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SPRING study: a study to design and evaluate the clinical and cost effectiveness of the SPRING prehabilitation and early rehabilitation interventions for people undergoing shoulder replacement surgery compared to NHS usual care

Submission date
08/08/2025

Recruitment status
Recruiting

Registration date
20/08/2025

Overall study status
Ongoing

Last Edited
20/08/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
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. But personalised support packages which encourage people to build knowledge, skills and confidence to manage day-to-day life have been perceived positively by people with other health conditions.

The SPRING project aims to develop and test two support packages of personalised self-management support for people having a shoulder replacement. One package will be prehabilitation, which will be given to people before their surgery to prepare them for what is ahead. The other package will be rehabilitation, which will be given to people after their surgery, to help them to adapt to day-to-day life with shoulder replacement. In this project, we aim to develop these two packages by working together with people with shoulder replacement and healthcare professionals.

Who can participate?
Adults who are having shoulder replacement and healthcare professionals who work with them.

What does the study involve?
We are looking for 390 people to take part. 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. 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. You will be asked complete the questionnaires again at the following times:
- 3 months after you were randomised to receive either usual NHS care prehabilitation (before surgery) or the SPRING prehabilitation support package
- 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
You may also be invited to take part in an interview with a researcher, this 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.

What are the possible benefits and risks of participating?
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 be of direct benefit to you. It should, however, help us to provide better care for others in the future.
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, there is also a small chance that you may experience some increased pain or discomfort while performing any exercises.

Where is the study run from?
Cardiff University (UK)

When is the study starting and how long is it expected to run for?
March 2025 to February 2029

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Gwenllian Moody, moodyg@cardiff.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 68561, NIHR166278

Study information

Scientific Title
Shoulder Replacement Prehabilitation and Rehabilitating Early (SPRING) project

Acronym
SPRING Co-design study

Study objectives
Primary objective:
To evaluate the clinical and cost effectiveness of the SPRING prehabilitation and early rehabilitation interventions for people undergoing shoulder replacement surgery compared to NHS usual care as measured by the Total SPADI.

Secondary objectives:
1. Complete an internal pilot in the first 8 months to examine whether moving to a definitive trial is feasible.
2. Generate evidence to consider whether the usual services plus one or two of the emergent interventions reduces pain, disability, pain self-efficacy, anxiety and depression, length of hospital stay, complications, quality of life, and improves sleep and quality of life and explore by key patient demographics.
3. Monitor and report trial specific adverse events and serious adverse events related to the emergent interventions.
4. To evaluate the cost-effectiveness of the SPRING interventions at 12 months post-surgery measured by healthcare resource use.
5. To conduct a mixed methods process evaluation to explore trial processes, intervention mechanisms and context, to inform further implementation.

Ethics approval required

Ethics approval required

Ethics approval(s)
Approved 17/06/2025, South Central Hampshire B REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 1048 088; hampshireb.rec@hra.nhs.uk), ref: 25/SC/0196

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Self management after shoulder replacement

Interventions
Phase 1: Separate small co-design group meetings (healthcare professionals and people with shoulder replacement)

At least 2 weeks before the co-design meetings, after written consent has been received, all participants will be sent a copy of an existing self-management tool (book) or resource (e.g., electronic pdf) developed by Bridges Self-management (a community interest company which co-designs and delivers self-management support programmes) for people with a different long-term health condition. Participants will also be sent a short demographic survey to collect information including age, sex at birth and ethnicity, and a phase 1 meeting invitation.

Overall we will aim to recruit 30–35 people with shoulder replacement for these small co-design meetings. Three or four groups will be held with 8–10 people in each group and separate small groups will be held with healthcare professionals.

All small group meetings will be hosted remotely, online using either Zoom or Microsoft Teams virtual platform. Each group will discuss their experiences of shoulder replacement, share their likes and dislikes of the example resource(s) sent to them, and share their ideas and priorities for new co-designed resources for shoulder replacement prehabilitation and early rehabilitation, and training for healthcare professionals. Group meetings will be jointly facilitated by the co-design research team and Bridges Self-management (Bridges), a community interest company who have over 15 years' experience in exploring how to support people to live better with long-term conditions.

