Shoulder Replacement Prehabilitation and Rehabilitating Early (SPRING study)

PARTICIPANT INFORMATION SHEET

We would like to invite you to participate in the SPRING study, which is looking at two new support packages designed to help people who are scheduled to have shoulder replacement surgery. The aim of these support packages are to provide you with the knowledge, confidence and skills to help you prepare well for your shoulder replacement and recover well afterwards. The SPRING study is led by Cardiff University, City St Georges University of London and Swansea University in collaboration with Bridges Self-Management. Throughout this information sheet, the use of the term “we” refers to the SPRING study team and sponsor (who we give details of below).

Before you decide whether to participate, it is important for you to understand why the study is being conducted and what is involved. In Part 1 we explain what taking part in SPRING involves, and in Part 2 we tell you how we will use and store your information. Please take the time to read the following information carefully and discuss it with others if you wish.

Part 1

What is the purpose of the study?

More and more people in the UK are having surgery to replace their shoulder joints because of painful arthritis or shoulder damage that makes it difficult for them to conduct everyday activities. It can take more than 6 months and sometimes over a year for people to fully recover from this surgery. In the early months after surgery, people may need help with washing, dressing and self-care and may need to wear a sling.

Supportive treatments either before (prehabilitation) or after surgery (rehabilitation) are critical.

We know that people who receive prehabilitation and are mentally and physically prepared for surgery (any type) seem to do better as they recover. We also know that people recover more quickly and have fewer problems if they start their rehabilitation as soon as they can after surgery. We do not know what type of prehabilitation or rehabilitation works best for people who have shoulder replacement surgery but the aim of SPRING is try and enhance on treatments that are considered usual NHS services.

The SPRING team has worked with people who have had shoulder replacement surgery to design a personalised support package including one to one support sessions and useful resources, to help others before the surgery and after. The format of the support package and where each of these elements will be delivered is still being designed. This will be a support package designed to deliver the SPRING interventions and will not be the same as a 'care package' that you may normally receive on the NHS. The SPRING study will evaluate these two new support packages (prehabilitation: before surgery and rehabilitation: after surgery) compared to the usual care available in the NHS. We want to know whether these two SPRING support packages can help individuals with the challenges experienced with shoulder surgery. To take part, you must agree to the support sessions being audio or video recorded. Recordings of sessions will be stored in a secure Microsoft Teams Channel. This will be hosted by Cardiff University. Separate files will be created for each practitioner who is observed. Only the practitioner, members of the process evaluation team, and select members of the trial team will be able to access each folder. Recordings will be securely stored for the duration of the study. No identifying participant or practitioner details will be used in the labelling of the file. Practitioners will check that a participant is happy to have their session/s recorded prior to starting the recording. Fidelity recordings will not be transcribed. Instead, these will be listened to by members of the process evaluation team. The team will listen for the nine key principles of the SPRING intervention and score each practitioner accordingly. The team will not only listen to what is said, but how it is said in response to what the participant is sharing.

Why have I been invited?

You are receiving this information as you are scheduled to have shoulder replacement surgery and you have indicated that you are happy to be given more information about the SPRING study.

What does taking part in the study involve?

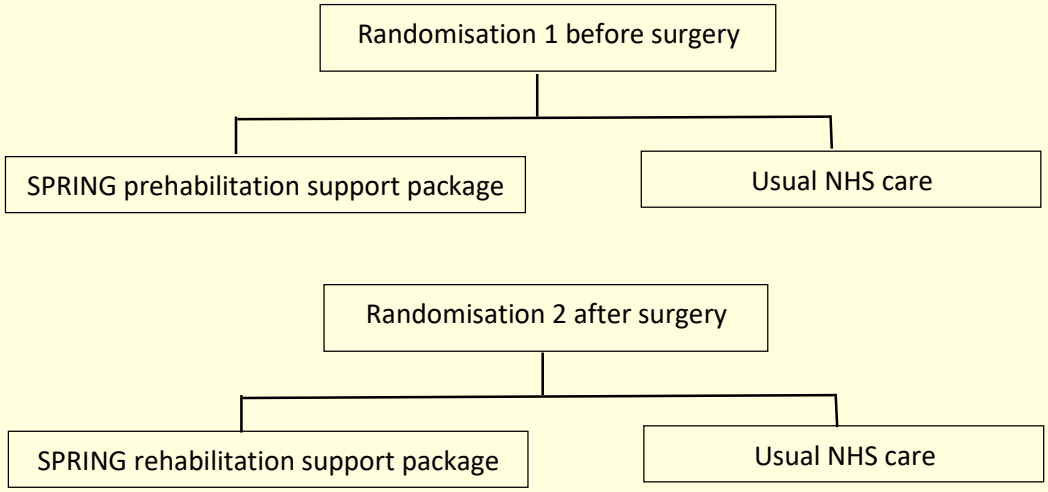
We are looking for 392 people to take part. If you are interested in taking part, you can check if you are eligible by completing eligibility questions on the study website. If you are eligible, and want to participate in the study, you will be asked to complete an informed consent form before any data collection can start.

