Portsmouth Hospitals University NHS Trust

Feasibility study

SAPIEN

Impact of a remote lifestyle coaching program on length of stay and complications in patients undergoing elective colorectal resection

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Sponsor: Portsmouth University Hospitals NHS Trust

Funder: Sapien Health

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List of abbreviations

AE- Adverse event
CI – Chief Investigator
GCP – Good Clinical Practice
NIHR – National Institute of Health Research
NHS – National Health Service
PI – Prime Investigator
PIS – Patient Information Sheet
SAE – Serious adverse event

Glossary

Laparoscopic surgery	Laparoscopy is a type of surgical procedure that allows a surgeon to access the inside of the abdomen (tummy) and pelvis without having to make large incisions in the skin
Morbidity	The condition of suffering from a disease or medical condition.
Perioperative medicine	the medical care of patients from the time of contemplation of surgery through the operative period to full recovery.
Pre-assessment clinics	An assessment of general health and fitness before surgery by carrying out various tests and investigations
Robotic surgery	Robotic surgery are types of surgical procedures that are done using robotic systems.

In this protocol patients are referred to as patients prior to entering the study the patients and are thereafter referred to as patients.

Executive summary

Sapien Health is a mobile app-based behavioural intervention for patients undergoing elective surgery. The programme combines personalised educational programmes with remote health coaching to support patients to optimise their modifiable risk factors for surgery, and support their recovery during the postoperative phase.

This study aims to assess the impact of this app on individual and population health through the modification of unhealthy lifestyle behaviours for patients undergoing elective surgery for bowel resection. It is also hoped that by facilitating the delivery of remote perioperative care, Sapien Health can play a supportive role in the NHS response to the COVID-19 pandemic.

Background and Problem

The last three decades have seen a change in how we define and practice perioperative medicine[1]. What was once considered a subspecialty of anaesthetics is now emerging as a truly integrated and multidisciplinary speciality, stretching from the point of consideration of surgery through to full recovery[2] [3].

The acknowledgement that the management of the surgical patient extends beyond the hospital inpatient admission saw pre-assessment clinics emerge as the standard of care in the 1980s and 1990s[1]. Pre-assessment clinics offered an opportunity for the screening and risk stratification of patients, comorbidity management, and targeted lifestyle modification. However, most patients are still seen too close to their surgery date for any behavioural interventions to influence outcomes[1].

The Enhanced Recovery After Surgery model (ERAS) has been instrumental in emphasising the need for an end to end approach, and its implementation has seen improvements in both clinical and financial outcomes[4]. Nevertheless, avoidable costs related to surgery remain high, with day of surgery cancellations estimated to cost the NHS £400m per year, and postoperative wound complications amounting to £980m per year[5] [6].

Encouraging patients to be more active patients in their own care before and after surgery is increasingly recognised as an opportunity to improve outcomes and reduce some of these avoidable costs[7]. This is especially true for patients undergoing major surgery, where the impact of modifiable lifestyle factors on surgical outcomes is particularly well-established[7]. Increasingly, the time before and after surgery is seen as a "teachable moment" - a window of opportunity to address unhealthy behaviours, with consequent individual and population health benefits[8].

Traditional approaches to lifestyle modification using patient information leaflets and isolated educational interventions during outpatient clinic appointments are now understood to be largely ineffective[9]. Reasons commonly cited for this include low health literacy and psychological reactance as a consequence of a failure to involve patients in the decision-making process[10] [11] [12]. For lifestyle interventions to be effective, a shared decision-making approach with active collaboration between patient and clinician is key[1] [13].

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[1] Grocott MPW, Edwards M, Mythen MG, Aronson S. Peri-operative care pathways: re-engineering care to achieve the 'triple aim'. Anaesthesia. 2019;74 Suppl 1:90-99. doi:10.1111/anae.14513

[2] Grocott MP, Pearse RM. Perioperative medicine: the future of anaesthesia? Br J Anaesth. 2012 May;108(5):723-6. doi: 10.1093/bja/aes124. PMID: 22499744.

