Shoulder Replacement Prehabilitation and Rehabilitating Early (SPRING study)

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Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the relevant trial regulations, GCP guidelines, and CTR's SOPs.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies from the trial as planned in this protocol will be explained.

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General Information

This protocol describes the SPRING clinical trial and provides information about the procedures for entering participants into the trial. The protocol should not be used as a guide, or as an aide-memoire for the treatment of other patients. Every care has been taken in drafting this protocol; however, corrections or amendments may be necessary. These will be circulated to the known Investigators in the trial. Problems relating to the trial should be referred, in the first instance, to CTR

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The SPRING trial is being coordinated by the Centre for Trials Research (CTR), Cardiff University, a Clinical Research Collaboration (UKCRC) registered trials unit.

This protocol has been developed by the SPRING Trial Management Group (TMG).

For **all queries,** please contact the SPRING team through the main trial email address. Any clinical queries will be directed through the Trial Manager to either the Chief Investigator or a Co-Investigators

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Serious Adverse Events:

SAE reporting
Where the adverse event meets one of the serious categories, an SAE form should be completed by the responsible clinician and submitted to the SPRING mailbox within 24 hours of becoming aware of the event (See section X for more details).
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Glossary of Abbreviations

AE	Adverse Event
CF	Consent Form
CI	Chief Investigator
CRF	Case Report Form
CTR	Centre for Trials Research
CU	Cardiff University
EHR	Electronic Health Record
GCP	Good Clinical Practice
GP	General Practitioner
HB	Health Board
HE	Health Economics
HTA	Health Technology Assessment
IC	Informed consent
DMC	Data Monitoring Committee
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trial Number
NHS	National Health Service
PI	Principal Investigator
PIAG	Participant Information Advisory Group
PIC	Participant Identification Centre
PIS	Participant Information Sheet
QA	Quality Assurance
QALY	Quality-adjusted Life Years
QC	Quality control
QL (QoL)	Quality of Life
R&D	Research and Development
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

1 Amendment History

The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version.

Amendment No. *(specify substantial/non-substantial)*	**Protocol version no.**	**Date issued**	**Summary of changes made since previous version**
2 non-substantial	1.5	29.09.2026	• Eligibility criteria clarified • Recruitment window clarified • Randomisation wording clarified • Interview time points clarified and new fidelity measure added. • Patients receiving private surgery withdrawal procedure has been updated. • Timing for randomisation 2 and the first early rehabilitation session has been updated.
1 non-substantial	1.4	06.07.2026	Eligibility criteria clarified, the use of the software 'Florence' added to store site file.
Changed before REC approval so no amendment	1.3	14.04.2026	Changes made as requested by REC: • Addition of information about intervention. • Added details of capacity and consultee Changes made not requested by REC: • We omitted including the data collection point for the BLOSSOM SWAT in the PIS (5 days post first

			randomisation) so have now included this. • included the word 'planned' for the total shoulder replacement to clarify that we are looking for planned surgeries and not emergency cases (they have to be planned in advance in order for a participant to be able to receive the prehabilitation intervention if they are randomised to this group). • clarified the exclusion criteria and removed some of these that we thought were unnecessary and would be removed at screening regardless. • Clarified how eligibility can be confirmed by site staff if participants are unsure of their own eligibility to take part. • repeated 'quality of life' in the secondary objectives so have corrected this. • Randomisation 1 will now not use minimisation by sex at birth. • Amending that follow-up post randomisation 1 does not necessarily happen at exactly 3 months but before surgery.

Changed before REC review so no amendment	1.2	10.02.2026	Added details of SWAT funding as requested by funder.
Changed before REC review so no amendment	1.1	18.12.2025	Made consistent throughout that 2nd intervention (rehab) was supposed to happen in 24 hours (not 48 hours)

2 Synopsis

Short title	Shoulder Replacement Prehabilitation and Rehabilitating Early (SPRING study)
Acronym	SPRING study
Internal ref. no.	
Development phase	Study phase 2 (2 phase study)
Funder and ref.	NIHR Health Technology Assessment (HTA) Programme (NIHR166278)
Trial design	A two-phase design: (1) Intervention co-design, piloting and refinement; (2) Randomised, multi-centre 2x2 partial factorial clinical and cost effectiveness trial and process evaluation. An 8-month internal pilot, with 2 monitoring points, will determine progression. This protocol covers phase 2 (but makes occasional reference to phase 1)
Trial participants	Adults referred for shoulder replacement at sites in England, Northern Ireland and Wales including those from underserved communities.
Planned sample size	392
Planned number of sites	24
Inclusion criteria	• Adults 18+. • Ability to provide informed consent. • Listed for planned total shoulder replacement (anatomical or reverse) because of osteoarthritis, rotator cuff arthropathy or inflammatory arthritis. • Living independently, or with carer support or in assisted living.
Exclusion criteria	• Have had a previous shoulder replacement(s) and/or a previous partial should replacement (revision replacement) in the same shoulder. • Shoulder replacement for malignancy, avascular necrosis, fracture or dislocation. • Partial shoulder replacement and resurfacing • Living in a care home (residential or nursing care). • Are taking part in another research study directly related to their shoulder replacement surgery
Treatment duration	The definition of treatment duration will be confirmed during the co-design phase but will be determined by participant preference and needs (personalised).
Follow-up duration	12 months