You will then be asked to complete several questionnaires about your pain in relation to your shoulder, ability to carry out everyday activities and your current quality of life. You can complete all forms and questionnaires online, by telephone or in person with your healthcare professional. If you complete the informed consent form online, telephone support will be available for you. It is also a good idea to try and find a family member or friend (a 'nominated supporter') who you may want to ask to help you complete any online forms if needed.

The online system is the 'ASSISTANT' system. This combines two secure databases: REDCap and a secure website ASSISTANT database designed by Baseline Software Ltd. All of your data will be stored and managed securely on these systems.

Once you have completed the questionnaires you will be randomised. Randomised means, if you agree to take part, you will be randomly put into one of four groups by a computer programme. Before your surgery you will either receive usual NHS care or the SPRING pre-rehabilitation support package. At the time of your surgery, you will be randomised again to receive either usual NHS care or the SPRING rehabilitation support package. The choice of group is based entirely on chance.

The four groups:



Group 1: SPRING prehabilitation support package before surgery AND SPRING rehabilitation support package after surgery.
Group 2: SPRING prehabilitation support package before surgery AND usual NHS care after surgery.
Group 3: Usual NHS care before surgery AND SPRING rehabilitation support package after surgery.
Group 4: Usual NHS care before surgery AND usual NHS care after surgery.
Everyone taking part in the study will continue with usual NHS care (if not already receiving this) after the SPRING support package has been completed (roughly 6 weeks after your surgery). You will continue to be supported post 6 weeks after your surgery regardless of whether you get the SPRING support package.

Usual NHS care may differ depending on what is offered at your NHS Trust, for more information about what usual NHS care looks like at your Trust, please ask your healthcare team to describe this to you.

The surgery you receive will not differ or be affected by whether you receive the SPRING support packages or not.

Follow-up Questionnaires

You will be asked to complete the questionnaires again at the following times:

- 5 days after randomisation and completing of your baseline questionnaire.

- after you were randomised to receive either usual NHS care prehabilitation or the SPRING prehabilitation support package and before surgery.
- 6 weeks after your shoulder surgery (after receiving either usual NHS care rehabilitation or the SPRING rehabilitation support package).
- 6 months after your shoulder surgery
- 12 months after your shoulder surgery

These questionnaires will include questions about your pain, quality of life, your contacts with healthcare services, amongst other things. You will be sent email reminders to let you know when these are due to be completed. We expect that filling out these forms will take roughly 30-60 minutes to complete each time. you do not need to complete them all at once, take breaks when you need to and come back to it. To thank you for the time and effort it takes to complete these, you will be entered into a prize draw with a 1 in 20 chance of receiving a £100 voucher if you complete all follow-up questionnaires.

SPRING Support Packages

You will be part of one of four groups in the SPRING study, which group you are in will be determined by the outcome of two randomisations.

First randomisation:

Before your surgery, you will be randomly allocated to receive either the SPRING prehabilitation support package or usual NHS care.

1. If you are randomised to the SPRING prehabilitation support package, you will receive: A prehabilitation resource handbook (available electronically and in paper format)
2. One-to-one sessions with a SPRING trained healthcare professional. The one-to-one sessions for prehabilitation will be delivered after you have received your pre-operative assessment for your surgery.

   The prehabilitation handbook has six main sections:

- stories of shoulder replacement from other people who have experienced one
- information about why people have the surgery
- information about what usually happens when you have the surgery
- information about how you can prepare for the surgery can prepare
- a space to prepare and plan and take away messages and information

You will receive up to four, one-to-one sessions, and this is dependent on your own needs. These sessions can be delivered face-to-face, via telephone, or via video conferencing software, you can agree with your healthcare provider the best way for you to receive each session. The sessions can last up to 45 minutes.

