Study Adult Participant Information Sheet

Study Title:

Randomised controlled study to investigate the impact of mobile health (mobile app and wearables) on the engagement with prescribed airway clearance techniques in people living with primary ciliary dyskinesia (PCD).

Version Number: 1.5

Dated: 21 November 2023

Sponsor: Aparito Ltd

Study Investigator: Dr Elin Haf Davies

Aparito

Unit 11 Gwenfro, Wrexham Technology Park

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Telephone Number: (+44) 01978 896191

Introduction

We would like to invite you to take part in a research project which seeks to understand whether use of physiotherapy and exercise for people with PCD can be improved using a smartphone and a wearable device (Garmin Vivosmart® 5 activity tracker).

This information sheet will give you more information about this study. Please contact us to ask as many questions as you like before you decide if you want to take part in the study. Do not sign this form if you have any questions that have not been answered. If you choose to take part in this study, you need to provide an electronic signature to confirm that you understand the study requirements and agree for you to participate. You will receive a copy of this form via email for your own records once the form has been fully signed.

What are we aiming to do?

The aim of the study is to test the value of a smartphone app and the activity tracker to improve your engagement and adherence with your physiotherapy routine, as recommended by your physiotherapist.

It also aims to detect changes in your quality of life and lung infections over the course of the study. The data captured through the activity tracker, such as the heart rate, the step count and the time spent being active will help us understand whether they could be used to predict a lung infection and to obtain information about lifestyle changes (e.g., exercise).

The study aims to explore if digital technology could help support people living with PCD to carry out their daily airway clearance/physiotherapy routine and help with the formation of good habits related with airway clearance. You will receive reminders about carrying out physiotherapy, and also rewards (e.g. digital bronze, silver and gold badges) for reaching certain goals.

The data that will be collected through the app and the wearables will be analysed by data scientists working at Aparito and peer reviewed by an independent data safety group which includes healthcare professionals from the UK and volunteers from the PCD Support Group.

In this study there will be two groups. Study participants will be randomly allocated to each group.

Group one will **only** use a study specific app to support their daily physiotherapy activities. Group two will use a study specific app to support their daily physiotherapy activities **and** a Garmin wearable device.

Randomization means that people will be allocated to each group purely by chance.

You will also be asked to answer questions about your well-being, engagement with your physiotherapy and the occurrence of lung infections. This will involve answering questionnaires.

How long will the study last and how many people will be in the study

Participants will be approached and recruited for this study over a period of two months. A total of 88 participants will be recruited and followed up for 12 weeks.

There will be an optional extension study for an additional 12 weeks, making the maximum study duration of 24 weeks (6 months). If you were initially randomised to use the specific study app only, but you consent to participate in the extension phase, you will receive a Garmin wearable device to be used along the study app for these additional 12 weeks.

What will we be asking you to do during this study?

Screening:

Before the study starts you will be asked to answer some questions to determine whether you are eligible to participate in the study. During the screening, you will be asked questions regarding your age, age at diagnosis of PCD and current health state.

You will also be asked to provide a proof of PCD diagnosis, such as a letter from your specialist centre, and genetic information, if available. The proof of diagnosis will only be reviewed by healthcare staff appointed on behalf of PCD Support UK to determine if you are eligible for the study. It will be destroyed afterwards.

Consent:

If you are eligible to participate, you will sign an electronic consent form to say that you agree to take part. Once you agree to take part you will also be asked to give your gender, month and year of birth (but not the actual day).

Study procedures:

After you've signed the consent form you will be given instructions on how to download the app on your smartphone.

If you are assigned to be part of the wearable group, you will receive a Garmin Vivosmart®5 wrist-worn wearable posted to your home address. You will need to provide your postal address for this.

If you are not assigned to use the wearable, you will be asked to just continue using the app.

You will be asked to complete some questionnaires regarding the physiotherapy routine that has been recommended by your physiotherapist and the occurrence of lung infections in the 3 months prior to the beginning of the study.

You will also be asked to complete an outcome measure called QoL-PCD, which assesses the impact of PCD on your quality of life, and another one called Patient Health Engagement scale, which aims to determine your engagement in the management of your own health care.

The time taken to engage with the app and /or wearable will approximately be:

- 10 minutes for consent and on boarding
- 5 minutes to set up the Garmin wearable if you are randomised to have one
- 2-3 minutes daily thereafter

Your wellbeing is really important to us. In order for you to have the best possible experience, we ask that you please :

- Consider your ability to provide full commitment to the study
- Follow the study directions as carefully as possible
- Tell us of any technical problems you may have
- Contact us to ask questions as you think of them
- Tell us if you change your mind about staying in the study.

University of Southampton sub-study

A related qualitative research study that will explore engagement with the mHealth devices will be conducted by Ben Ainsworth PhD, Associate Professor at the University of Southampton. You may be contacted to see if you wish to participate in a qualitative interview with researchers from the University of Southampton. If you agree, we will pass on your email address to their research team who will contact you to arrange a 1-hour interview on your engagement with the features of the PCD-ENGAGE study app.

In addition, your anonymised data related to compliance with the study procedures (e.g. compliance with responding questionnaires/diaries) will be shared via secure data transfer.

What are the risks?