[3] Mythen MG, Berry C, Drake S, et al. Peri-operative medicine: the pathway to better surgical care. London: Royal College of Anaesthetists, 2015

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[7] Grocott, M.P.W., Plumb, J.O., Edwards, M. et al. Re-designing the pathway to surgery: better care and added value. Perioper Med 6, 9 (2017). https://doi.org/10.1186/s13741-017-0065-4

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This need for a more person-centered approach to care is seemingly at odds with the demands of a healthcare system which faces increasingly constrained resources everyday. Physicians routinely point to time pressures as a barrier to the implementation of person-centered care, and calls have been made for the restructuring of perioperative care pathways to facilitate a more collaborative relationship between clinician and patient[7]. Moreover, the COVID-19 pandemic now presents a new challenge, with surgical waiting lists at record levels, and face-to-face care delivery no longer practicable in many cases.]

During COVID- 19 pandemic elective operating services are greatly restricted, with exception of cancer cases requiring surgical management, as advised by NHS England. Moreover, a large number of changes have been implemented during the pre-operative and intraoperative period. In order to minimize the risk of transmission. This included avoidance of face-to-face outpatient appointments, use of personal protective equipment, avoidance of leakage of air in laparoscopic and robotic surgery and reduction in the surgical staff during the operation[25].

During the post operative period, patients have an added risk to demonstrate COVID 19 symptoms, which would increase the complications rate, morbidity, mortality, and hospital stay of these patients[24]. In order to avoid that, specific pathways were implemented in order to avoid the exposure of elective patient to the virus.

In recent years, organisations such as the Centre for Perioperative Care (CPOC)[14] and the International Prehabilitation Society[15] have been important in championing a shift towards person-centered care, and a number of innovative solutions to the problem have emerged. South Tees' Prepwell project, a community-based prehabilitation program, demonstrated some impressive early results, and has received funding to support the development and expansion of the service[16]. At the same time, the ERAS+ program, born out of Manchester Royal Infirmary, has successfully demonstrated the role which technology can play in addressing the problem.

Proposed Intervention

Sapien Health is a mobile app-based behavioural intervention for patients undergoing elective surgery. The Sapien Health model combines personalised digital guidance with 1-to-1 remote health coaching to help optimise 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
- Reduced alcohol intake
- Improve diet
- Improve sleep duration and quality
- Enhance preparedness for their perioperative journey

It is hoped that by facilitating the delivery of remote perioperative care, Sapien Health application can play a role in the NHS response to the COVID-19 pandemic.

[14] https://cpoc.org.uk/ [accessed 15/01/2021]
[15] https://prehabsociety.com/ [accessed 15/01/2021]
[16] Tew GA, Bedford R, Carr E, *et al*Community-based prehabilitation before elective major surgery: the PREP-WELL quality improvement project*BMJ Open Quality* 2020;**9:**e000898. doi: 10.1136/bmjoq-2019-000898

Health coaching is a supported self-management intervention favoured as part of the NHS's Long Term Plan[17], and has been shown to be effective in improving multiple biomarkers/risk factors for ill health, reducing hospital admissions and improving health-related quality of life[18] [19]. Furthermore, its benefits are most pronounced in those of greatest health need, and it has been shown to be equally effective when administered remotely as compared with face-to-face coaching[20] [21].

The Sapien Health application works alongside existing models of care and should be seen as an augmentation of existing pathways, rather than a replacement. The programme builds on NHS England's Comprehensive Personalised Care Model[22] by supporting patients in developing the knowledge, confidence and skills to successfully prepare for and recover from surgery. Patients in need of more targeted or specialist interventions will continue to access this care via existing channels, but it is anticipated that newly unburdened hospital clinicians should be able to redistribute scarce time and resources to those of greatest health need.

The solution will be offered to surgical patients listed for elective colonic resection. Results of this initial study will inform any further plans for expansion of the service across different surgical domains and patient populations.

Aims and Objectives

This study is a feasibility study to provide evidence for the achievability of a larger multicentre study which aims to assess the effectiveness of remote health coaching to support patients in addressing modifiable risk factors for surgery through lifestyle modification and improved self-management. The evaluation will also assess the impact of the intervention with respect to clinical and operational outcomes, behavioural change and patient experience.