Planned trial period	48 months
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	• Complete an internal pilot in the first 8 months to examine whether moving to a definitive trial is feasible. • Generate evidence to consider whether 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 explore by key patient demographics. • Monitor and report trial specific adverse events and serious adverse events related to the emergent interventions. • To evaluate the cost-consequences of the SPRING interventions, including cost per quality adjusted life year gained, at 12 months post-surgery . • To conduct a mixed methods process evaluation to explore trial processes, intervention mechanisms and context, to inform further implementation.
Tertiary/Exploratory objectives	n/a
Primary outcome	Total Shoulder Pain and Disability Index (SPADI) at 12-month follow-up post randomisation 2
Secondary outcomes	• Global impression of change: Patient Global Impression of Change Scale (PGI-C) collected at 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, 6-month follow-up post randomisation 2, 12-month follow-up post randomisation 2. • Pain: SPADI pain subscale collected at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, 12-month follow-up post randomisation 2. • Disability: SPADI disability subscale collected at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, 12-month follow-up post randomisation 2. • Anxiety via Hospital Anxiety and Depression Scale (HADS) collected at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, 6-month follow-up post randomisation 2, 12-

	month follow-up post randomisation 2.6-month follow-up post randomisation 2, 12-month follow-up post randomisation 2. • Depression via Hospital Anxiety and Depression Scale (HADS) collected at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, 6-month follow-up post randomisation 2, 12-month follow-up post randomisation 2.612-month follow-up post randomisation 2.Pain self-efficacy: Pain Self-Efficacy Questionnaire (PSEQ) collected at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, 12-month follow-up post randomisation 2. • Sleep: Patient Reported Outcome Measurement Information system (PROMIS) Sleep Disturbance Short Form collected at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, 12-month follow-up post randomisation 2. • Length of stay in hospital post surgery collected at 6-week follow-up post randomisation 2. • Surgical complications collected at 6-week follow-up post randomisation 2, 6-month follow-up post randomisation 2, 12-month follow-up post randomisation 2. • Serious adverse events (related and unrelated) and trial specific adverse events collected throughout. • Quality of life: EQ-5D-5L health utility and EQ-5D-5L VAS collected at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, 6-month follow-up post randomisation 2, 12-month follow-up post randomisation 2. • Healthcare resource use and costs: Resource Use Measure designed in-house collected at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, 6-month follow-up post randomisation 2, 12-month follow-up post randomisation 2. • Additional questions on quality of life issues related to shoulder pain collected at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, 12-month follow-up post randomisation 2. We will also be collecting: • Demographics at baseline.

	• Surgical (in hospital) outcomes collected at time of surgery. • Beliefs and priorities collected at baseline.
Tertiary/Exploratory outcomes	n/a
Intervention	Intervention: Supported self-management prehabilitation and early rehabilitation focused on enhancing individuals' self-efficacy through acquiring knowledge, building confidence, and developing skills to manage and collaborate on actions to optimise recovery. Personalised 1:1 coaching will be delivered by trained healthcare practitioners. Participants will have access to co-designed resources. Intervention participants will cease to receive the intervention 6 weeks post-surgery and can receive usual care at their study site. Control: Usual care.

