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Impact of a remote lifestyle coaching program on the length of hospital stay and complications in patients undergoing knee and hip arthroplasty surgery

Submission date
31/10/2022

Recruitment status
No longer recruiting

Registration date
14/11/2022

Overall study status
Completed

Last Edited
15/03/2023

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
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 knee and hip arthroplasty. 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.

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. 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.

Encouraging patients to be more active in their own care before and after surgery is increasingly recognised as an opportunity to improve outcomes and reduce some of these avoidable costs. This is especially true for patients undergoing major surgery, where the impact of modifiable lifestyle factors on surgical outcomes is particularly well-established. 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.

Traditional approaches to lifestyle modification using patient information leaflets and isolated educational interventions during outpatient clinic appointments are now understood to be largely ineffective. 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. For lifestyle interventions to be effective, a shared decision-making approach with active collaboration between patient and clinician is key.

Who can participate?
Adults aged 18 years old and over listed for elective knee and hip arthroplasty

What does the study involve?
The study will assess if using the app increases a patient's knowledge, skills and confidence in managing their own well-being. These will be measured using a questionnaire called PAM (Patient Activation Measure). Evidence shows that when people are supported to become more active, they benefit from better health outcomes, improved care experiences and fewer unplanned admissions. This study will also see if using the app helps to reduce patients' length of hospital stay following surgery, postoperative complications, re-admission to hospital following discharge and surgery cancellation rate. We will measure these things by randomly assigning half the patients who have chosen to participate in the study to use the app and comparing it against the PAM score and surgical outcome metrics of half the patients who will not use the app.

What are the possible benefits and risks of participating?
No benefits and risks were provided at registration.

Where is the study run from?
Sherwood Forest Hospitals NHS Foundation Trust, Kingsmill Hospital (UK)

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

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Rebecca Barker (UK)
rebecca.barker6@nhs.net

Contact information

Type(s)
Principal Investigator

Contact name
Dr Rebecca Barker

Contact details
Sherwood Forest Hospitals NHS Foundation Trust
Kingsmill Hospital
Sutton in Ashfield
Mansfield
Nottingham
United Kingdom

NG17 4JL
+44 (0)1623 622515
rebecca.barker6@nhs.net

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
311052

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52124, IRAS 311052

Study information

Scientific Title
Impact of a remote lifestyle change program on length of stay and complications in patients undergoing elective knee and hip arthroplasty

Acronym
SAPIEN SBRI 19

Study objectives
As a solution to patients having a remote lifestyle, 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:
1. Increase physical activity levels
2. Stop smoking
3. Reduce alcohol intake
4. Improve diet
5. Improve sleep duration and quality
6. Enhance preparedness for their perioperative journey

The study will assess if using the app increases PAM (Patient Activation Measure) score, this is a questionnaire which measures a patient's knowledge, skills and confidence in managing their own wellbeing. Evidence shows that when people are supported to become more active, they benefit from better health outcomes, improved care experiences and fewer unplanned admissions. This study will also see if using the app helps to reduce patients' length of hospital stay following surgery, postoperative complications, re-admission to hospital following discharge and surgery cancellation rate. We will measure these things by randomly assigning

half the patient population who have chosen to participate in the study use of the app and comparing it against the PAM score and surgical outcome metrics of half the population who will not use the app.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/03/2022, East Midlands - Nottingham 2 Research Ethics Committee (C/o: Carolyn Halliwell, Approvals Specialist, Equinox House, City Link, Nottingham, HRA1 Meeting Room, NG2 4LA, UK; +44 (0)207 1048098; nottingham2.rec@hra.nhs.uk), ref: 22/EM/0063

Study design
Interventional randomized controlled multicentre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Behavioural intervention for patients undergoing primary lower limb arthroplasty

Interventions
This clinical trial will randomise 200 patients to either the intervention arm (use of the app) or control (usual care.) A randomisation code will be computer generated, in permuted blocks of 10 patients and stratified according to age. The 100 patients in the interventional arm will use the app within their peri-operative management for at least 6 weeks pre-operative. The data collected from these patients will be compared to data from the 100 patients (comparison arm), for these patients only the primary outcome and secondary outcomes 1, 2, 3 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, 3 and 4 will be evaluated by means of comparison between the ‘interventional arm’ and the ‘comparison arm’.

Study Duration
For the ‘interventional arm’ the Sapien Health application will be available for a maximum of 10

weeks 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 6 weeks pre-surgery required to make effective use of the app. Study duration for the ‘control arm’ will be a maximum of 6 weeks prior to surgery and for up to 90 days post-operative to allow collection of outcomes from patients' medical notes.

Intervention Type
Behavioural

Primary outcome measure
Intervention success measured using the Patient Activation Measure (PAM) scoring at programme entry and pre-operatively (before surgery) and up to 30 days post-surgery

Secondary outcome measures
1. Postoperative complications within 30-days of surgery (pulmonary and cardiac) measured using medical records electronic and paper 30 days post-surgery
2. Readmission to the hospital within 30 days after surgery measured using an electronic database called CareFlow that sends notifications regarding research patient admissions at any time from randomisation
3. Length of stay measured using medical records and the hospital database that records admission and discharge data
4. The proportion of cancellations of surgeries measured using data collected from randomised patients and recorded on the trial database. Collected by the trial team and analysed by Sapien Health.
5. Health behaviour change measured using questionnaires provided by Sapien and recorded on REDCap. Sapien health to then analyse.

Overall study start date
23/12/2021

Completion date
01/10/2023

Eligibility

Key inclusion criteria
1. Adults aged 18 years old and over listed for elective knee and hip arthroplasty
2. Date of the surgery is (or is expected to be) a minimum of 6 weeks from the date of onboarding for the control and intervention arms
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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 200; UK Sample Size: 200

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

Date of first enrolment
29/06/2022

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sherwood Forest Hospitals NHS Foundation Trust
Kings Mill Hospital
Mansfield Road
Sutton-in-ashfield
United Kingdom
NG17 4JL

Study participating centre
Royal Berkshire NHS Foundation Trust
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

Sponsor information

Organisation
Sherwood Forest Hospitals NHS Foundation Trust

Sponsor details
C/o: Alison Steel
Sherwood Forest Hospitals NHS Foundation Trust
King's Mill Hospital
Mansfield Road
Sutton in Ashfield
Mansfield
Nottingham
United Kingdom
NG17 4JL
+44 (0)1623 622515
alison.steel1@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.sfh-tr.nhs.uk/

ROR
https://ror.org/04ce87537

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

1. Planned publication in a high-impact and peer-reviewed journal
2. Findings will be made available to Sherwood Forest Hospitals and Royal Berkshire Hospital for dissemination internally and any relevant hospital communications
3. Data will also be presented in lay language on the Sapien Health website
4. Presentation at conferences

Intention to publish date

01/04/2024

Individual participant data (IPD) sharing plan

1. Findings will be made available to Sherwood Forest Hospitals and Royal Berkshire Hospital for dissemination internally and any relevant hospital communications. Data will also be presented in lay language on the Sapien Health website.
2. 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.
3. The datasets, including the type of surgery, surgery date, postoperative complications, readmission to hospital, email address, questionnaire results and trial numbers, will be available 30 days post last patient recruited from Luke Eastwood, luke@sapienhealth.io (Sapien Health). Consent from participants was required and obtained. Data were anonymized and will be identified by the trial ID given on REDCap.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No