Outcome Measures

Primary evaluation outcome measure

The primary outcome metric used to evaluate the success of the program will be reduction in length of stay.

Secondary evaluation outcome measures include

1-Postoperative complications within 30-days of surgery,

[17] https://www.england.nhs.uk/wp-content/uploads/2020/03/health-coaching-implementation-and-quality-summary-guide.pdf [accessed 26/01/2021]
[18] https://www.betterconversation.co.uk/images/A_Better_Conversation_Resource_Guide.pdf [accessed 26/01/2021]
[19] Long H, Howells K, Peters S, Blakemore A. Does health coaching improve health-related quality of life and reduce hospital admissions in people with chronic obstructive pulmonary disease? A systematic review and meta-analysis. Br J Health Psychol. 2019 Sep;24(3):515-546. doi: 10.1111/bjhp.12366. Epub 2019 Apr 29. PMID: 31033121; PMCID: PMC6767143.
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[22] https://www.england.nhs.uk/wp-content/uploads/2019/01/universal-personalised-care.pdf [accessed 21/01/21]

2-Readmission to hospital within 30 days after surgery,

3-The Patient Activation Measure (PAM).

PAM is a validated and licensed tool that measures people's knowledge, skills and confidence in managing their own wellbeing. Evidence shows that when people are supported to become more activated, they benefit from better health outcomes, improved experiences of care and fewer unplanned care admissions[23]. PAM will be collected from participating patients at programme entry and pre-admission (before surgery).

4- Cancellation of surgery,

5- Health behaviour change.

The following secondary outcome data points will be collected from patients at program entry, pre-admission (before surgery) and up to 90 days post-surgery.

- Physical activity level
  - DASI
  - Physical fitness - Self assessment using Numerical Rating Scale 0 (Very unwell) to 10 (Very well)

- Smoking status
- Alcohol consumption (units per week)
- Diet - self rated assessment using Numerical Rating Scale 0 (Very unhealthy) to 10 (Very healthy)
- Sleep
  - Sleep quality - self rated assessment using Numerical Rating Scale 0 (Very poor) to 10 (Very good)
  - Sleep duration - self reported sleep duration

- Mental and emotional wellbeing - self rated assessment using Numerical Rating Scale 0 (Very unwell) to 10 (Very well)

Patients 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.

App engagement and adherence

[23] https://www.england.nhs.uk/wp-content/uploads/2018/04/patient-activation-measure-quick-guide.pdf [accessed 25/01/21]

[24] S. Lei, F. Jiang, W. Su, C. Chen, J. Chen, W. Mei, L.-Y. Zhan, Y. Jia, L. Zhang, D. Liu, Z.-Y. Xia, Z. Xia, Clinical characteristics, and outcomes of patients undergoing surgeries during the incubation period of COVID-19 infection, EClinicalMedicine. (2020) 100331. https://doi.org/10.1016/j.eclinm.2020.100331.

[25] Impact of the Coronavirus (COVID-19) pandemic on surgical practice - Part 1.Al-Jabir A, Kerwan A, Nicola M, Alsafi Z, Khan M, Sohrabi C, O'Neill N, Iosifidis C, Griffin M, Mathew G, Agha R.Int J Surg. 2020 Jul;79:168-179. doi: 10.1016/j.ijsu.2020.05.022. Epub 2020 May 12. PMID: 32407799

The following Sapien Health application platform metrics will be collected:

- Program completion rate - defined as the percentage of patients who complete a key action* in the final third of the program.
- Engagement rate - defined as the percentage of patients who complete a key action each week.
- Product activation rate - defined as the percentage of new patients who complete a key action within the first 7 days.

*Key actions: set a goal, track a health metric (e.g. steps or weight), consume discover content or message their coach.

Additionally, patient experience will be measured upon completion of the program by asking patients to give a numerically rated satisfaction score.