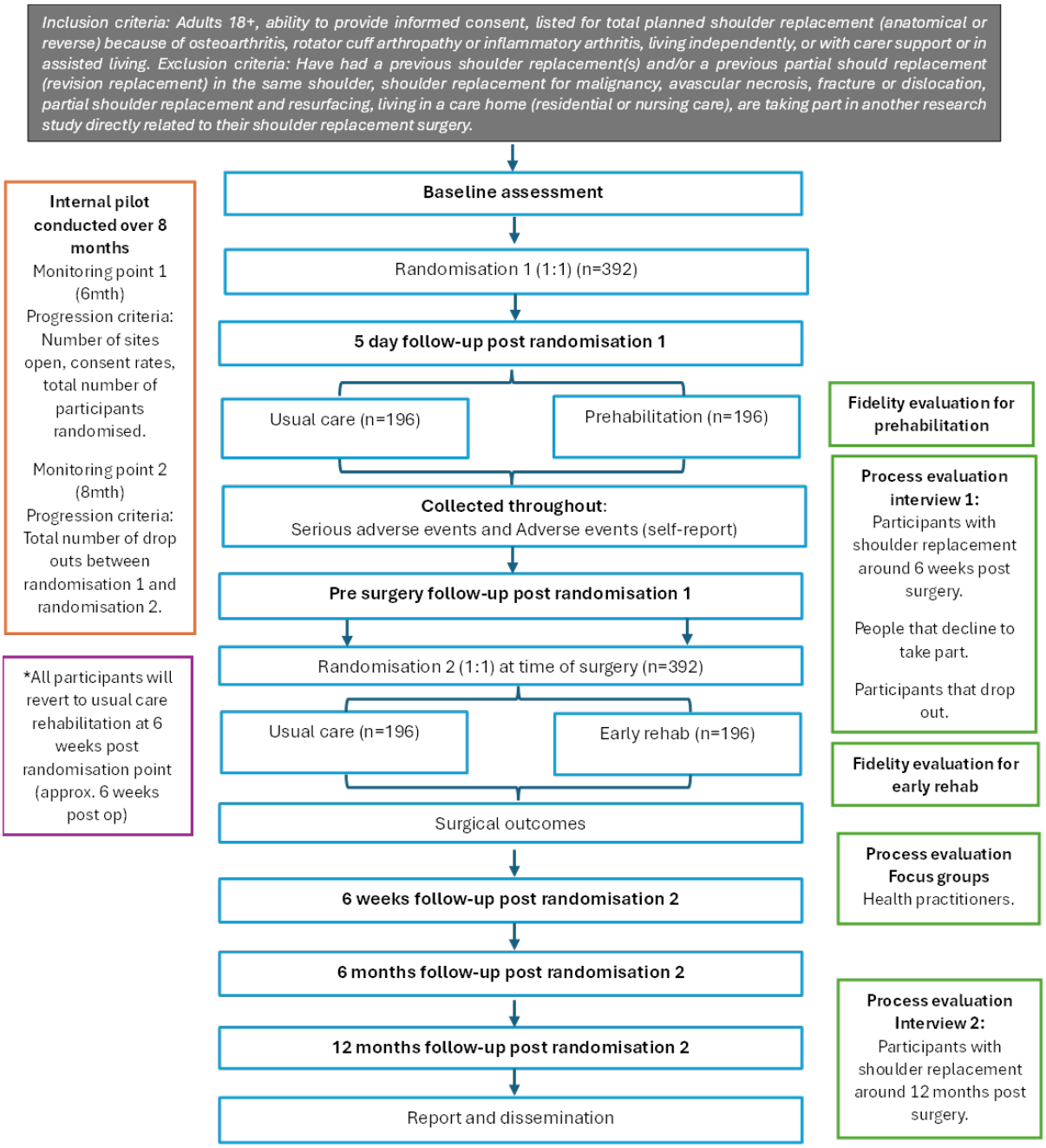
3 Trial Summary & Schema

3.1 Trial Schema

See participant flow diagram.

3.2 Participant Flow Diagram

Figure 1. Participant Flow Diagram



3.3 Trial Lay Summary

Why do we want to conduct the SPRING 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 recover from this surgery. In the early months after surgery, people need a lot of 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. It is possible 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 if people start rehabilitating as soon as they can after surgery, they seem to have fewer problems and recover quicker. However, prehabilitation is not offered routinely and many people struggle to access rehabilitation and when they do it may not meet their specific needs. We do not know what type of prehabilitation or rehabilitation works best for people who have shoulder replacement surgery, and if any prehab or rehab is better than usual care.

What do we want to accomplish?
We want to test new prehabilitation and rehabilitation treatments in people who will have and have had shoulder replacement surgery.

How will we perform this study?
We will hold interviews with people who have undergone or who are preparing to have a shoulder replacement to help us develop prehabilitation and early rehabilitation treatments. We will ask professionals such as physiotherapists, occupational therapists, nurses and orthopaedic surgeons about their ideas, and ask for suggestions on how to embed these ideas into treatments. We will trial the treatments with a small group of participants and practitioners across the UK. All of this development work will be done before we start our trial. In our trial, once the new treatments are finalised, we will test if they work with about 392 adults who have been referred for shoulder replacement in England, Wales and Northern Ireland. We will use a randomised design, by which we mean that people who agree to take part will receive either the care they would normally get in the NHS or one of the two new treatments. We will measure pain and ability to carry out daily activities before and after receiving their different treatments and will continue to do these measurements for twelve months after shoulder replacement. We will check that our new treatments are safe, that people can follow the treatments and that they are delivered by the health professionals in the way we would expect.

4 Background

What is the problem being addressed?

Demand for shoulder replacement surgery is rising, given its potential to reduce pain and increase function and quality of life[1-3]. In England, in the last 2 decades, the standardised incidence has quadrupled from 2.6 to 10.4 per 100,000 population[4]. Assuming linear trends, forecasts to 2050 indicate a more than doubling of annual procedures and tripling in associated costs with the greatest prevalence in adults aged between 65-85 years[5]. This is coupled with increasing waiting times for surgery and the deterioration in health-related quality of life, anxiety, pain and function whilst waiting for surgery and potential negative impact on post-operative outcomes[6, 7]. Health inequalities, particularly in those from more deprived socioeconomic groups, ethnic minorities, those with multimorbidity and older adults who are known to have higher risk of serious adverse events post-surgery with longer hospital stays, are also a major contributing factor to post-operative complications which must be addressed[4, 8, 9].

Prehabilitation with the intention of improving mental and physical readiness for such major surgery, is of increasing relevance[10, 11]. Personalised multi-modal prehabilitation interventions addressing health behaviours (e.g. nutritional support and physical activity), psychological wellbeing and management of co-existing health conditions are likely to be impactful but are not well described or tested[12, 13]. In this population, the levels of readiness for surgery and the ways in which individuals might access prehabilitation are unknown[14].

Whilst rehabilitation after shoulder replacement surgery is considered essential to maximise timely recovery, reduce length of hospital stay and minimise complications[15], early protocol led, clinician directed, rehabilitation runs the risk of reinforcing fear avoidance behaviour and dependence on healthcare professionals. In addition, the protocols and interventions (within 24 hours of surgery) are highly variable[16-18] and their benefit and safety have not been established in high quality trials.

