Participant Information Sheet (PIS)

Co-design with people with shoulder replacement

Title: SPRING (Shoulder Replacement Prehabilitation and Rehabilitating Early)

Version: 1.1 **IRAS ID:** 356493 **Date: 03.06.2025**

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why this study is being carried out. Please take time to read the following information carefully. Please contact the study researchers if you would like to discuss anything further. Their contact details are provided at the end of this information sheet.

OVERVIEW

We have provided a brief overview of this information sheet below. It is split into four sections. Please read each section to find out more information.

PART A: Introduction to the Study

What is this study about and who are we?

In the UK, there is no consistent standard of support for people experiencing shoulder replacement surgery. People experiencing shoulder replacement can receive varying degrees of support before surgery and rehabilitation after their surgery. For some people, this can result in them not feeling prepared for the surgery and their shoulder replacement and being fearful of exercise and movement of their shoulder afterwards. However, personalised support packages which encourage people to build knowledge, skills and confidence to manage day-to-day activity have been perceived positively by people with other health conditions.

This study is called SPRING. In this first phase of this study, we aim to work in partnership with people living with shoulder replacement and healthcare professionals to design two packages of personalised self-management support. One of these packages will be prehabilitation, designed to be received before shoulder replacement surgery. The other package will be early rehabilitation, designed to be delivered after shoulder replacement surgery.

To do this, a team of academics with the expertise to see this study through has been assembled. The SPRING co-design team is led by Professor Fiona Jones from City St George's, University of London, alongside Dr Fiona (Fi) Leggat (City St George's, University of London) and Paula Otter (Bridges Self-Management). Professor Jones and the team have expertise in co-design, self-management and rehabilitation, and will work with a range of professionals with expertise in shoulder replacement, healthcare research and person-centred care.

When we refer to 'we', we mean this co-design study team.

Who is organising and funding the research?

This research is funded by the UK National Institute for Health Research.

The SPRING study is being sponsored by Cardiff University and being led by Professors Kate Button and Monica Busse from Cardiff University. As described above, the first phase of this study is being undertaken by a team from City St George's University of London and Bridges Self-Management in collaboration with Cardiff University.

Bridges Self-Management (Bridges) is a community interest company based upon 15 years of healthcare research. Bridges provides opportunities for both patients and professionals to work collaboratively to enhance people's knowledge, confidence and self-management skills, and aims to understand how best to support individuals to self-manage long-term conditions. Bridges has worked with health and social care teams across the UK and worldwide.

Why have I been invited?

You have been invited because you have experienced a total shoulder replacement. Your personal experiences and views will help with developing a package of personalised self-management support,

along with training materials for healthcare professionals to support individuals about to experience, or who have experienced total shoulder replacement.

Do I have to take part?

It is entirely up to you to decide whether or not to take part. Please take time to read the rest of this information sheet to help you to decide. If you choose not to be involved in this study, this will not affect your clinical care in any way, now or in the future.

PART B: What do I need to do and how will participating impact me?

What does taking part in the study involve?

If you decide to take part in this study after you have read this information sheet, you will be asked to provide your written consent electronically. This can either be completed via a Microsoft Form link or electronically signing and returning a copy of the consent form. These options will be emailed to you by the research team. There may also be an option to do this over the telephone if you cannot access the internet. After this, you will be asked to complete a short demographic questionnaire and be invited to a series of meetings and activities which will be held remotely online through Zoom or Microsoft Teams. By taking part in all the meetings and activities, you will get the chance to be fully involved in the design of prehabilitation and rehabilitation support resources. However, you will be able to opt in and out of different meetings activities as you choose. These are outlined below.

1. ***People living with shoulder replacement co-design groups:*** The first group meetings will be with other people living with shoulder replacement. You will be part of one small group with up to 8 other people. Two weeks before the group meeting, we will send an online meeting link by email and an electronic copy and/or hard copy of an example resource book. This book will be an example of a self-management resource that has been developed previously for people with a different health condition.

   In the online meeting, your group will have the opportunity to share your experiences of shoulder replacement, discuss what you liked/didn't like about the exemplar resource, and share what you would want to include in prehabilitation and rehabilitation resources for people with shoulder replacement. You will also discuss what should be included in training for healthcare professionals to support people with shoulder replacement. The groups' experiences, ideas and priorities will be summarized and sent to you and all the other participants by email before the next group meeting.

2. ***Large mixed co-design groups:*** Following the first small meetings, you and other people with experience of shoulder replacement in the co-design groups will be invited to join a larger online group meeting. Healthcare professionals will also be invited to this meeting, and it will consist of around 20 people.

