

Participant Information Sheet

Study Title: Do-It-Yourself Artificial Pancreas: Improving Understanding of Factors Affecting Decisions TO Use or Stop Using

Invitation to take part

You are being invited to take part in a research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the project?

An important technical innovation for type 1 diabetes therapy is the introduction of artificial pancreas systems. These systems are effective in improving glycaemic control and reducing glycaemic variability as well as user confidence in diabetes management, however only one system is currently available commercially. DIY AP systems, also known as open source, include the OpenAPS, Loop, and AndroidAPS systems. Such systems enable users to mix and match different pump and CGM devices with DIY hardware and software algorithms. Do-it yourself artificial pancreas systems are increasingly popular among people with type 1 diabetes but little is known about the factors influencing healthcare professionals' choice whether to provide support or not to patients presenting with such a system.

Why have I been chosen?

You have been chosen because you have type 1 diabetes or are the parent of a child with type 1 diabetes, who is using a DIY AP system or has used a DIY AP system in the past.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a participant agreement form. You can withdraw from participation at any time and without giving a reason. If you decide to withdraw we will usually remove any data collected about you from the study. Once the data collection activities have finished you can may still be able to withdraw your data up to the point where the data is analysed and incorporated into the research findings or outputs. At this point your data will usually become anonymous, so your identity cannot be determined, and it may not be possible to identify your data within the anonymous dataset. Withdrawing your data at this point may also adversely affect the validity and integrity of the research.

What would taking part involve?

You will be contacted by a member of the research team and asked to take part in a study where you will be invited to be interviewed, either face to face or over the phone, about use of the DIY AP system.

What are the advantages and possible disadvantages or risks of taking part?

Whilst there are no immediate benefits for those people participating in the project, it is hoped that this work will inform guideline development to clarify the role of healthcare professionals in the context of DIY AP systems.

What type of information will be sought from me and why is the collection of this information relevant for achieving the research project's objectives?

You will be asked questions about your thoughts on DIY AP systems, for example what care or support can you receive from your healthcare provider? What support you think should be provided? Who should provide that support? What are the benefits and challenges of using a DIY AP system?

Will I be recorded, and how will the recorded media be used?

Yes, the interview will be recorded with your permission.

How will my information be kept?

All the information we collect about you during the course of the research will be kept strictly in accordance with current data protection legislation. Research is a task that we perform in the public interest, as part of our core function as a university. Bournemouth University (BU) is a Data Controller of your information which means that we are responsible for looking after your information and using it appropriately. BU's Research Participant Privacy Notice sets out more information about how we fulfil our responsibilities as a data controller and about your rights as an individual under the data protection legislation. We ask you to read this [Notice](#) so that you can fully understand the basis on which we will process your information.

Publication

You will not be able to be identified in any external reports or publications about the research without your specific consent. Otherwise your information will only be included in these materials in an anonymous form, i.e. you will not be identifiable.

Security and access controls

BU will hold the information we collect about you in hard copy in a secure location and on a BU password protected secure network where held electronically.

Except where it has been anonymised your personal information will be accessed and used only by appropriate, authorised individuals and when this is necessary for the purposes of the research or another purpose identified in the Privacy Notice. This may include giving access to BU staff or others responsible for monitoring and/or audit of the study, who need to ensure that the research is complying with applicable regulations.

Sharing and further use of your personal information

We will not share your personal information with any third parties. The information collected about you may be used in an anonymous form to support other research projects in the future and access to it in this form will not be restricted. It will not be possible for you to be identified from this data. Anonymised data will be added to BU's [Data Repository](#) (a central location where data is stored) and which will be publicly available.

Retention of your data

All personal data collected for the purposes of this study will be held for one year from the date of publication of the research. Although published research outputs are anonymised, we need to retain underlying data collected for the study in a non-anonymised form for a certain period to enable the research to be audited and/or to enable the research findings to be verified.

Contact for further information

If you have any questions or would like further information, please contact Prof Katharine Barnard on kbarnard@bournemouth.ac.uk

In case of complaints

Any concerns about the study should be directed to Professor Vanora Hundley, Deputy Dean for Research & Professional Practice, Health and Social Sciences, Bournemouth University by email to researchgovernance@bournemouth.ac.uk.

Finally

If you decide to take part, you will be given a copy of the information sheet and a signed participant agreement form to keep.

Thank you for considering taking part in this research project.