How we propose to address this problem?

This study is specifically addressing the requirement to develop and test the clinical and cost-effectiveness of separate and combined prehabilitation and early rehabilitation (within 24 hours post-operatively) interventions, for people having a shoulder replacement. Our approach will tackle the deleterious physical and mental health impact of long surgical waiting lists, by supporting people to prepare for their surgery. It will unify the pre- and post-operative rehabilitation pathways which are often perceived as being separate and managed in isolation. It will give people the knowledge,

confidence and skills to navigate the total shoulder replacement pathway, enabling them to make decisions about their physical and mental health and rehabilitation, using healthcare professionals as a supportive resource rather than to direct their recovery.

The SPRING study has a two-phase design. The first involves an intervention co-design, piloting and refinement phase (14 months) (described in detail in other protocols). The second, a randomised, multi-centre 2x2 partial factorial clinical and cost effectiveness trial and process evaluation (described in this protocol).

Based on existing evidence, we propose a 1:1 personalised self-management approach integrated into prehabilitation, and early rehabilitation interventions, in a way that meets individual needs and preferences. The interventions will utilise codesigned resources and training and use specific sources of self-efficacy such as self-discovery, reflection, support, goal setting, problem solving, knowledge and taking action, to build confidence, skills and knowledge of people having a total shoulder replacement. The effectiveness of self-management approaches based on self-efficacy principles on recovery and outcomes has been demonstrated for a variety of long-term conditions and are associated with improvements in health-related quality of life[19-23]. We have previously developed and tested (and are currently testing) the effectiveness of personalised self-management support interventions for a range of long-term conditions and healthcare settings including community-based stroke rehabilitation[24], for people with primary progressive Multiple Sclerosis and those living with Long Covid[25, 26].

Throughout we will ensure appropriate recruitment strategies to engage with individuals from diverse backgrounds and with a range of experiences of shoulder replacement. This addresses our underpinning assumptions that everyone regardless of geography, gender or social situation should have equal opportunities and access to a personalised self-management approach to navigate their shoulder replacement pathway. We propose that this will allow individuals to have a quicker recovery and live well after surgery with reduced healthcare costs. This more efficient approach aligns with the NHS policy for transforming and modernising planned care and reducing waiting lists[10, 27, 28].

Why is this research needed now?

Despite the view that prehabilitation and rehabilitation are likely critical aspects within the shoulder replacement pathway, the National Institute of Health and Care Excellence (NICE) guidelines for joint replacement (primary) of the hip, knee and shoulder[14, 15], were unable to make any recommendations on prehabilitation or early mobilisation for shoulder replacement due to insufficient evidence and no published trials or trials underway on the topic. They did however suggest that the benefits were likely to be similar those seen after hip or knee replacement.

Provision of prehabilitation for shoulder replacement within the National Health Service (NHS) is limited. Indeed, a recent review of NHS shoulder replacement protocols from 43 UK Trusts identified only 10 which referred to some form of functional assessment, discharge planning, prehabilitation or advice prior to the surgery, all of which were poorly specified[16]. The waiting times between initial consultation, listing for surgery and receiving a total shoulder replacement are considerable[10, 27]. Our public and patient involvement engagement (PPIE) discussions and expert group consultation activities have confirmed waiting periods can be anywhere between 6 months and 5 years. During this time, individuals are frequently left feeling abandoned, experience a deterioration in their physical and mental health status and in some cases become unfit for surgery[13, 29]. Our PPIE group indicated that levels of pain can escalate during this time so that basic self-care can become extremely difficult, independence is lost, with inability to take part in sports and hobbies. The PPIE representatives that we spoke to had not routinely received any formal prehabilitation, which supports the view that prehabilitation for navigating the shoulder replacement pathway is not widely implemented in practice.

Early rehabilitation within 24 hours of shoulder replacement and before discharge would typically include ambulation, advice on managing self-care, sling use, safety, and shoulder and upper limb exercises, which are HP-directed but there is no consistent standard of practice across the UK or internationally for immobilisation and early commencement of shoulder mobilisation[2, 16-18, 29-31]. Three non-randomised studies in the UK have evaluated protocols with early active or active assisted shoulder movement within pain limits, sling use for comfort and use of shoulder in basic self-care tasks. These studies were associated with a positive outcome, but the inherent study design limitations preclude generalisability.

4.1 Rationale for Current Trial/Justification of Treatment Options

We suggest that although rehabilitation and early mobilisation within the shoulder replacement pathway may lead to favourable outcomes, this needs to be personalised to the individual preferences and their surgical procedure[32]. The uniqueness of our personalised self-management support approach is that it will shift from HP directed care to empower people to develop knowledge, confidence and skills to make decisions and take action about their health and rehabilitation based on their psychological and physiological readiness.

This is a novel approach as there is no consistent standard of practice across the UK or internationally for prehabilitation and immobilisation and early commencement of shoulder mobilisation after surgery. Relevant, relatable, accessible, and replicable prehabilitation and early rehabilitation (within 24 hours of surgery) are a priority, to support mental and physical preparedness for surgery and ensure that those undergoing surgery are appropriately equipped to engage with early post-operative rehabilitation. Interventions that support self-management focus on enhancing individuals' self-efficacy through acquiring knowledge, building confidence, and developing the necessary skills to effectively manage and make informed decisions about their care[33] are urgently needed. Such interventions which help people prepare for surgery can reduce inequities and result in better recovery[34, 35].