During this meeting, the key priorities will be shared and discussed, and together, you will decide on the important content for the new prehabilitation and rehabilitation self-management resources (book, website, electronic pdf) and training content for healthcare professionals to support people living with shoulder replacement. At the end of the meeting, we will ask you whether you would like to support further co-design of the prehabilitation resources and/or the rehabilitation resources and take part in a filmed interview. The groups' priorities will be summarized and sent to you by email for additional reflections.

3. ***Small mixed co-design groups*** **and filmed interviews**

   a. ***Co-design groups for prehabilitation and/or rehabilitation:*** Based upon preferences identified during and/or following the large meetings, two smaller working groups will be formed for each resource package – one group for prehabilitation and one group for rehabilitation. Each group will contain no more than 15 people (including people with shoulder replacement and healthcare professionals). It is anticipated that each group will meet twice.

      In these groups, you will work together to refine the final content of the self-management resource packages (book, website, electronic pdf) for people with shoulder replacement and training for healthcare professionals. You may be able to see some filmed interviews from people with shoulder replacement either in film or written form during the resource design. Following each meeting, the groups' discussions will be summarized and sent to you by email for additional reflections.

   b. ***Filmed interviews:*** If you feel comfortable doing this, you can also take part in a filmed interview carried out by one of the research team. In this interview, you will be asked to share your own experiences of shoulder replacement. Depending upon the priorities decided upon in the co-design meetings, we may ask you to talk about what went well, what you found challenging and what tips and advice you would share with others. The interview will be arranged between you and the study researcher at a time that suits you.

Following this stage, the first draft of the prehabilitation and rehabilitation resources will be put together by the research team and shared for feedback. At this stage, you may be contacted via email for additional thoughts and reflections, and comments about the content, language, and layout of the resources. Here, you can choose to respond and provide as little or as much feedback as you wish.

4. ***Final refinement following a small-scale evaluation:*** Following the construction of draft prehabilitation and rehabilitation resources, a small group of different people experiencing shoulder replacement will be invited to evaluate the resources. These people will not have participated in the co-design. You will not be involved in this evaluation.

   After the small-scale evaluation, you will be invited to share your feedback on any subsequent changes suggested. Here, you may be contacted via email for your reflections, invited to attend

one further online group meeting or asked to complete a brief survey about the content, language, and layout of the resources and/or training before final versions are produced.

All co-design group meetings will be recorded, anonymised and key issues summarized by a member of the study team. No one outside of the study team will see the summaries or hear the recordings. You can read more about how this data will be securely stored in Part C of this information sheet.

What do I do if I want to take part, but cannot attend an online Zoom/Microsoft Teams meeting?

If you do not have Zoom or Microsoft Teams, or do not know how to use either of these platforms, just let us know. We can send you some guidance on how to install and use Zoom or Microsoft Teams from a computer or a smart phone, and how to use the program functions (e.g., breakout groups). Alternatively, you can contribute to the study by talking to one of the research team members on the telephone. Just let us know about this, and we will contact you on a phone number of your choice. The topics you discuss on the phone will be the same as those discussed in online group meetings.

How much time will I need to give to this study?

The co-design study will run for approximately 11 months, commencing in June 2025 until May 2026.

We expect co-design phase 1 to start in June 2025 and for co-design phase 3 to end by January 2026. The co-design study will pause for 2-3 months (expected January/February 2026) while the separate small-scale evaluation is completed. The final co-design phase, resource refinement, will commence following this evaluation in March/April 2026. By May 2026, all the resources you have helped to develop should be finalised in electronic and print form. As a co-design participant, you will receive access to the resources after the co-design phase has ended.

Each small group meeting should last no longer than 90 minutes, and the large meeting, no longer than two hours. All meetings will contain at least one short break. The filmed interview, if you decide to take part in it, will involve no more than an extra 60 minutes.

What are the benefits of taking part?

You may not benefit directly from this research, but you will be given vouchers in recognition of your time and involvement in the study. If you participate in filmed interviews, and a greater number of co-design activities, you will be given vouchers of greater value, reflecting your greater contributions.

By participating in the study, you will support the development of a new and improved package of self-management resources to support those experiencing a shoulder replacement. You will also have the opportunity to influence how healthcare professionals support people experiencing shoulder replacement. At the end of the SPRING study, you will be able to receive a copy of the co-designed shoulder replacement resources.

What are the possible risks or disadvantages of taking part?

There are no major disadvantages of taking part. The only disadvantage is that you will need to give up time to take part in the group meetings and/or a filmed interview and complete the online survey.

There are very few risks from participating. If you are participating in a group co-design discussion, there is also a risk that you might disagree with others. If disagreements occur, the facilitator will invite you both to put your point of view forward. Expressing different points of view for many people is a normal part of discussion and sharing of experience but for some people, disagreements can feel awkward or hurtful.