Methods

This feasibility study aims to recruit 44 patients (interventional arm) into the study. These 44 patients will use the app within their peri-operative management for at least 2 weeks pre-operative. The data collected from these patients 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 a maximum of 2 months prior to surgery and for 1 month after. The exact amount of time patients 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 patients medical notes..

Patient Identification and Recruitment

Inclusion criteria:

- Adults (>18 year) of age listed for elective bowel resection for colorectal cancer

- 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, patients can be entered into the 'control arm'.
- Access to a smart phone with Apple IOS or Android operating systems and willingness to install the Sapien Health application
- Sufficient confidence in written and spoken English to provide informed consent and utilise the Sapien Health application

Exclusion criteria:

- Individuals undergoing emergency surgery
- Pregnant or breastfeeding individuals.

Recruitment and informed consent

The study will be offered prospectively to patients undergoing elective bowel resection for colorectal cancer or benign pathology cancer. Following the decision to operate, the clinical team will identify these patients as potential patients and introduce them to the study. The patient information sheet (paper or digital) will be given to potential patients in person or remotely (via post or email).

Patients will be given sufficient time to consider their involvement and ask any questions they have. Potential patients will be clearly informed that involvement is completely voluntary, and they can decline or withdraw at any time without reason or penalty. Patients can choose to withdraw from using the app without withdrawing from the study. We will retain the data we have already collected if they withdraw and will continue to collect information from their medical records unless they ask us not to.

The Prime Investigator has overall responsibility for informed consent at their site to ensure staff listed on the delegation log are appropriately trained, experienced and competent in receiving informed consent. Informed consent will be received by an appropriately trained member of the research team who have been delegated to do so and have been signed onto the delegation log for this task by the CI/PI. Patients consenting into the comparison arm will explicitly sign that they are happy for their details (name, initials, date of birth, phone number and email address) to be passed onto the Sapien Health team. The Sapien Health team will contact patients directly to introduce them to the Sapien Health application and to give educational materials on how to use the application.

<u>In person informed consent</u>
Patients will be provided with the study information as described above. Patients are able give informed consent once they feel they have had sufficient time to consider participation, no minimum timeframe is defined as some patients may read the information and wish to consent at that time. After consent, patients will have the opportunity to further consider their involvement and withdraw either by contact with the research team or when the Sapien Health team contact them to introduce them to the application. Patients who wish to have more time to consent are able to do so and, when ready, can give informed consent remotely to prevent additional visit burden.

<u>Remote consent</u>
Remote consent can be received by witnessed verbal consent via telephone or by trust approved video call platforms. Patients will be provided (in person/ post / email) with a copy of the Patient Information

sheet (paper or digital) to read and review. The call/video must be witnessed by a member of staff at site who is not part of the study team (this may be a member of the clinical team or a research nurse from another team) who will confirm in writing that the study was explained, questions answered, time given for patients to consider and patients informed all involvement is voluntary and can withdraw at any time without penalty (this document should be signed and a copy filed in site file and patients medical notes). After remote verbal consent is received the member of the study team receiving consent will sign the consent form and clearly document the consent was performed via remote witnessed consent. The consent form is to be countersigned by the witness. The original consent form should be filed in the site file, a copy of the consent form provided to the patient (post or email) and another copy filed in the medical notes.

Safety considerations

The Sapien Health application has been designed and built-in accordance with NHS Digital Clinical Safety standards (DCB0129 and DCB0160). Dr Robbie Huddleston is the nominated Sapien Health Clinical Safety Officer and has undergone specialist training in this role. Prior to the launch of the evaluation, a Clinical Safety Case Report will be made available to Queen Alexandra Hospital. This report provides a summary of all identified hazards associated with the use of the Sapien Health application, alongside evidence of implemented risk control measures and any transfer of risk to the deploying organisation (Queen Alexandra Hospital).

Throughout the duration of the project medical safety netting will be ensured by signposting patients to contact the Queen Alexandra Hospital Team or their primary or secondary care provider as appropriate.

The Sapien Health team will have direct access to contact the Queen Alexandra Hospital Team if this is felt necessary for any patient safety concerns. Any medical treatment required will be provided by the clinical care team as per standard care.