5 Trial Objectives/Endpoints & Outcome Measures

The aim of the trial is to test the clinical and cost-effectiveness of these interventions, in comparison to usual care, in improving function and reducing pain.

5.1 Primary Objectives

To determine whether there is benefit of prehabilitation and early rehabilitation interventions over usual services alone in improving shoulder function and reducing pain for people undergoing total shoulder replacement.

5.2 Secondary Objectives

- Complete an internal pilot in the first 8 months to examine whether moving to a definitive trial is feasible.

- Generate evidence to consider whether 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 explore by key patient demographics.
- Monitor and report trial specific adverse events and serious adverse events related to the emergent interventions.

- To evaluate the cost-consequences, including cost per quality adjusted life year, of the SPRING interventions at 12month follow-up post randomisation 2.
- To conduct a mixed methods process evaluation to explore the context, trial processes, intervention perceptions, intervention mechanisms and participant outcomes, to inform further implementation.

5.3 Primary Outcomes Measure(s)

Primary and secondary outcome measure selection has considered core outcome domains and sets for shoulder disorders[36,37]. The primary outcome measure is total Shoulder Pain and Disability Index (SPADI) which contains 13 items divided into two subscales for pain and disability[38] measured at the 12-month post randomisation 2. The pain sub-scale has five items and the disability sub-scale eight items. Each item is scored using an 11-point numeric rating scale. The score of each sub-scale is calculated by summing the scores of each item in the sub-scale and dividing by the respective number of items. The total SPADI score is calculated as an average of the pain and disability sub-scales and is expressed as a percentage.

5.4 Secondary Outcomes Measure(s)

- Global impression of change: Patient Global Impression of Change Scale (PGI-C): Singular item measuring improvement or deterioration over time on a 7-point numerical rating scale ranging from very much worse to very much improved for global change, range of motion and muscle strength[39] collected at 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, 6-month follow-up post randomisation 2, 12-month follow-up post randomisation 2.
- Pain: SPADI pain subscale[38] collected at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, 12-month follow-up post randomisation 2.

- Disability: SPADI disability subscale[38] collected at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, 12-month follow-up post randomisation 2.
- Pain self-efficacy: Pain Self-Efficacy Questionnaire (PSEQ). A 10-item scale rating participants confidence in their ability to engage in daily activities despite pain[40] collected at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, 12-month follow-up post randomisation 2.
- Anxiety via Hospital Anxiety and Depression Scale (HADS): a seven-item scale to measure the symptoms of anxiety Each item has with scores ranging between 0 and 3 to create of total between 0 and 21[41] collected at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, 12-month follow-up post randomisation 2.
- Depression via Hospital Anxiety and Depression Scale (HADS): seven-item scale to measure the symptoms of depression. Each item has with scores ranging between 0 and 3 to create of total between 0 and 21[41] collected at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, 6-month follow-up post randomisation 2, 12-month follow-up post randomisation 2.
- Sleep: Patient Reported Outcome Measurement Information system (PROMIS) Sleep Disturbance Short-Form 8a contains 8 items and assesses sleep disturbance over the previous 7 days[42] collected at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, 12-month follow-up post randomisation 2.
- Length of stay: Duration of hospitalisation calculated by subtracting day of admission from day of discharge collected at 6-week follow-up post randomisation 2.
- Surgical complications: This will include but not limited to deep and superficial surgical site infections, re-operation including dislocation, revision shoulder replacement (time to event) collected at 6-week follow-up post randomisation 2, 6-month follow-up post randomisation 2, 12-month follow-up post randomisation 2.
- Serious adverse events (related and unrelated) and trial specific adverse events. Number of hospital readmissions related to the total shoulder replacement will be reported as related SAEs. All SAEs and AEs will be managed at site, centrally monitored and reported at the trial management group meetings, the Trial Steering Committee meetings, and the Independent Data Monitoring Committee meetings.

- Quality of life via EQ-5D-5L health utility: a measure of health status across five dimensions (mobility, self-care, ability to undertake usual activities, pain and discomfort, anxiety and depression)[43] collected at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, 6-month follow-up post randomisation 2, 12-month follow-up post randomisation 2. It supports cost effectiveness evaluations. The dimensions included are a good representation of the problems that have been identified by the Patient Participant Involvement and Engagement (PPIE) group.
- Quality of life via EQ-5D-5L visual analogue scale (VAS): a self-rated health measure which reflects patients own judgement of their health on that day collected at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, 6-month follow-up post randomisation 2, 12-month follow-up post randomisation 2.
- Healthcare resource use and costs (direct and indirect): Resource Use Measure designed in-house to collect information on primary/community care, medications, hospital admissions, rehabilitation contacts (including any pre or post operative usual care rehabilitation), private healthcare, and impact on ability to work similar to the measure used in another study (TRAK-MSK study[44]) at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, 6-month follow-up post randomisation 2, 12-month follow-up post randomisation 2. Hospital records will be accessed for details of surgery, outpatient appointments and scans (data collected in the surgical complications and surgical outcomes CRFs. Intervention costs including training of staff involved will also established through therapist notes and discussion with the research team.
- Additional questions to capture quality of life issues specifically related to shoulder disability and sleep disturbance collected at baseline, 3-month follow-up post randomisation 1, 6-week follow-up post randomisation 2, 12-month follow-up post randomisation 2.

