PARTICIPANT INFORMATION SHEET

Long title:

Acronym: DREAM Path (Domiciliary recovery after medicalisation Pathway)

Part A

PART A: SUMMARY PARTICIPANT INFORMATION SHEET

Your surgeon has told you that you will be undergoing major surgery, which can be associated with expected complications, particularly in the first few weeks after the operation.

We would like to invite you to take part in a study that will explore the use of remote monitoring after discharge from hospital following major surgery.

If you decide to take part in the study, your research nurse or surgeon will ask you to sign the consent form at the end of this information sheet. You will then be treated as follows:

- Your surgery will proceed as arranged with your clinical team
- After surgery, you will be seen by a member of the research team and issued a kit for remote monitoring called the HALO kit. This consists of peripheral oximeter, wrist-worn tracker with heart-rate monitor and pedometer, thermometer and a cellular broadband device. Basic operations of the devices will be explained to you.
- After discharge, you will be asked to wear a smart watch for the 30 days after discharge from hospital, which will measure your mobility and heart rate. You will also be asked to measure your blood pressure, heart rate and temperature twice a day using the kit provided – the same way you have your observations taken in hospital. Additionally, you will be asked to complete a short questionnaire about your physical health and wellbeing daily.
- At the end of the 30-day monitoring period, you will be asked about any visits to the Accident & Emergency Department, hospital and GP in this period.
- If you have been admitted to hospital during the monitoring period, you are not expected to use the HALO kit while you are in hospital. However, you will be asked to keep a log of your hospital admission dates.

- If you decide not to take part, your surgery will proceed in line with the standard of care.
- If after reading Part A: Summary Participant Information Sheet you are interested in participating in the study, please familiarise yourself with Part B: Detailed Participant Information Sheet on the following pages **before** signing the study consent form.

Part B

PART B: DETAILED PARTICIPANT INFORMATION SHEET

We would like to invite you to take part in this study. Before you decide whether to take part, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to make your decision. You can talk to others (such as your GP, family and friends) about the study, if you wish, before reaching a decision.

What is the purpose of the DREAM Path study?
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.

Why am I being invited to take part?
You are being invited to take part because your surgeon has offered you the option of surgery for your condition. As part of the DREAM Path study, patients undergoing major surgery are invited to participate.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without providing a reason. This will not affect the standard of care you receive.

What is being studied?
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.

What will happen to me if I take part?
Everyone who agrees to take part will be receiving the normal investigations and treatment for their condition. Your doctor or clinical nurse specialist will talk to you about the standard tests, treatment and the follow-up which all patients receive.

If you agree to take part, the research team will register you and record your clinical and contact details as well as any relevant test results. 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 do I have to do for the activity tracking device to collect data?
The device you will be issued is like a bracelet that you can wear on your wrist. This is to be worn daily for 30 days. The battery life of the watch Is approximately 2 days, but daily charging is recommended. Charging for half an hour per day would be sufficient for device usage. While the device is waterproof, we do not recommend using it taking it into the shower or shower. Instead, we suggest using this time to charge the device.

What do I have to do to collect clinical observations?
Twice a day, you will be asked to use the thermometer, pulse oximeter, blood pressure machine etc to take readings. These will automatically get tabulated on the companion device provided, and will be ready to review at the end of the study.

How do I fill out questionnaires during the study?
You will be asked to fill out one questionnaire with 15 questions daily, and this should be completed once per day on the companion device provided.

Will the data collected be reviewed in real-time by someone from the hospital?
No, the data you will be providing will only be reviewed at the end of the monitoring period (30 days). At this point, we need more information to understand if these readings will be useful in

clinical decision-making. During the monitoring period, the study team will only know that readings are being collected, but not the values being collected.

What should I do if I feel unwell during the study period?
If you feel unwell during the study period, you should seek medical advice as you normally would. As the measurements and questionnaire data is not monitored in this study, you should seek help as you would normally do.

Would I be expected to collect data if I am away during the study period?
We would encourage you to collect data as far as possible. Exceptions would be if you are admitted to hospital during this visit, in which case you will be ask to keep a record of your admission dates. If you are unable to engage with the HALO kit due to a hospital admission or other reasons, you can continue to use it as per the schedule stated above once you are back at home.

Would I be held responsible if any of the devices are lost or accidentally damaged during the study period?
We will minimise breakages and losses by taking necessary precautions, but you will not be held responsible for any or accidentally damaged devices. However, devices will be locked to your study number and the trial system, and will be made redundant remotely if lost or damaged.