Group discussions will include breakout rooms and interactive activities to generate discussion and enable ideas to flow freely. Meetings will be recorded for the purpose of summarising key experiences and will not exceed 90 minutes each in duration. Each meeting will include at least one comfort break.

Bridges have developed clear summaries and guidance for accessing Zoom and Microsoft Teams, and using their platform functions (e.g., breakout rooms) which will be sent to participants. Alternatively, for participants who do not have internet access, telephone calls will be offered so that they can still contribute to the co-design. For participants who are comfortable using Zoom, but who cannot attend the specific meeting dates and times, additional smaller Zoom meetings will be offered with the research team. These could be one-to-one or in smaller groups with two to three people.

Following each small group meeting, discussions will be summarised by the research team and sent to participants with the opportunity for further reflection. Participants will be encouraged to share experiences they may not have felt comfortable to within the group setting by email or follow-up phone call. For participants who engage with the co-design outside of small group meetings, their experiences and inputs will be integrated into overall co-design meeting summaries. There will be no identifiable information included in meeting summaries. All summaries will be shown to our PPI group for feedback and input.

Phase 2: Large mixed co-design group meetings

Participants from all separate small group meetings in phase 1, plus anyone who attended a separate meeting/telephone call, will be invited to come together in one of two larger meetings (approximately 20 people) comprised of both healthcare professionals and people with shoulder replacement. Prior to the meeting, the phase 1 meeting summaries will be shared with the group alongside some guiding questions for the phase 2 meetings.

In these meetings, there will be the opportunity to share further reflections from the phase 1 small co-design meetings. Feedback on the experiences and priorities shared in phase 1 will be discussed in small breakout rooms. The joint event will be recorded but dialogue in breakout rooms will not be captured. Instead, anonymised notes will be taken by the research team as breakout groups feed back to the group. This meeting will last no longer than two hours and will include screen and comfort breaks. A final summary will be developed by the research and Bridges team to send out to all participants following the meeting. For participants that might have contributed via telephone in phase 1, we will again ask if they wish to contribute by means of a telephone conversation with a member of the study team.

Phase 3a: Small mixed co-design group meetings

Following phase 2, all participants (people with shoulder replacement and healthcare professionals) will be invited to join a specific themed group (a workstream) to develop either prehabilitation resources and training, and/or early rehabilitation resources and training. Each workstream will consist of at least two meetings, each up to 90 minutes in duration, to decide upon final content of the self-management resources and training content for healthcare professionals, comprising each intervention.

During meetings, participants will inform and be able to access a bank of written narratives (stories of people’s experiences of shoulder replacement), collected in parallel phase 3b, which

will form the content. For participants who do not have internet access, we will again ask if they wish to contribute by means of a telephone conversation with a member of the study team. Summaries will be provided to all participants at the end of each group.

Phase 3b: Filmed narrative interviews (for people with shoulder replacement only)

Approximately 16 people with shoulder replacement from phase 2 will be invited for interview. This will be carried out with the research team recorded on Zoom or Microsoft Teams and transcribed so that content can be extracted for digital and paper-based resources. Discussions in the interviews will be used to capture content on people's stories, challenges, experiences of shoulder replacement surgery, hints and tips, and advice for healthcare professionals. Interviews will be less than 60 minutes in length and allow for screen and comfort breaks as required.

Following phase 3, first drafts of the prehabilitation resources and training, and early rehabilitation resources and training, will be put together by the research team. These will be shared via email with participants to provide further reflections and ideas if they choose. Participants will be informed that they can provide as little or as much feedback as they wish.

After phase 3, but before phase 4, a small-scale qualitative evaluation of the two resource and training packages will be undertaken. This will be done with a different sample of people with shoulder replacement and healthcare professionals. It will not be part of this co-design study, but will form a separate linked study. A substantial amendment or linked ethics application will be submitted for this study at a later date.