We will also be collecting:

- Demographics: age, sex at birth, gender, ethnicity, household structure, employment, self-administered comorbidity questionnaire (SCQ)[45], socio-economic status (parental occupation[46] and previous occupation) at baseline.
- Surgical (in hospital) outcomes: replacement type, pain medication , reasons for delayed mobilisation collected at time of surgery by treating therapist.

- Beliefs and priorities: an in-house designed set of items to ascertain beliefs and priorities on surgery at baseline.

6 Trial Design & Setting

The SPRING study has a two-phase design. The first involves an intervention co-design, piloting and refinement phase (14 months) which is underway. The second, a randomised, multi-centre 2x2 partial factorial clinical and cost effectiveness trial and process evaluation. This protocol provides the detail relevant to the second phase of the study (namely the factorial trial). There is a separate protocol detailing the co-design.

The RCT will recruit for 18 months, with an eight-month internal pilot. The pilot will have two assessment points, and the results of this will determine progression. The first assessment point will be after 6 months to evaluate progression criteria in relation to the number of sites opened, open site consent rates and total number recruited (randomised). Drop out (participants who withdraw from study or lost to follow-up) between randomisations will be evaluated at 8 months. Extra time is required to evaluate this criterion to accommodate the period between first and second randomisation and for completion of any prehabilitation. A traffic light system of progression criteria will be utilised to guide our decision to continue the trial, with green resulting in continuing as planned; amber, the trial continuing with changes; red, the trial stops[47]. The progression criteria are detailed in Table 1. Whilst retention rate, data completeness and participant diversity and intersectionality will not be formal progression criteria they will be assessed as part of the internal pilot with mitigating strategies implemented as needed. Numbers of participants who are not offered surgery in the six months after the first randomisation will need to be monitored as this will have a bearing on how many participants can be included in the final analysis, this will not be a formal progression criteria.

Table 1. Pilot phase progression criteria

Progression criteria	Red	Amber	Green
Number of sites opened	<60% (n=≤13)	60-99% (n=14-23)	100% (n=24)
Total number of participants recruited (randomised)	<50% (n=84)	50%-80% (n=85-134)	>80% (n=135)
Drop out between first and second randomisation	>15% of those randomised	5-15% of those randomised	<5% of those randomised

Phase 2: Randomised Controlled Trial (including internal pilot) and Process Evaluation.

392 adults undergoing planned total shoulder replacement surgery from hospital settings in England, Wales and Northern Ireland will be randomised at two time points:

- Randomisation 1: allocation provided following completion of baseline. Participants will be randomised to either receive the prehabilitation intervention, or usual care.
- Randomisation 2: allocation provided following surgery (in 24 hours post surgery). At this point, the prehabilitation intervention will be concluded for those allocated to the intervention arm through randomisation i.e. Participants will be allocated to either receive the early rehabilitation intervention, or usual care.

Intervention participants will cease to receive the intervention at about six weeks post surgery, depending on intervention timelines, this will be confirmed post co-design phase. They may at this point receive the usual care offered at their site.

Outcome data will be collected from participants at five timepoints: baseline, 3-month follow-up post randomisation 1 and 6-week, 6month, and 12-month follow-ups post randomisation 2.

Pilot

The internal pilot will take place in the first eight months of the randomised trial. There will be two assessment points, one at month six, and one at month eight.

At the first assessment point at six months, the progression criteria assessed will be:

- Number of sites open
- Total number of participants recruited

(see table 1 for details of the progression criteria)

At the second assessment point at eight months, the progression criteria assessed will be:

- Total number of drop-outs between randomisation one and randomisation two. Drop-outs will be defined as both withdrawals and losses to follow-up (not completing follow-up data questionnaires).

6.1 Risk Assessment

A Trial Risk Assessment has been completed to identify the potential hazards associated with the trial and to assess the likelihood of those hazards occurring and resulting in harm. This risk assessment includes:

- The known and potential risks and benefits to human subjects
- How high the risk is compared to standard practice
- How the risk will be minimised/managed

This trial has been categorised as low risk, where the level of risk is comparable to the risk of standard medical care. A copy of the trial risk assessment may be requested from the Trial Manager. The trial risk assessment is used to determine the intensity and focus of monitoring activity (see section 25.1).

7 Site & Investigator Selection

This trial will be carried out at participating sites within England, Wales and Northern Ireland. All sites who are interested in participating in the trial will be required to complete a registration form to confirm that they have adequate resources and experience to conduct the trial.

Before any site can begin recruitment a Principal Investigator (PI) at each site must be identified. The following documents must be in place and copies sent to the SPRING Trial email account (see contact details on page 4):

- The confirmation of Capability &Capacity from the site's R&D Department following sharing of local information pack
- Favourable opinion of host care organisation/PI from Main Ethics committee
- A signed Trial Agreement
- Current Curriculum Vitae (CV) and GCP training certificate of the PI
- Completed Site Delegation Log and Roles and Responsibilities document
- Full contact details for all host care organisation personnel involved, indicating preferred contact
- A copy of the most recent approved version of the Participant Information Sheet(s) and Consent Form(s) on host care organisation headed paper
- A copy of the most recent approved GP letter on host care organisation headed paper

Upon receipt of all the above documents, the Trial Manager (TM) will send written confirmation to the PI detailing that the centre is now ready to recruit participants into the trial. This letter/email must be filed in each site's Site File. Along with the written confirmation, the site should receive anything relating to trial intervention and a trial pack holding all the documents required to recruit into the Trial. Occasionally during the trial, amendments may be made to the trial documentation listed above. The CTR will issue the site with the latest version of the documents as soon as they become available. It is the responsibility of the CTR to ensure that they obtain local R&D approval for the new documents.

Site initiation will be by teleconference.

8 Participant Selection

Adults listed for planned total shoulder replacement will be approached for inclusion. Participants are eligible for the trial if they meet all of the following inclusion criteria and none of the exclusion criteria apply. All queries about participant eligibility should be directed to the Trial Manager before randomisation/registration.

8.1 Inclusion Criteria

- Adults 18+.
- Ability to provide informed consent.

- Listed for planned total shoulder replacement (anatomical or reverse) because of osteoarthritis, rotator cuff arthropathy or inflammatory arthritis.
- Living independently, or with carer support or in assisted living.

8.2 Exclusion Criteria

- Have had a previous shoulder replacement(s) and/or a previous partial should replacement (revision replacement) in the same shoulder.
- Shoulder replacement for malignancy, avascular necrosis, fracture or dislocation.
- Partial shoulder replacement and resurfacing.
- Living in a care home (residential or nursing care).
- Are taking part in another research study directly related to their shoulder replacement surgery which may impact the processes and/or outcomes of the present study.

9 Recruitment, Screening & Registration

9.1 Participant Identification

Potential participants will be identified from secondary care musculoskeletal clinics and surgical waiting lists by the PIs and other members of the clinical team at site. Eligibility will be confirmed by Research Nurse or other appropriately trained site staff member, patients can also confirm eligibility online but when unsure if they are eligible this will have to be checked by site staff. We will recruit from at least 24 sites across England, Wales and Northern Ireland, including sites that would not typically participate in orthopaedic trials and those in socio-economic disadvantaged areas. The sites will reflect high proportions of older adults, individuals from underserved groups in respect to socioeconomic level, population density and ethnicity and regions that have not traditionally recruited individuals to musculoskeletal studies. These site characteristics will be evaluated when bring sites on board.

9.2 Screening Logs

A screening log of all ineligible and eligible but not consented/not approached individuals will be kept at each site (In Site File held in Microsoft Teams or Florence folders) so that any biases from differential recruitment can be detected. Logs will be checked by Trial Team Data Manager, included

in the monitoring plan and reviewed at TMG meetings. When at site, logs may contain identifiable information but this **must** be redacted prior to being sent to the CTR. The screening log should be sent to the SPRING email address (SPRING@Cardiff.ac.uk) every 1 month (see section 19 for further detail on data monitoring/quality assurance). Screening logs are kept in Sites' ISF on 'Microsoft Teams'. They are updated by Sites, and monitored/checked by CTR DM. Screening logs will contain initials, and month and year of birth as identifiers.

9.3 Recruitment Rates

The overall study recruitment target for the effectiveness evaluation is 392 (across 24 sites), which equates to each site recruiting ~16 participants, requiring a monthly recruitment target of ~1.2 participants per site over 18 months. Participant recruitment should take place between 6 months and 6 weeks prior to the surgery date.

9.4 Informed Consent

Given that eligibility for the trial requires an individual to be listed for shoulder replacement surgery, our primary recruitment strategy is via the surgical waiting lists and clinic attendance lists. Potential participants will be given an information sheet in clinic, or this will be sent to them after their clinic visit. A poster will also be displayed at clinics advertising the study. If they want to discuss the project they will be given contact details for the research team, they will also be asked if they are happy to be contacted in order to be followed up by a member of the research team and given more information about the study, if so then the screening log will be completed. We will use the recruitment strategy developed with PPIE including films and advice on how to take part to ensure inclusion of people from marginalised groups.

A member of the research team, who have been fully trained in trial procedures, will explain the trial in detail, including randomisation. If happy to take part, informed consent will be obtained. The participant, on completion of EOI/Registration and deemed eligible, will complete a Consent form online if they are happy to take part. Participants can complete eligibility questions online, but if the are unsure of their eligibility, site will be asked to confirm this. Telephone consent (study team) and Clinician Consent (telephone or in person) can also be used whereby the form is completed on behalf of the participant.

A poster will be displayed with study information, and participants who want to take part will be directed to speak to their healthcare provider to access the full PIS and detailed study information before they can complete an EOI.