What if new information becomes available?
Sometimes during a research project, if new information becomes available about any aspect of the study you will be informed about it. As this study is not changing your treatment you will not have to worry. If any new information is made available that could affect you, your doctor will notify you and discuss with you whether you want to continue in the study. If you decide to withdraw, your research doctor will make arrangements for your care to continue. If you decide to continue in the study, you will be asked to sign an updated consent form (if applicable).

What are the possible benefits of taking part?
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.

What are the possible disadvantages and risks of taking part?
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.

How will confidentiality be maintained?
Scientific and medical employees of UCL, and those conducting the study as well as members of regulatory bodies, may need to examine your medical records to ensure the study is being run according to protocol and that the information collected on the forms is accurate, but your confidentiality will be protected at all times.

If you consent to take part in the research, your medical records may be inspected by the sponsor for the research which is UCL, for purposes of analysing the results. Your information may also be viewed by people from the UCL and from regulatory authorities to verify that the study is being carried out in accordance to protocol. Any identifiable information that you provide, however, will not be disclosed outside the hospital/GP surgery or the research team. All information which is collected about you during the course of the study will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address removed.

Your medical notes will be seen by authorised members of the research team at your hospital in order to collect information needed for the DREAMPath study. When you join the study, your personal details will be anonymised and you will be given a trial number that would be used when we pass your data onto the sponsor and coordinating DREAMPath team at UCL where the study is being coordinated. You will be given a unique trial number, which will be used together with a subject identifier on forms. All information about you will be coded with this trial number and will be stored securely in locked cabinets. Again, your information will be treated as strictly confidential and no information that might identify you will be revealed to any third party. All the information that is sent to the UCL Trials Office will be kept for 10 years after the study has ended.

What happens if I change my mind during the study?
You are free to withdraw from the study at any time. You do not have to give a reason and your future treatment and care will not be affected.

What if something goes wrong?
Every care will be taken in the course of this study. If you are not satisfied with the general care and treatment you receive, please speak first to your doctor, who will try to resolve the problem. If you remain dissatisfied and wish to complain formally about the care and treatment received during the study, you may do so under the standard NHS complaints procedure which is available to you from your study doctor's hospital.
To find out about it, ask a member of staff, look on the hospital website or contact the Patient Advice and Liaison Service (PALS).

PALS
Ground Floor Atrium
University College Hospital
235 Euston Road
London NW1 2BU

Telephone: 020 3447 3042 Email: uclh.pals@nhs.net

In the unlikely event that you are injured by taking part, compensation may be available. If you are harmed due to the negligence of someone treating you, then you may have grounds for legal action for compensation. NHS Trusts are responsible for clinical negligence and other negligent harm to individuals that are under their care and covered under the NHS Indemnity Scheme. UCL insurance applies for aspects of the study not covered by the NHS Indemnity scheme.

What will happen to the results of the research study?

A team of independent experts will review the progress of the research, and the results will be published in a respected medical journal once we are sure they are reliable. No information that could identify you will be included and you will not be identified in any report or publication.

We will summarise the results for participants once they are available. Your study team will send you a copy of the results upon request. This study has been placed on an internet directory of clinical trials (www.clinicaltrials.gov) and the result, once available will be posted here.

Who is organising and funding the research?

The research is approved and funded by The Urology Foundation.

UCL is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. UCL will keep identifiable information about you for 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting [insert site contact].

University College London Hospitals NHS Foundation Trust will keep your name and contact details confidential and will not pass this information to UCL. University College London Hospitals NHS Foundation Trust will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from UCL and regulatory organisations may look at your medical and research records to check the accuracy of the research study. UCL will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

University College London Hospitals NHS Foundation Trust will keep identifiable information about you from this study for 10 years after the study has finished/ until 2030.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

UCL will collect information about you for the DREAMPath study from your local hospital records. The local hospital research team will not provide any identifying information about you to UCL. We will use your medical records to access information about your recovery from surgery.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

You can find out more about how we use your information by contacting your local research team.

Who has reviewed the study?

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, to protect participants' safety, rights, wellbeing and dignity. DREAM Path has been reviewed and approved by the South West – Cornwall & Plymouth Research Ethics Committee.

Contact for further information:

If you have any further questions concerning this study please contact your surgical team:

Name: …… **on** ……..

Or your **research/specialist nurse**:

Name: …… **on** ……

Who else can I talk to?

Alternatively, if you or your relatives have any questions about this study you may wish to contact the following organisation that is independent of the hospital at which you are being treated:

What to do next

If you are at all unsure whether to take part in this study, you can have more time to think it over.

If you decide you would like to take part then please read and sign the consent form. You will be given a copy of this information sheet and the signed consent form to keep.

Thank you for taking the time to consider participating in the study and for reading this leaflet.

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