may be performed. In no case will your intended treatment be changed as a result of your participation in the study. Observational studies are necessary to gain additional knowledge about already proven medical procedures. The purely online-based implementation offers maximum flexibility and the possibility to record your actual life circumstances.

The responsible ethics committee has issued a favorable opinion on this observational study, as well as on the subject information and consent form.

1. What is the purpose of this study?

The purpose of this 30-day study is to investigate whether an online app-based education and training programme while wearing a continuous glucose monitor (CGM) for four weeks successfully supports you to establish healthy daily habits to achieve a stable glucose status and thus improve your physical, psychological and social well-being and cognitive performance. This study is conducted in cooperation with Roots Health GmbH (with their smartphone app HELLO INSIDE).

2. How does the observational study work?

The study will be conducted purely online. The planned study duration is 30 days. You will be interviewed via an online questionnaire at the beginning (day 1-3), middle (day 15) and end (day 28-30) of the study. All questionnaires will be in English. Cognitive performance assessment needs to be performed in your native language.

You will be asked to participate in a virtual onboarding session and to enter online-based information on body measurements and complete questionnaires or assessments to record your cognitive performance on the study days mentioned below. In addition, you will be asked to enter lifestyle events, such as diet, exercise and mood, using a smartphone application. The exact contents per study day are as follows:

The following information will be collected and assessed

- Your **Blood Glucose Parameter** will be assessed via Continuous Glucose Measuring (CGM).
- You will collect your **Body Measurement (Height, Weight, Hip and Waist Circumference)** by yourself at home and add the data to an online questionnaire.
- Your **Cognitive Performance** will be assessed via online assessment. The domains attention, working memory, short term memory and reaction time will be tested.
- Your **Quality of Life, Lifestyle, Nutritional Habits and Wellbeing** will be assessed via online-based questionnaires.
- Your daily **Food-, Movement- and Mood (lifestyle events)** data will be logged in the HELLO INSIDE Smartphone App.

The events per study date are the following:

Study day	Content
1-3	<ul style="list-style-type: none"> • Start of the study, through virtual training & education (recorded online, 30 minutes): <ul style="list-style-type: none"> - eConsent, FAQ and next steps - Sensor application - App installation with download and start of the HELLO INSIDE App - Starting the educational program <p>You will also be asked to share your body measurements on an online platform.</p> <p>As a final step you will answer a questionnaire that should take no longer than 30 minutes on the topics of lifestyle, nutrition, quality of life and cognition.</p>
4-14	<ul style="list-style-type: none"> • You'll be focusing on using your CGM and logging lifestyle events, cognitive and mental well-being in the Hello Inside app. • You will be able to use the online educational program every day.
15	<ul style="list-style-type: none"> • This is the day when you'll change your biosensor yourself. You will be able to review the procedure of how to change it online. on (5 min) • Repetition of the lifestyle questionnaire (online, 5 minutes)

16-27	<ul style="list-style-type: none"> ● You will be focusing on using your CGM and logging lifestyle events, cognitive and mental well-being in the Hello Inside app. ● Daily use of online programme (educational content), 15 minutes per day
28-30	<p>Repeat</p> <ul style="list-style-type: none"> ● Enter your body measurements (online, 5 minutes) ● Completion of questionnaires & assessments covering the topics of: lifestyle, nutrition, quality of life, cognition ● Study completion

3. What is the benefit of participating in the observational study?

By participating in the study, you will receive information about the connection between your cognitive performance and fluctuations in blood glucose levels. Together with the information provided by the HELLO INSIDE app, this may help you in the future to design your diet even better to support your performance. The immediate and tailored feedback on diet, exercise and other lifestyle factors via the guided online program can also support the achievement and maintenance of a healthy lifestyle.

4. Are there risks, complaints and side effects?

No.

5. In what way will the data collected in this observational study be used?

Unless otherwise provided by law, only the study physicians and their staff have access to the confidential data in which you are named ("personal" data). Furthermore, if necessary, representatives of domestic and foreign health authorities, the responsible ethics committee and persons who have been commissioned by the study director and/or the study sponsor to control the data quality may inspect these data in order to verify the accuracy of the records. These persons are bound to secrecy.

The data will only be passed on for statistical purposes and you will not be mentioned by name without exception. You will also not be named in any scientific publications of the data from this study.

The provisions of the Data Protection Act in its current version will be observed.

6. Opportunity to discuss further questions

If you have any further questions in connection with this study, please do not hesitate to contact your study doctor and her staff.

Name of contact person: Dr Anne Latz

Reachable at all times at: research@helloinside.com