Phase 4: Final resource and training refinements

Following the small-scale evaluation, each workstream (prehabilitation, early rehabilitation), formed of people with shoulder replacement and healthcare professionals, will be invited to review an anonymised summary of the evaluation findings. Participants will be asked how these findings can be integrated to form adapted and refined resources and training for prehabilitation and early rehabilitation. Depending upon the evaluation data obtained, participants may be invited to contribute their thoughts via one further group meeting. Instead, an online survey, comprised of open and closed questions, hosted on Microsoft Forms, may be used. A link to this form will be shared with co-design participants via email. Participants may add as little or as much feedback in this phase as they choose.
Following phase 4, the research team will finalise the resources and support for people with shoulder replacement and training programmes for healthcare professionals. Those who have shared their narratives within the resources will be invited to review content one final time before materials are printed and /or uploaded for use within the SPRING randomised controlled trial.

Intervention Type
Behavioural

Primary outcome measure
Pain and disability is measured using the Total Shoulder Pain and Disability Index (SPADI) at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, 12-month follow-up post randomisation 2.

Secondary outcome measures

1. Global Impression of change is measured using the Patient Global Impression of Change Scale (PGI-C) at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, 6-month follow-up post randomisation 2, and 12-month follow-up post randomisation 2.
2. Pain is measured using the SPADI pain subscale at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, and 12-month follow-up post randomisation 2.
3. Disability is measured using the SPADI disability subscale at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, and 12-month follow-up post randomisation 2.
4. Pain self-efficacy is measured using the Pain Self-Efficacy Questionnaire (PSEQ) at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, and 12-month follow-up post randomisation 2.
5. Sleep is measured using the Patient Reported Outcome Measurement Information System (PROMIS) Sleep Disturbance Short Form at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, and 12-month follow-up post randomisation 2.
6. Beliefs and priorities are measured using an in-house designed beliefs and priorities measure at baseline.
7. Length of stay is measured by calculating length of hospital stay at 6-week follow-up post randomisation 2.
8. Surgical complications are measured using an in-house designed measure at 6-week, 6-month, and 12-month follow-up post randomisation 2.
9. Surgical (in-hospital) outcomes are measured using an in-house designed measure at the time of surgery.
10. Serious adverse events (related and unrelated) and trial-specific adverse events are measured throughout the trial.
11. Quality of life is measured using the EQ-5D-5L health utility and EQ-5D-5L VAS at baseline, 3-month follow-up post randomisation 1, 6-week, 6-month, and 12-month follow-up post randomisation 2.
12. Healthcare resource use and costs are measured using an in-house designed Resource Use Measure at baseline, 3-month follow-up post randomisation 1, 6-week, 6-month, and 12-month follow-up post randomisation 2.
13. Demographics are collected at baseline.
14. Additional questions on quality of life issues related to shoulder pain are collected at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, and 12-month follow-up post randomisation 2.

Overall study start date
01/03/2025

Completion date
28/02/2029

Eligibility

Key inclusion criteria
People with shoulder replacement:
1. Have experienced a total shoulder replacement either anatomical or reverse because of

osteoarthritis, rotator cuff arthropathy or inflammatory arthritis
2. >=18 years of age
3. English speaker or have access to someone who can act as a translator.

Healthcare professionals:
1. Work in NHS shoulder replacement surgery or rehabilitation services as allied healthcare professionals, nurses, surgeons, consultants, support workers or have personal experience of shoulder replacement e.g., family members/friends

Participant type(s)
Patient, Health professional

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
390

Key exclusion criteria
People with shoulder replacement:
1. Have experienced a revision joint replacement or total shoulder replacement because of malignancy, avascular necrosis, fracture or dislocation, where the surgical procedure precludes early rehabilitation

Date of first enrolment
01/07/2025

Date of final enrolment
30/10/2027

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
-
United Kingdom
-

Sponsor information

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Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Healthcare Professionals version 1.1	03/06/2025	20/08/2025	No	Yes
Participant information sheet	People with Shoulder Replacement version 1.1	03/06/2025	20/08/2025	No	Yes