To the best of our knowledge, the things you will be doing in this study have no more risk of harm than the risks of everyday life. Please only perform the physiotherapy and exercise that you have been trained to do and that have been recommended by your physiotherapist and that you consider safe to take.

You may share any concerns you have with Aparito study staff Dr Elin Haf Davies via elin@aparito.com or 01978896191.

Will this project benefit me?

This study may not help you, but the information we get might help other people living with PCD in the future. However, this study may help you develop new routines that support your physiotherapy, and it may help you build a realistic picture of your engagement with exercise, physiotherapy and the number of infections you have.

What are the alternatives to participating in this study?

This study is for research purposes only and will not replace any support or care that you may be receiving.

Will my personal details be kept safe?

Aparito Ltd is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. As a Health Technology Company, Aparito Ltd has a legitimate interest processing your personal data under GDPR (General Data Protection Regulation (EU) 2016/679).

This means that we are responsible for looking after your information and using it properly. Aparito will keep identifiable information about you for 7 years after the study has finished. Aparito Ltd will use your data collected in the course of the research study in the ways needed to conduct and analyse the outcomes of the study.

How will we use information about you?

We will need to use information from you and your medical records for this research project.

This information will include your:

- Age (year and month of birth)
- Gender
- Contact Details
- Year of Diagnosis (and proof of diagnosis)

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Once you have been screened, you will be assigned a study number, this is called pseudonymisation and no identifiable data will be stored in the platform.

The following people will have access to your data:

- The study investigator and study staff who will conduct the research including researchers at the University of Southampton
- Others required by law to review the quality and safety of research.

Pseudo-anonymised and aggregate data will be used for scientific journals where the data is published or at scientific conferences where the data may be presented.

We may also share pseudo-anonymised and aggregate data with biotech and/or pharmaceutical companies that are undertaking research in PCD.

Your data and your child's data will be kept in a secure location in the UK (on Microsoft Azure cloud) until the data are destroyed.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by reading the accompanying GDPR Participant Information Sheet

If you want to be explained more about how your information is handled, you should contact the research team or the Aparito Ltd Data Protection Officer], Mr Chris Frost (raqa@aparito.com). If you are not happy with their response or believe they are processing your data in a way that is not right or lawful, you can complain to the information Commissioner's Office (ICO) (www.ico.org.uk) or 0303 123 1113.

Do I have to take part in the study?

No, you don't have to take part as the study is completely optional. You may not want to be in this study, or you may leave the study at any time without having to give a reason.

If you choose to leave the study, you can also ask for all your information to be deleted and not used in the study any further.

The study investigator may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the study instructions
- If we later find out, forever reason that you should not be in the study
- If the study is stopped for any reason

If you leave the study, no more information about you will be collected for this study.

Will I get paid for taking part in the study?

You will not be paid over the course of the study however we will be providing you with one Amazon voucher of £20 as an expression of our appreciation for this study. This will be issued via the study app at the end of the study.

If you are randomly assigned to receive the Garmin Vivosmart® 5 wearable device, or if you participate in the extension study, you will be able to keep the wearable at the end of the study.

Who has reviewed this study?

This study has been reviewed by the following people and organisation:

- Volunteers via the PCD Support Group who have collaborated as part of the Patient Group Accelerator to design this study
- Physiotherapists at The Royal Brompton & Harefield N H S Trust and Leeds Teaching Hospitals NHS Trust.

- Reading Independent Ethics Committee on 30/11/2021 and amendment 12/12/2023 www.hra.nhs.uk

WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS?

If you have questions, concerns, or complaints about this study contact:
Aparito
Unit 11-12 Gwenfro
Wrexham Technology Park
Wrexham
Wales
LL13 7YP

Phone: +44 1978 896 191
Email: info@aparito.com

Alternatively please contact PCD Support UK via

PCD Support UK
PO Box 2233
Buckingham
MK18 9DX
Phone:
https://pcdsupport.org.uk/contact-us/
Email: chair@pcdsupportuk.org

You can also use the study email address: pcd-engage@aparito.com

If you require help or medical attention, please make an appointment with your GP.

Before you sign the Informed Consent Form, feel free to contact us to ask questions about anything that you do not understand. The study staff will happily answer any questions before, during and after the research study.

Thank you for taking the time to read this Participant Information Sheet.

CONSENT FORM

Please tick the boxes that you agree with:		
		TICK HERE
1.	**I confirm that I have read and understand the information provided in this document and have contacted the study staff if I had questions**	
2.	**I understand that my participation is voluntary, and we are free to stop or withdraw at any time, without giving any reason.**	
3.	**I understand that my proof of diagnosis will be reviewed by medical staff appointed on behalf of PCD Support UK and I**	

	give permission for those individuals to access the records I share.	
4.	**I understand that my health data, month and year of birth will be entered on a secure and confidential cloud database managed by Aparito Ltd and reviewed by members of the project team.**	
5.	**I also give permission for my anonymised and aggregated data to be used in scientific publications and conferences and/or other interested parties such as biotech**	
6.	**I agree to take part in this project (12 weeks)**	
7.	**I agree to take part in the extension study (additional 12 weeks, total 24 weeks)**	
8.	**I give permission to be contacted regarding the University of Southampton study and for my anonymised data to be shared with researchers at the University of Southampton**	

_____	_____	_____
Name of Study Participant	**Date**	**eSignature**