We anticipate that it will be unlikely that sharing experiences of shoulder replacement during group settings, or in a filmed interview, will bring up difficult emotions. However, if you experience any distress from participating, please contact [INSERT SITE PI] who will signpost you to local support services at your NHS site. Alternatively, you can contact the Samaritans who can provide free, confidential support 24 hours a day, 7 days a week on the following telephone number: 116 123 from any landline or mobile telephone number.

What happens if I join, but don't want to carry on?

You will be free to withdraw at any time without giving a reason. A decision to withdraw or not to take part will have no effect on your current or future care and will remain confidential to the study team.

If you decide to withdraw from the study, your personal information and anything you have written or recorded (filmed interview) for the resources will be removed from the study and deleted. However, this will only be possible before your filmed interview or written story has been included in the resources. After inclusion in resources, we may not be able to remove your information and will retain and use this in the study. We may also be unable to remove your contributions to the group discussions as discussions will be anonymised, and so we will not be able to distinguish your own statements from anyone else's.

PART C: What will happen to my data?

How will we use information about you?

We will need to use information from you for this research project.
This information will include your:

- Name and Initials
- Age
- Sex
- Gender
- Contact details (including your address and postcode)
- Information about your general health and shoulder surgery.

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, contact details, or any personal identifiable information. Your data will have a code number instead.

Cardiff University is sponsor of this research and are delegated as responsible for looking after your information during the study.

We will share your information related to this research project with the following types of organisations:

- Cardiff University
- Bridges Self-Management

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

- Storing your information on secure, password protected City St George's University of London servers;
- Removing any names or identifiable details (e.g., location) from co-design meeting summaries and filmed interview transcripts;
- Only using encrypted methods of data transfer to secure Cardiff University servers where the data will be stored and retained;
- Abiding by the relevant Cardiff University and City St George's University of London Information Handling and Data Protection Policies;
- Not retaining any personal information longer than is necessary for the purposes of the study.

Your data will not be shared outside the UK.

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 15 years. The study data will then be fully anonymised and securely archived or destroyed.

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.

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

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

- by asking one of the research team
- by sending an email to fleggat@citystgeorges.ac.uk, or

- by ringing us on [INSERT].
- by Contacting the Cardiff University Data Protection Officer (inforequest@cardiff.ac.uk) at University Secretary's Office, Cardiff University 42 Park Place, Cathays, Cardiff, CF10 3BB.

What will happen to the results of the research study?

We will publish the study results in a scientific journal and present these at scientific conferences. All publish data will be anonymised and no identifiable information will be used in any reports. We will also produce lay summaries to disseminate findings to all participants. If you would like a copy of the findings, please get in touch with the team who will be happy to send you these.

After this part of the SPRING study, the resources you have helped to develop will be used as a part of a large trial, to see to what extent they help people experiencing shoulder replacement. If the trial is successful, the resources, including extracts of your filmed interview or written story of shoulder replacement will be disseminated and may be used by people who were not part of the SPRING study. We will ask for your consent to do this before you join the first co-design meeting and remind you if you decide to take part in a filmed interview.

PART D: Management of the research

Who has reviewed the study?

The study has approval for conduct in the NHS from a Research Ethics Committee (REC) that is legally "recognised" by the United Kingdom Ethics Committee Authority for review and approval. The NHS REC which has approved this study is [insert name of NHS REC when known].

What if there is a problem or I have any concerns?

If you have any concerns about any aspect or conduct of the study, you should ask to speak to the co-design research team, led by Prof Fiona Jones (fjones@citystgeorges.ac.uk), who will do their best to answer your questions. If you remain unhappy, you can contact the SPRING study leads, based at Cardiff University: SPRING@cardiff.ac.uk

If you wish to formally complain, you can do this by contacting:
Dr Rachel McNamara
Director of Brain Health and Mental Wellbeing,
Centre for Trials Research, Neuadd Meirionnydd, Heath Park, Cardiff, CF14 4EP
Tel: +44 (0)29 2068 7614 Email: mcnamara@cardiff.ac.uk

What happens next?

If you feel you might like to take part in this co-design study, or if you would like to ask any further questions, you can contact Dr Fi Leggat, our study researcher. You can do this via email or by telephone using the contact details below.

City St George's SPRING Co-Design Team:
INSERT

Dr Fiona (Fi) Leggat
fleggat@citystgeorges.ac.uk

Prof Fiona Jones
fjones@citystgeorges.ac.uk

School of Health & Medical Sciences
City St George's University of London,
Tooting Campus, London, SW17 0RE.

Cardiff SPRING Study Team:
INSERT

SPRING Team (inc. Prof Kate Button & Prof Monica Busse)
SPRING@cardiff.ac.uk

SPRING Study Team, Centre for Trials Research, Cardiff University, Heath Park, Cardiff, CF14 4YS.

Thank you very much for considering taking part in the SPRING study and taking the time to read this study information sheet.