Second randomisation:

After your surgery, you will be randomly allocated to receive either the SPRING rehabilitation support package or usual NHS care.

After your shoulder surgery if you were randomised to the SPRING rehabilitation support package, you will receive:

1. An early rehabilitation resource handbook (available electronically and in paper format)
2. One-to-one sessions with a SPRING trained healthcare professional. The first one-to-one sessions for early rehabilitation will be delivered in the first 24 hours after you have received your surgery. The remaining three sessions will be delivered within six weeks of surgery.

<u>The early rehabilitation handbook</u> is comprised of six main sections:

- stories of shoulder replacement from others who have experienced one
- information about what happens after shoulder surgery
- information about people's challenges and ways of coping
- movements and exercises you can do
- a space to plan and reflect on recovery and final messages and take away messages and information.

You will receive up to four one-to-one sessions in the rehabilitative intervention, and this is dependent on your own needs. These can be delivered face-to-face, via telephone, or via video conferencing software, you can agree with your healthcare

provider the best way for you to receive each session. The sessions can last up to 45 minutes. You will go back to NHS usual care 6 weeks after your surgery when the rehabilitation intervention is finished.

Both interventions are designed to allow you to support your own preparation for surgery and recover after surgery, they focus on enhancing your confidence by providing you with information and knowledge. The interventions will help you develop the best skills to help you recover.

Interviews

You may be invited to take part in an interview with a researcher using Zoom, Teams or by telephone. The purpose of this interview is to capture your experience of taking part in the study. You may be asked about your experiences of the SPRING interventions, and/or standard NHS care for your shoulder replacement before and after your surgery. The interviews should not exceed 60 minutes and will happen either after the prehabilitation (before surgery) or after the rehabilitation (after surgery). Not all participants will be invited for interview, but those who are will be invited via email. Not everyone is asked to take part in an interview as we are looking to get a 'flavour' of the themes that participants might want to discuss. If you are invited for an interview, and you participate, you will receive a £15 shopping voucher as a token of appreciation from the research team. All interviews will be recorded. Recordings and transcripts will be uploaded and stored in a secure Microsoft Teams Channel and on City St George's OneDrive system. This will be hosted by Cardiff University. Only members of the process evaluation team and the creator of the Teams channel from Cardiff university will be able to access the folder. Recordings will be securely stored for the duration of the study. Interviews will be transcribed by an external company called Typing Works or Essential Secretary. These will be securely transferred using a password protected folder. The transcript will be anonymized and sent back to the research team using the same method. No identifying participant details will be used in the labelling of the files. Instead, these will be labelled with a participant number. Participants will be informed and will give consent for the interview to be recorded. They will be told that they can share as

much or as little as they choose but any potential identifiable will be anonymised during the transcription and will therefore not be included in the analysis or write up.

Your Safety

If during the 12 months when you are participating in the study you are (1) admitted to hospital for any reason, (2) your shoulder pain symptoms get substantially worse or (3) there is any other incident you feel relevant that you haven't previously told us about, please let us know either via the website or by telling your local study healthcare practitioner. If there are any concerns about your health we may need to let your GP know.

We would also like you to think about someone you can nominate who can decide if you should continue with the study if you lose capacity to make your own decisions during your time on SPRING. They can be a relative, friend, unpaid carer or court appointee (this cannot be someone who is paid to look after you), alternatively, you can nominate your or GP or someone else in your healthcare team to make these decisions.

Are there any benefits for me?

We are running this study because we do not know if the new SPRING prehabilitation and rehabilitation support packages are better than usual care so taking part may not directly benefit to you. However, it will help us to provide better care for others in the future.

Are there any risks for me?

There is a chance that you might find some topics sensitive or challenging whilst taking part in one-to-one support sessions or whilst answering questionnaires. Performing exercises may cause you to experience some increased pain or discomfort, this will be monitored by your healthcare practitioner. This however could be the case with any exercises you receive as part of NHS usual care post shoulder surgery.

If you are at any point randomised to receive the SPRING support package, you will not receive the usual NHS prehabilitation or rehabilitation care at the same time, but you may receive usual NHS care around six weeks after your surgery when the SPRING package is finished. You will also receive the usual post-surgery care when you are in hospital.

Do I have to take part?

