ISRCTN62293620 https://doi.org/10.1186/ISRCTN62293620

DREAMPath – A prospective observational study to measure patient compliance with remote monitoring following discharge from hospital after major surgery

Submission date
29/03/2019

Recruitment status
No longer recruiting

Registration date
05/04/2019

Overall study status
Completed

Last Edited
07/04/2022

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
DREAM Path is a study assessing acceptability of remote monitoring, in a group of patients undergoing major surgery. The purpose of the DREAM Path study is to evaluate how well patients comply with the use of a group of smart devices to fill out questionnaires and self-measure clinical observations. We will also evaluate if remote monitoring using questionnaires and clinical observations has a relationship with hospital admissions.
We are investigating whether patients will be able to use simple devices to measure clinical observations and fill out questionnaires after going home following major surgery. A set of devices used together will be referred to as the Home And Locally Observed (HALO) kit.
Patients who go home after major surgery are often at risk of complications after discharge from hospital, and usually present to their GP or hospital if they feel unwell. In DREAM Path, we will be testing if patients will be able to use a number of devices to self-measure the observations we usually take in hospital wards, and fill out a short questionnaire. We will also be exploring whether data we collect from these self-measurements has any link with hospital re-admissions or unplanned GP visits. All recordings will be anonymised to maintain your confidentiality and therefore patient identifiable details will not be recorded.

Who can participate?
Anyone over 18 years of age who is scheduled to undergo or recently undergone major intra-cavity surgery.

What does the study involve?
After your surgery, a member of the research team will provide you with the HALO kit before you are discharged from hospital. If you are recruited at the pre-assessment clinic before your surgery, a member of the trial team may ask you some questions about your medical history.
The study period is the first 30 days after you are discharged from hospital following surgery. During the study period, you will be asked to do the following:
1. Wear an Apple Watch or similar device continuously, with up to an hour for charging daily

during which the device will not be used
2. Check clinical observations such as blood pressure, heart rate, blood oxygen level etc twice a day (after waking up and before bedtime)
3. Answer a short questionnaire once a day (in the morning)
At the end of the study interview, a short interview will be conducted asking about your experience in the study and any hospital or GP visits during the monitoring period. Issued devices will be collected from you at this time.

What are the possible benefits and risks of participating?
The information learned from this study may help us to improve ways to improve surgical care in the future. The results of this study will help us to design new ways to monitor patients undergoing major surgery. There are no disadvantages or risks in taking part in this study as it is an observational study and your treatment would be standard of care.

Where is the study run from?
University College London Hospital

When is the study starting and how long is it expected to run for?
November 2018 to March 2021 (updated 05/03/2020, previously: March 2020)

Who is funding the study?
Urology Foundation, UK
St Peter's Trust for Kidney Bladder & Prostate Research, UK

Who is the main contact?
Pramit Khetrapal, p.khetrapal@ucl.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
244239

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS Project ID: 244239

Study information

Scientific Title
Domiciliary recovery after medicalisation Pathway

Acronym
DREAMPath

Study objectives
The overarching aim of the study is to test the feasibility of using smart technology to collect physiological and Patient Reported Outcome Measures (PROMs) in patients following discharge from hospital after major intra-cavity surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/08/2018, South West - Cornwall & Plymouth Research Ethics Committee (Rooms 2 /3, Tamar Science Park, Plymouth, PL6 8BX; 0207 104 8059; nrescommittee.southwest-cornwall-plymouth@nhs.net), ref: 18/SW/0206

Study design
Multi-centre observational cohort study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Major surgery

Interventions
This is a prospective observational study to assess patient compliance with smart technology devices - the Home and locally observed (HALO) kit. The study will recruit patients undergoing any major intra-cavity surgery which is associated with a re-admission rate of >15% within 30 days of surgery, or >20% in the first 90 days of surgery.

The HALO consists of a sphygmomanometer, peripheral oximeter, wrist-worn tracker with heart-rate monitor and pedometer, thermometer and a cellular broadband device.
Patients will be issued a HALO kit before discharge from hospital, and will be monitored remotely for 4 weeks. Patients will be instructed to wear the tracker continuously, and shown how to measure blood pressure, and temperature twice daily – morning and evening. Additionally, they will be asked to complete a QoR15 once daily.
The HALO kit is designed to be used with a cellular broadband device, such as a 4G-capable mobile phone, which can be used to complete questionnaires electronically. The broadband device remotely uploads data to an anonymised database. Patients will be registered and provided with a trial ID to ensure all transmitted data is anonymised. Patients will be contacted via telephone to confirm activation of the system. At time of consent, patients will be informed that the data collected will not be reviewed for clinical decision-making and that the all data is anonymised. Re-admissions and other engagement with healthcare such as GP visits, A&E visits will be collected as 'events'. Post-operative complications will be recorded as per the Clavien-Dindo (CD) Classification, and the Post-operative morbidity score (POMS). An exploratory study to understand whether there is a relation between measured physical parameters and healthcare events will be conducted. Upon completion of the study, patients will be asked to return the devices, and information about unplanned healthcare events and adverse events will be collected.

Intervention Type
Device

Primary outcome(s)
Patient compliance with wearable and interactive smart technology in the 4 weeks following discharge from hospital after major intracavity surgery. Compliance will be defined as completion of 70% of daily PROM questionnaires, or wearing the wrist-worn trackers for at least 10 hours per day for the study duration

Key secondary outcome(s))
1. To explore the relation between unplanned healthcare events and physiological measurements and PROMs in the post-discharge setting for patients undergoing major surgery.
2. To explore the correlation between PROMs (QoR15) and physiological measures (wrist-worn-device tracking) in patients in the post-discharge setting measured daily.

(Physiological measures collected will be blood pressure, pulse oximetry, temperature twice a day, as well as continuous monitoring of heart rate and physical activity through the wrist-worn wearable device.)

Completion date
31/03/2021

Eligibility

Key inclusion criteria
1. Over 18 years of age
2. Scheduled to undergo or recently undergone major intra-cavity surgery with a re-admission rate of >15% within 30 days, or >20% within 90 days
3. Able to give informed written consent to participate

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Deemed unfit for surgery
2. Unable or unwilling to comply with remote monitoring for any reason
3. Unable or unwilling to fill in a questionnaire in English

Date of first enrolment
30/11/2018

Date of final enrolment
28/02/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London Hospital
University College Hospital
235 Euston Road
London
United Kingdom
NW1 2BU

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Urology Foundation

Alternative Name(s)
TUF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
St Peter’s Trust for Kidney Bladder & Prostate Research

Alternative Name(s)
St Peter’s Trust for Kidney, Bladder and Prostate Research, St Peter’s Trust for Kidney Bladder & Prostate Research, SPT

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		06/04/2022	07/04/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet		28/08/2018	05/04/2019	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes