

SAPIEN

Feasibility Study

Impact of remote lifestyle coaching program on the length of stay and complications in patients undergoing elective colorectal resectional surgery

Patient Information Sheet

Version 2.3, 7 December 2021

IRAS: 302319

You have been invited to take part in a research study named SAPIEN. Before you decide if you would like to be involved, we would like to explain why this research is being done and what it will involve.

Please read this information carefully and discuss it with others if you wish to. You can take as much time as you need to make this decision and if you have any questions please contact us (our contact information is at the end of this document).

Portsmouth Hospitals University NHS Trust is the sponsor for this study, which means we are responsible for the study and how your data is protected. Sapien Health are funding this study. This will not influence the results of the study.

What is the purpose of the study?

This study aims to assess the role of Sapien Health's lifestyle coaching mobile app in supporting patients to make positive changes to their health before and after surgery. The Sapien Health app is a mobile health coaching application that uses personalised educational programs and remote health coaching with a qualified health coach to support patients during their operative journey. We want to find out if this app can help patients undergoing colorectal surgery to make positive health changes and improve patient's recovery after surgery.

Making positive health changes before and after surgery is widely accepted to improve patient's overall health. This can improve post-surgery outcomes and reduce the costs related to avoidable complications. In this study we want to understand patients experience using this app and will collect this information from questionnaires through the app. We want to see if using the app will help reduce patients; length of hospital stay following surgery, post-operative complications, re-admission to hospital following discharge and surgery cancellation rate. We can do this by comparing post-surgery outcomes of patients who use the Sapien Health app to those who do not.

The Sapien Health app is designed to work alongside existing pathways and you will still have access to all existing support before and after your surgery. The app can be easily downloaded onto any IOS or Android device (such as a smartphone, tablet, iPhone or iPad). Alongside the digital content on the app, you will have access to a health coach who will be able to communicate with you remotely (via the app or phone) about your health and personalised plan.

Why have I been chosen?

You are being offered the opportunity to participate in this research as you have been offered an elective bowel resection surgery and are expected to have at least 2 weeks before your surgery date.

Do I have to take part?

No, participation is entirely voluntary. If you decide you do not want to take part in this study, you will still receive the same treatment and level of care. If you choose to participate, you can withdraw at any time without reason or penalty.

What will I have to do if I take part?

If you decide to take part, we will ask you to sign an informed consent form, which can be done in person or over the telephone. With your permission, we will provide the Sapien health team with your name and contact information (name, initials, date of birth, email and phone number) so they can support you to download and use the app. The Sapien Health team will keep this information for no longer than 12 months after the study has finished.

You will have access to all the app resources and remote coaching for a minimum of 2 weeks before your surgery and up to 1 month post-surgery. We understand that immediately after your surgery you may not feel up to using the app and you are welcome to continue using the app when you feel ready. During the study the clinical team looking after you (including the research team) will collect information needed for the study from your medical records.

The app aims to improve your health by helping you:

- Be more active
- Eat better
- Reduce/stop smoking
- Drink less alcohol
- Sleep better and for longer
- Support you to be more prepared for your surgical journey.

You can choose what health improvements you want to make and your health coach will

work with you to develop your personalised plan.

Participating in this study does not change the treatment you receive in any other way. The surgeons will carry out standard surgical procedures as per their expertise. You will not have any additional medical examinations or tests and will not need to attend the hospital for any additional appointments. Participating in this study will not delay or change the date of your operation.

With your permission, we will inform your GP of your participation in this study.

What are the possible benefits and risks of taking part?

Taking part in this study will not change the treatment you receive from the clinical team caring for you and you will still have access to existing NHS pre- and post-operative support. You will be cared for by the same surgeon and receive the same high standard of care throughout your treatment pathway.

As part of the study, some patients may seek to modify their physical activity levels and mental wellbeing. For some this may increase risk of injury if they are unfamiliar with exercises and techniques utilised. There are no additional risks from using this app than you would have starting your own exercise or mental wellbeing regime independently. If you have any concerns, or are unsure, please speak to your health coach or clinical team before completing any exercises you are not confident with. You do not have to do any activities you do not want to. Additionally, if you experience any pain or light headedness while exercising, we advise you to stop and discuss this with your clinical team.

We hope that by taking part in this study and using the Sapien Health application you will be able to make some positive health changes. This may help you to improve some aspects of your health. We do not know if taking part in this study will have a benefit to you.

How will we use information about you?

We will need to use information from you and from your medical records for this research project. This information will include your name, initials, date of birth, contact details (including your phone number and email address) and NHS number. 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. Your data will have a code number instead. We will keep all information about you safe and secure.

Some of your information will be shared with the Sapien Health team. They must follow our rules about keeping your information safe. You will be allocated a unique study number to pseudo-anonymise your data. Only people who need to know who you are will be able to access your identifiable information, such as your Sapien health coach.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records and your medical notes. If you do not wish this to happen, tell us and we will stop. If you lose capacity during the course of the study, you will be withdrawn. Identifiable data collected with consent up to this point would be retained and used in the study. No further data will be collected from the point of withdrawal and no other research procedures will be carried out.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

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/, by asking one of the research team, sending an email to Bethany.Armstead@porthosp.nhs.uk or by phoning 02392 286000 x6678

Who has reviewed the study?

This study has been approved by Wales Research Ethics Committee 7.

What will happen to the results of the research study?

Results of this study will be published in medical journals. They may be used for scientific presentations and may be forwarded to health authorities worldwide. You will not be identified in any reports or publications resulting from the study. If you would like to be informed of the results, please ask your surgeon or a member of the research team. The results of the study will also be added to the SAPIEN website at the end of the study. This will be accessible to you via the link below:

<https://sapienhealth.io/portsmouthstudy>

What if there is a problem?

If you have a concern about any aspect of this study, you can speak to the researchers who

will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. To do so, you can contact the hospitals Patient Advice and Liaison Service on by telephone on number 02392 286309 or via email on PHT.PALS@porthosp.nhs.uk

Study team

If you have any questions please contact your study team.

Principal Investigator:

Prof Jim Khan

Study team:

Beth Armstead / Pedro Braga Sardo

02392 286000 x6678

Thank you for taking time to read this information sheet.