No. It is your choice. If you choose to take part, you can change your mind, or your level of participation, or completely stop taking part in the study at any time, without giving a reason. Not taking part or deciding to change your level of participation, will have no impact or influence on your healthcare. The study team will send a letter to your GP to let them know of your involvement and what the study involves.

If your surgery and your surgery aftercare are completed out of [insert details of local site], you will no longer be able to receive the SPRING support package, but we will ask if you are still happy to complete the follow up questionnaires.

Part 2

What will happen to the results of the study?

Results from the study will be published in scientific journals and also presented at relevant conferences. We will also share results with all study participants. All study results presented to the public will be made anonymous so that you cannot be identified from the data.

Who do I contact if I have any concerns?

If you have a concern about any aspect of this study, you should ask to speak to the study researchers who will do their best to answer your questions [SPRING@cardiff.ac.uk].

You can also contact [insert details of local contact organisation at site e.g. PALS] for more support.

If you remain unhappy and 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

If you have any concerns about our use of your personal information, you can make a complaint to Cardiff University as study Sponsor at inforequest@cardiff.ac.uk.
You can also complain to the ICO if you are unhappy with how we have used your data.

The ICO's address:
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF
Helpline number: 0303 123 1113
ICO website: https://www.ico.org.uk

In the event that something does go wrong, and you are harmed during the research, and this is due to someone's negligence then you may have grounds for legal action for compensation against Cardiff University, but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you (if appropriate).

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
- contact details (including your postcode)
- information about your general health and your shoulder surgery
- GP 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 or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Cardiff University is the sponsor of this research. Cardiff University is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- Universities (City St Georges University of London and Swansea University)
- Bridges Self-Management
- National Joint Registry

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

- Storing your research data on secure servers at Cardiff University. If the result of the study is published, your identity will remain confidential.
- What you say/communicate in one-to-one sessions and interviews will be typed out by a professional transcriber to make a transcript. All identifiable information in the transcript will then be made anonymous by changing your name and locations, for example.
- Your contact details will be kept securely on Cardiff University secure servers and/or locked storage facilities at Cardiff University.
- Only people involved in this study or in making sure it is run correctly (e.g., auditors and regulatory authorities) will have access to your information. No identifiable information will be used in any reports.

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. Personal data will be securely destroyed within 3 months of the end of the study. The study data will then be fully anonymised and securely archived or destroyed.

Routine NHS Data Collection

As part of the consent process, we will also ask your permission to securely send some personal information collected from you as part of the study (such as name, date of birth, gender, NHS number) to the National Joint Registry, who hold information about outcomes in joint surgery.

The purpose for us sending your information to this organisation is so that they can match your details to some of your NHS healthcare records about the surgery you receive.

The healthcare information that the research team will receive will be limited to information that is relevant to this research project. Access to the information will be restricted to trained researchers from the study team. We will not share this information with anyone else and will only have access to this information for the duration of the study, until we complete our analysis.

Under the General Data Protection Regulation (GDPR), the lawful basis we rely on for processing this information would be public task.

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 the information about you that we already have, unless you specifically request otherwise.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

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/
- By asking one of the research team
- By sending an email to SPRING@cardiff.ac.uk
- By viewing the Cardiff University Data Protection Policy and Privacy Notices: https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection
- By contacting Cardiff University's Data Protection Officer on inforequest@cardiff.ac.uk, or in writing to: Compliance and Risk, University Secretary's Office, Cardiff University, 42 Park Place, Cathays, Cardiff, CF10 3BB

Who is running the study?

The study is being sponsored by Cardiff University and the Centre for Trials Research at Cardiff University is managing the study on a day-to-day basis. The study is funded by the National Institute of Health and Care Research and has been set up by the Universities of Cardiff and City St Georges University of London in collaboration with Bridges Self-Management.

What happens next?

You can express interest in several ways:

- Speak to your healthcare practitioner,
- Visit the SPRING website https://springstudy.org.uk click on the 'expression of interest' button and complete the form.
- Email SPRING@cardiff.ac.uk.

Or contact us:

The SPRING Team Contact Details

Ring us:

+44 29 2251 4750Monday to Friday (09:00 – 17:00)

Email us at: SPRING@cardiff.ac.uk

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

If you need assistance completing the online forms for SPRING, please ask your nominated supporter to assist you or contact +44 29 2251 4750