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A study to determine the feasibility and impact of using a remote (app-based) lifestyle change program to reduce the length of stay and complications after colorectal resection surgery

Submission date	**Recruitment status**	[_] Prospectively registered
19/01/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/02/2022	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
03/02/2022	Surgery	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
'Perioperative medicine' is care occurring or performed at or around the time of an operation with the intention of increasing the chances of success of the operation and shortening recovery time. The last three decades have seen a change in how we define and practice perioperative medicine. During this period, it is well established that the management of surgical patient extends beyond the hospital inpatient admission and we have seen that interventions such as pre-assessment clinics, patient information leaflets and enhanced recovery after surgery models improve both clinical and economical outcomes. However, all these lifestyle modifications not only require more time in order to be more effective, but also require a more person-centred approach.
As a solution to the above problem Sapien, a mobile app-based behavioural intervention for patients undergoing elective surgery, combines personalized digital guidance with 1-to-1 remote health coaching to help optimize patients preoperatively, and support their recovery during the postoperative phase.
The app aims to modify risk by supporting patients to:
Increase physical activity levels
Stop smoking
Reduce alcohol intake
Improve diet
Improve sleep duration and quality
Enhance preparedness for their perioperative journey

Who can participate?
Adult (over 18 years) patients undergoing elective bowel resection.

What does the study involve?
Patients will be offered remote health coaching. Patients who choose to opt in this study will be introduced to the service and receive educational materials on how to use the app. Patients who

do not wish to use Sapien will still be eligible for the standard perioperative care pathway with no changes. The intervention will be available 2-4 weeks prior to surgery and 1 month after. The data collected from these participants will be compared to data from previous patients who did not receive the intervention (comparison arm).

What are the possible benefits and risks of participating?
Participants will have access to health coaching and 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. 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.

Where is the study run from?
Portsmouth Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
September 2021 to January 2023

Who is funding the study?
Sapien Health Limited (UK)

Who is the main contact?
Professor Jim Khan, jim.khan@porthosp.nhs.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
302319

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 51187, IRAS 302319

Study information

Scientific Title
SAPIEN Feasibility Study - Impact of a remote lifestyle change program on length of stay and complications in patients undergoing elective colorectal resection

Acronym
SAPIEN Feasibility Study

Study objectives
A remote lifestyle change program can have a positive impact on the length of hospital stay and complications in patients undergoing elective colorectal resection

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/12/2021, (), ref: 21/WA/0379

Study design
Interventional non-randomized

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Colorectal cancer surgery

Interventions
This feasibility study aims to recruit 44 participants (interventional arm) into the study. These 44 participants will use the app within their peri-operative management for a minimum of 2 weeks pre-operatively. The data collected from these participants will be compared to group matched retrospective data from 44 patients (comparison arm), for these patients only the primary outcome and secondary outcomes 1, 2 and 4 will be collected by the clinical team.

The data collected by the clinical team from both arms will be anonymized before being provided to the Sapien team for analysis. Data collected by the Sapien application will be made available to the clinical team where applicable. The effects of the Sapien Health application on the primary outcome and secondary outcomes 1,2 and 4 will be evaluated by means of comparison between the ‘interventional arm’ and the ‘comparison arm’.

The data collected for the comparison arm will be anonymous, and patients will not be able to be identified from these metrics. The described metrics (length of stay, complications, hospital readmission and cancellation of surgery) are widely available measurements that are collected by NHS organisations to measure patient outcomes and cost. This data will be collected within the hospital by the clinical team with no patient specific information being included and as such consent will not be sought.

Study Duration
For the 'interventional arm' the Sapien Health application will be available for 1 to 2 months prior to surgery and for 1 month after. The exact amount of time participants utilise the Sapien Health application prior to surgery will vary with a minimum of 2 weeks pre-surgery required to make effective use of the app. Study duration for the 'control arm' will be less than 2 weeks prior to surgery and for up to 90 days post-operative to allow collection of outcomes from participants medical notes.

Intervention Type
Behavioural

Primary outcome(s)
Length of stay (days) measured using patient records at the end of the study

Key secondary outcome(s))
Measured using patient records:
1. Postoperative complications within 30-days of surgery
2. Readmission to hospital within 30 days after surgery
3. The Patient Activation Measure (PAM) at programme entry and pre-admission (before surgery). This will be done via the SAPIEN application.
4. Cancellation of surgery

Collected from participants at program entry,pre-admission (before surgery) and up to 90 days post-surgery:
5. Physical activity level measured using DASI
6. Physical fitness - Self assessment using Numerical Rating Scale 0 (Very unwell) to 10 (Very well)
7. Smoking status
8. Alcohol consumption (units per week)
9. Diet - self rated assessment using Numerical Rating Scale 0 (Very unhealthy) to 10 (Very healthy)
10. Sleep quality - self rated assessment using Numerical Rating Scale 0 (Very poor) to 10 (Very good)
11. Sleep duration - self reported sleep duration
12. Mental and emotional wellbeing - self rated assessment using Numerical Rating Scale 0 (Very unwell) to 10 (Very well)

13. Participants will be invited to take part in optional semi-structured telephone interviews at various points throughout
their programme to capture qualitative feedback that may be used to inform design changes at a later study and
enable better PPI involvement

Completion date
03/01/2023

Eligibility

Key inclusion criteria
1. Adults (>18 years) of age listed for elective bowel resection for colorectal cancer
2. Date of surgery is (or expected to be) a minimum of 2 weeks from the date of onboarding for entry into the 'interventional arm' if less, participants can be entered into the 'control arm'.
3. Access to a smartphone with Apple IOS or Android operating systems and willingness to install the Sapien Health application
4. Sufficient confidence in written and spoken English to provide informed consent and utilise the Sapien Health application

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Individuals undergoing emergency surgery
2. Pregnant or breastfeeding individuals.

Date of first enrolment
03/01/2022

Date of final enrolment
01/11/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen Alexandra Hospital
Portsmouth Hospitals University National Health Service Trust
Southwick Hill Road
Cosham

Portsmouth
United Kingdom
PO6 3LY

Sponsor information

Organisation
Portsmouth Hospitals NHS Trust

ROR
https://ror.org/009fk3b63

Funder(s)

Funder type
Industry

Funder Name
Sapien Health Limited

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version 2.3	07/12/2021	02/02/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.4	02/12/2021	02/02/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes