Workshops to develop a support programme for people experiencing social and financial barriers after major surgery

Participant Information Sheet
(Patients and members of the public)

IRAS ID: 358742

Study Title: Co-design of candidate interventions for HIPPOCRATES: Health Inequalities in PerioPerative Outcomes – CreATing and Evaluating targeted Support interventions

We would like to invite you to take part in a research study which will help us understand how the NHS can help people who need a big operation to recover better afterwards. We particularly want to talk to people who have experienced financial challenges, or live in an area where there is a lot of financial hardship. We invite you to share your experience of being able to access help with your health or your finances, how you feel talking to doctors and other healthcare professionals about improving your health, and how well you feel the health system supports you. Before you decide we would like you to understand why the study is being done and what it would involve for you. One of our team will answer any questions you have. Talk to others about the study if you wish.

Part 1 - *What is involved in the Research Study?*
Tells you the purpose of this study and what will happen to you if you take part.

Part 2 – *Supporting Information*
Gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear. Take time to decide whether or not you wish to take part. We appreciate it may not answer all of your questions, so please do not hesitate to contact a member of the study team on the email addresses given at the end of this Information Sheet if you would like to discuss any aspect of the study further.

Important things you need to know

- This is a study to develop a support programme for people experiencing social and financial barriers after big surgical operations. This research study will contribute to the PhD projects of three students. After this study is finished we will test the support programmes we develop in a trial involving patients and hospitals across the NHS.

- You may be able to take part in this study if you can share your experience of social or financial barriers whether or not you have had surgery. If you have had surgery, then we would also be interested to talk to you about how you were helped to prepare for

surgery, about if financial support or other help was offered to you before or after surgery and what you felt about your care after surgery, including after going home from hospital.

- You will be invited to up to five workshops over the next 3 months or so. The workshop will be voluntary, the location of each workshop will take place either in person or online, and will last approximately two hours.
- The study will last approximately 1 year, but your involvement will only be for the workshops you take part in.
- The research team will require your consent before any workshops with you can begin.
- You may withdraw from the study at any time without giving a reason.

Part 1 - What is involved in the Research Study?

1. What is the purpose of the Study?

We want to help people who have experienced financial hardship to recover better and more quickly when they have a big operation. To do this, we want to develop new ways of supporting people having major surgery – for example by getting them fitter before their operation, helping them with their finances, or having the NHS keep in closer touch with them after they have left hospital. To work out what might work best, we want to talk to people who have experienced financial hardship, or have had a big operation, or both. We will use what we learn from you to design a support programme which could work for people in these situations.

2. Why have I been invited?

We would like to invite you to be part of this study to understand your experience of financial hardship, or major surgery, or both.

3. Do I have to take part?

It is up to you to decide to join the study. We will answer any questions you may have. If you agree to take part, we will then ask you to sign a consent form, you will be given a copy of the consent form to take away with you. You are free to withdraw at any time without giving a reason.

4. What will happen to me if I decide to take part?

The study is being led by a team of researchers from University College London (UCL) who will invite you to up to five workshops, to share your experiences.

You may be sent an email by a researcher to invite you to a workshop. This participant information sheet and consent form will be given to you before you attend a workshop, and you will be able to ask any questions before the workshop. Once your questions have been answered, you will be asked to sign a consent form before the workshop. We will ask you to send us the signed consent form via email before the workshop.

Where it is not possible for you to share written consent you can provide verbal consent instead. If you require any documents in another language or have any accessibility requirements, please let us know.

5. What will I have to do?

During the workshop we will talk with you to understand your experiences of social or financial difficulties. If you have had surgery before, we will talk about whether hospitals or your GP helped you prepare or get fitter before surgery; whether you were offered financial support before or after surgery and how; and if the hospital staff or any other healthcare workers kept in touch with you after your operation. We will ask you to contribute to ideas on how a support programme could best help patients experiencing social or financial difficulties.

There will also be an option to have follow up conversations with the research team, should you wish to share further information directly with the research team, rather than in the workshop setting.

We will take notes of the discussion, an audio-recording, video-recording and photographs will also be made. Within the photographs and videos faces of people would be either not captured, or removed/blurred if captured. All information gathered will be treated as confidential by the research team and will be anonymised for analysis.

You can decide to stop participating at any time, and you are also free to decline consent to any future involvement in the research, but data collected before you withdrew will not be destroyed.

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

This is a low risk study. We will ensure that any of your personal information (such as name and contact details) gathered for this research is kept confidential unless we learn of serious risk to patients or staff from the information disclosed.

Furthermore, there is a small chance that you may find the workshop upsetting,if you recall uncomfortable or painful events. You can stop taking part in the workshop at any point, for this or any other reason. If you feel upset, we will offer you support from wellbeing services.

7. What are the possible benefits of taking part?

In terms of your direct benefits, you will be offered a small token of our appreciation for your time participating in the workshop; this will be in the form of a voucher. In terms of broader benefits for society, the information that you provide will help researchers understand how to develop programmes that may improve the support available for patients facing social and financial barriers.

8. What if there is a problem?

If you want to make a complaint about something to do with the study, please follow the process detailed in Part 2 of this information sheet – Supporting Information.

9. Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled confidentially. The details are included in Part 2 – Supporting Information.

10. Expenses and payments

You will be offered a token of our appreciation for your time participating in the workshop – this will be a shopping voucher. We will also cover the costs of you travelling to and from our workshops if you attend in person. If you attend in person, we will also provide some food and soft drinks.

11. Contact Details

Primary contact email address: hippocrates@ucl.ac.uk

Chief Investigator

Name: Professor Ramani Moonesinghe
Email address: ramani.moonesinghe@nhs.net

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2 - Supporting Information

1. What if relevant new information becomes available?
We might consider it to be in your best interests to withdraw you from the study, if so, we will explain the reasons. If the study is stopped for any other reason, we will tell you why.

2. **What will happen if I don't want to carry on with the study?**
As mentioned, your participation in the study is voluntary and you can withdraw from the study at any time without giving a reason, but we will keep information about you that we already have. If you are no longer able to consent for yourself during the study you would be withdrawn from the study. Any data already collected with consent would be retained and used in the study. No further data would be collected and no further research would be carried out with you.

3. What if there is a problem?
University College London holds insurance against claims from participants for harm caused by their participation in this research study. Participants may be able to claim compensation if they can prove that UCL has been negligent.

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. Their contact details can be found at the bottom of this document.

However, if you remain unhappy or have a complaint about any aspect of this study and wish to speak to someone independent of the research team, please email the UCL Joint Research Office on: research-incidents@UCL.ac.uk

Every care will be taken to ensure your safety. However, in the unlikely event that you are injured in the course of the study, compensation may be available.

If you suspect that the injury is the result of the Sponsor's (University College London) then you may be able to claim compensation. Please make the claim in writing to Prof Ramani Moonesinghe who is the Chief Investigator for the study and is based at UCL and UCLH. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. If you have a claim then it might be helpful to consult a lawyer.

Participants may also be able to claim compensation for injury caused by participation in this study without the need to prove negligence on the part of University College London or another party.

4. How will we use information about you?
We will take notes of the discussion, an audio-recording, video-recording and photographs will also be made. Within the photographs and videos faces of people would be either not captured, or removed/blurred if captured. All information gathered will be treated as confidential by the research team and anonymised for analysis.

We will need to use information from you for this research project.

This information will include your name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

University College London is the sponsor of this research.

University College London is responsible for looking after your information. We will share your information related to this research project with a transcription agency who we share a data sharing agreement with.

We will keep all information about you safe and secure by:

- The implementation of policies and procedures that tell our staff and students how to collect and use your information safely;
- Training our staff and students to ensure they understand the importance of data protection and how to protect your data;
- The implementation of security standards and technical measures that ensure your information is stored safely and securely;
- All research projects involving personal data are scrutinised and approved by a research ethics committee;
- Contracts with third parties have clauses setting out each party's responsibilities for protecting your personal information;
- We carry out data protection impact assessments on high-risk projects to ensure that your privacy, rights as an individual or freedoms are not affected.

5. International transfers

Your data will not be shared outside the UK.

6. How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 20 of years. The study data will then be fully anonymised and securely archived or destroyed.

7. What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

8. Where can you find out more about how your information is used?

You can find out more about how we use your information.

- at www.hra.nhs.uk/information-about-patients/
- on our website UCL OR UCLH General Privacy Notice for Participants and Researchers in Health and Care Research Studies

  UCL Privacy Statement:

  https://www.ucl.ac.uk/joint-research-office/about-us/data-protection-statement
- by asking one of the research team (contact details at the bottom of this document)
- by sending an email to hippocrates@ucl.ac.uk
- by sending an email to the sponsor's data protection officer at data-protection@UCL.ac.uk

Further information can also be found at; http://www.hra.nhs.uk/patientdataandresearch (if you are unable to access the internet and/or would prefer a paper copy, please ask us and we can provide a print out).

9. What will happen to the results of the study?
The results of the study will be available after it finishes and will usually be published in a medical journal or be presented at a scientific conference. The information provided by you and all other participants at workshops will be anonymous and none of the people involved in the study will be identified in any report or publication. Should you wish to see the results, or the publication, please ask the research team (contact details at the bottom of document). We will also send a separate summary of the study results to you.

10. Who is organising and funding the research?
The study is funded by the National Institute for Health and Care Research and sponsored by University College London.

11. How have patients and the public been involved in this study?
The research protocol and participant facing study materials such as this Participant Information Sheet have been reviewed by two Patient Public Involvement and Engagement representatives.

12. Who has reviewed the study?
All research in the NHS is looked at and approved by independent group of people, called a Research Ethics Committee and the Health Research Authority, to protect your interests. This study has been reviewed and given favourable opinion by Black Country Research Ethics Committee *and Health Research Authority approval.*

13. Further information and contact details
You are encouraged to ask any questions you wish, before, during or after your involvement in this research. If you have any questions about the study, please speak to the research team (contact details below). If you require any further information or have any concerns while taking part in the study please contact one of the following people:

Research team
Primary contact email address: hippocrates@ucl.ac.uk

Chief Investigator

Name: Professor Ramani Moonesinghe
Email address: ramani.moonesinghe@nhs.net

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.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.