

Participant Information for the OBH Sense360 pilot study

Please read the following information carefully:

This study is a non-commercial research study funded by Innovate UK and Outcomes Based Healthcare. Taking part in this pilot research study is voluntary. If you decide to take part you must consent in the Sense360 app by clicking "Join study". We will send you a copy of this participant information sheet and the consent form to your email address.

Why is this study being done?

To help manage your diabetes it is important to know how your condition impacts your life, such as your quality of life and other outcomes that matter to you. These outcomes such as quality of life are currently only sporadically measured by long paper questionnaires. This study aims to find a more accurate way of measuring your quality of life and other outcomes through how you use and interact with your smartphone. To work this out, we will ask you to complete daily questionnaires about how diabetes affects your life, and compare this with data from your smartphone sensors.

What will happen in the study?

The study requires you to use the OBHSense360 smartphone app to answer survey questions. You will not be required to perform any other tasks, or any tasks related to your diabetes.

You need to have a smartphone operating **Android version 4.1** or later and at least **75MB** memory available.

The app will take you through the consent process and ask for your name and email address, you can download a copy of the completed consent document from the "About" page in the app menu. If you decide not to take part this data will be deleted. If you do take part, this data will **not** be associated with any other data gathered during the study.

The study lasts 28 days and there will be 18 questions every day. These should take about 5 minutes to complete, and you can choose to receive a reminder at a convenient time. There will also be a weekly set of 18 questions.

The app uses your smartphone's built-in sensors to track of your activity and smartphone usage.

It collects data on:

- **Movement** (accelerometer, gyroscope, step counter, proximity, rotation, Geomagnetic rotation, GPS location, nearest cell tower)
- **Smartphone usage** (smartphone type, android version, smartphone hardware, apps installed, apps currently running, battery status, screen unlocks, bluetooth connections, Wifi connections)
- **Environment** (light, screen pressure)
- **Communication** (number of contacts, calls, SMS sent/received; number of videos, photos and audio recordings taken; number of browser searches; number of browser bookmarks)

The app cannot detect or record the *content* of any communications, internet searches or media on the phone. Location will be used for distance travelled, not to identify places you visit.

Please carry your smartphone on you as much as possible (eg. in your pocket, and near you when you sleep) and complete as many daily questions as you can to help the accuracy of the study. The app uploads data over WiFi. If you have not connected to WiFi for 1 week you will be asked if you want to upload data via your mobile network.

Once we have analysed the data, we will send you your personal report from your questionnaire answers which may give you an interesting insight into your diabetes.

What are the risks and inconveniences from being in this research study?

This study does not involve testing any new drugs or therapies, or make any suggestions or changes to diabetes treatment so we do not expect any medical effects from taking part. Do not use the app while driving or doing any activities that could result in injury. There is a small risk of an unforeseen data

breach, however OBH and all partners comply fully with the Data Protection Act so this risk is considered minimal.

What are the benefits of being in this research study?

By taking the daily questionnaire and reviewing your final report you may get a better insight into how diabetes affects your life. Taking part may ultimately benefit everyone with diabetes. This is a pilot study, but we plan to conduct more research to improve the measurement of the outcomes that matter to you.

Will taking part affect my care?

No. Your decision to participate or not will not change the care you get in any way. This is a pilot research study and no data from it will inform the healthcare system.

What if I want to stop taking part?

You can leave the study at any time, by clicking 'Withdraw' in the side navigation bar or contacting the research group at hello@obhsense360.com. Your decision will not result in any penalties or affect your diabetes care. You can choose to delete the app and all your data. If you do not complete the 28-day study, both the sensor data and the questionnaire data will be deleted permanently.

Will I be paid to take part?

No. There is no compensation or payment for taking part in this study.

How will you protect my privacy?

We have taken care to avoid using your personal information in any notifications that appear on the lock screen of your phone. Your identity (name, email and any personally identifying information) will be stored separately from your app data. The app data will be anonymised and researchers will be unable to connect it back to individual users. The data will be encrypted using NHS recommended encryption so that others cannot interpret the data or associate it back to you. The data will be sent to secure servers maintained by Amazon Web Services (AWS) and Parse.com. Both comply with data security standards ISO27001. OBH is certified to store and process personal data securely (ICO registered and HSCIC IG toolkit level 2). Your data will never be sold or rented to third parties. The anonymised and aggregated results may be published in a research journal or presented at conferences. We will store your data for 2 years after the study to allow for full analysis and publication.

If I have questions or want to complain whom can I contact?

You can contact the study investigator team at hello@obhsense360.com

Informed Consent and Authorisation

I confirm I have read the Participant Information Sheet dated January 2016 for the above study. I have had the opportunity to consider the information and have no further questions.

I understand taking part is voluntary and I am free to withdraw at any time without giving reason. My medical care or legal rights will not be affected.

I understand data collected during the study may be looked at by researchers from Outcomes Based Healthcare where it is relevant to the research. I give permission for these individuals to have access to the data collected from my smartphone.

I agree to take part in the above study.