All patients will receive the same quality of care, both on perioperative and intra operative period. For patients who increase their physical activity, by introducing unsupervised new activities or exercises, there may a small risk of injury, this risk is no greater than if they were to start their own unsupervised exercise regimes independently. Patients will be encouraged to communicate with their clinical teams if they have concerns or develop an injury.

All serious adverse events related to the app should be reported immediately to the CI and clinical team. The immediate reports should be followed promptly by detailed, written reports. The immediate and follow-up reports should identify subjects by unique code numbers assigned to the trial subjects rather than by the subjects' names, personal identification numbers, and/or addresses. The investigator should also comply with the applicable regulatory requirement(s) related to the reporting of unexpected serious adverse drug reactions to the regulatory authority. Any expected adverse events resulting from the surgery itself will not be reported.

If the trial is prematurely terminated or suspended for any reason, the investigator/institution should promptly inform the trial subjects, should assure appropriate therapy and follow-up for the subjects, and, where required by the applicable regulatory requirement(s), should inform the regulatory authority.

Data Analysis Plan

Descriptive statistical techniques will be used to assess and narratively compare the baseline characteristics of both arms (e.g. means and standard deviations, or medians and interquartiles ranges, as appropriate). In the interventional arm, trends in longitudinal measurements related to secondary outcomes 3 and 5 will be described.

For the primary analysis, the length of stay in each group will be compared using an independent samples t-test (or appropriate non-parametric counterpart if necessary on evaluation of data distributions). Event counts for secondary endpoints 1,2 and 4 may be too low to formally analyse (i.e. with Pearson's Chi-squared or Fisher's exact tests) but this will be reviewed and may form an exploratory analyses. In the interventional arm , baseline and final measurements of factors that will be repeatedly measured (e.g. secondary endpoint 5 sub-levels) will be analysed using paired sample t-tests.

An economic evaluation in the form of a simple cost analysis will also be conducted to provide an estimate of the cost-effectiveness of the Sapien Health intervention when compared with standard care at Queen Alexandra Hospital.

Data handling, Governance, and Regulatory Compliance

Sapien Health is ISO27001(Information Security) certified and meets the standards for the NHS Data Security Protection Toolkit (DSPT). This project will comply with all requirements under GDPR and NHS governance. Personal patient data required for referral to Sapien Health will be transferred between the Queen Alexandra Hospital and Sapien Health securely on NHS mail. Following initial enrolment of patients, further data shared between organisations will be anonymised and transferred against a unique patient identifier.

Sapien Health is registered with the Information Commissioner's Office. Luke Eastwood is the appointed Data Protection Officer and Dr Robbie Huddleston is the appointed Caldicott Guardian. Both staff members have the requisite training to hold these roles.

The clinical team will hold patient identifiable information on secure NHS computers in line with the Data protection Act 2018, General Data Protection Regulation 2016 and Privacy and Electronic Communication Regulations 2013.

We will permit trial-related monitoring, audits, IRB/IEC review, and regulatory inspection(s), providing direct access to source data/documents. In order to provide quality control and quality assurance we will organize monthly meetings to review the data and monitor the progress of the study. Data will be available to be audited.

Ethics

Patient Confidentiality

The study staff will ensure that the patients' anonymity is maintained. The patients will consent for their name, date of birth and contact information to be passed to Sapien Health. After this they will only be identified only by a unique patient ID number on the CRF and any electronic database. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act which requires data to be anonymised as soon as it is practical to do so.

Declaration of Helsinki

The study protocol will be carried out in accordance with the declaration of Helsinki.

ICH Guidelines for Good Clinical Practice

All research staff at each site will be checked for having up to date ICH GCP certification and will be monitored by the sponsor, Portsmouth University Hospitals, according to the risk-based monitoring plan agreed, to ensure adherence to GCP.

Dissemination of findings

Findings will be made available to Portsmouth Hospitals NHS Trust for dissemination internally and any relevant hospital communications. Data will also be presented in lay language on the Sapien Health website.
The findings will be written up as a case study and Sapien Health will seek to publish in relevant academic journals and present at conferences.

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