Consent and completion of baseline questionnaires will be done via the study website, telephone, or in clinic and will be guided by participant preference. Based on our experience of recruiting from similar populations in other studies we will maximise the use of telephone and in person support so that people are provided with the level of information they need to decide to participate. Preferences for follow-up data collection will be obtained to ensure that participants are being contacted in the way that suits them best. They can change their mind at any stage. Participant information sheets and intervention resources will be made available in English, Welsh and the 4 most common languages used in the UK other than English (Polish, Romanian, Punjabi and Urdu). Telephone and Language Line support will be available. Participants will have access to a study website where they can self-complete outcome measures. As part of the consent process all participants will be asked to consider sharing contact details for longer-term follow up for multiple methods of contact (address, telephone, email address).

The right of the participant to refuse to participate in the trial without giving reasons must be respected and participants will remain free to withdraw at any time from the trial without giving reasons and without prejudicing their further treatment.

Only when informed consent has been obtained from the participant AND they have been randomised/enrolled into the trial will they be considered a trial participant.

Loss of capacity is a possibility for this participant population as they will likely come from an older population, and therefore more likely to be living with multiple long term conditions including conditions such as dementia. Only participants with capacity will be recruited, however as part of the consent process we will ask participants to agree that a consultee will be asked to advise about whether they should continue in the trial but that their wish is to remain in the trial should they lose capacity during the course of their participation. Withdrawing those who lose capacity from follow up will limit the ability to inform care of this important population in future. Following initial provision of informed consent, participants may experience a decline in their cognitive function during their

participation in the trial. Where concerns about a participant's ability to provide ongoing consent to remain in the trial are raised (e.g., during contact with the participant or via concerns raised by their nominated supporter), capacity will be assessed by an appropriately trained member of the research team in accordance with the Mental Capacity Act 2005. Where a participant is assessed as lacking capacity to consent to remain in the trial, a personal consultee will be approached to provide advice about their continued participation. We will ask participants to name a relative, friend, unpaid carer or court appointee in the first instance to become their consultee on capacity (this cannot be someone that is paid to look after them), if there is no one suitable, we will give them the option to select their GP or someone else in their healthcare team to become their consultee. The consultee will be provided with a consultee information sheet and asked for their advice about whether the participant would want to continue in the trial. If the consultee advises that the participant would wish to continue in the trial, they will be asked to complete a consultee declaration form.

A focus on equality, diversity, inclusion and sustainability will be incorporated throughout. We have considered the INCLUDE Ethnicity framework[48] in combination with our PPIE activities in our approach to designing this study. We will develop a recruitment and communication strategy to recruit those that are not normally recruited into trials but who have worse outcomes such as low socioeconomic groups and different ethnic groups[49, 50]. To allow for variation in the way people engage with the research, due to cognition, health literacy, mobility and cultural norms, we will offer participants options of how the interventions are delivered (in clinic, online or over the telephone) and how outcome questionnaires are collected (e.g. website, telephone or postal). A nominated supporter can be included to support participation in the intervention and completion of study outcomes. All study materials will be designed using accessibility principles such as large text and images to accompany text. Translation and interpreter costs have been included for those that do not read or speak English. The participant information sheets, flyers and adverts, and the intervention books will be translated into Welsh as mandated by the Welsh Government. The participant information sheets, flyers and adverts will be translated into the 4 most common languages used in the UK other than English (Polish, Romanian, Punjabi and Urdu)[51] as well as into Welsh.

9.5 Registration & Randomisation

9.5.1 Registration

SPRING is a randomised, multi-centre 2x2 partial factorial trial.

9.5.2 Randomisation

See section 16.1. for details.

10 Withdrawal & Lost to Follow-up

10.1 Withdrawal

Participants have the right to withdraw consent for participation in any aspect of the trial at any time. The participants care will not be affected at any time by declining to participate or withdrawing from the trial because they will still receive care as usual. If a participant initially consents but subsequently withdraws from the trial, clear distinction will be made as to what aspect of the trial the participant is withdrawing from. These aspects will be:

- Withdrawal from either intervention (prehabilitation or early rehabilitation) but continue with data collection
- Partial withdrawal from future follow-up data collection (e.g., some questionnaires, interviews)
- Complete withdrawal from further data collection

Participants cannot withdraw from the trial but still receive the intervention. If they withdraw from the trial then they will receive usual care only. Participants who consent and subsequently withdraw should contact a member of site staff or trial team to complete a withdrawal form on the participant's behalf based on information provided by the participant. This withdrawal form should be sent to the Trial email address. Any queries relating to potential withdrawal of a participant should be forwarded to the Trial Manager.

Participants who enter the trial and then have their surgery done privately should then withdraw from the intervention. These patients can go into follow up for data collection unless they withdraw from this aspect also.

10.2 Lost to follow up

Participants who do not complete the 12-month follow-up data collection will be considered lost to follow-up. The trial team will monitor retention throughout the trial. In order to minimise loss to follow-up participants completing all the follow-ups will be eligible to be entered into a prize draw for vouchers worth £100 with a 1 in 20 chance of receiving the incentive[52]. Two draws will be held. Incentives (£15 vouchers) will be available to participants that are interviewed. To allow for variation in the way people engage with the research, due to cognition, health literacy, mobility and cultural

norms, we will offer participants options of where the intervention is delivered and how we will collect the outcomes. This will include remote or clinic-based delivery of the intervention and carer participation in the intervention and assistance with completion of study outcomes with the participant. All study materials will be designed using accessibility principles such as large text and images to accompany text. Study information will be written in lay, easy to read language. Participants will have access to a study team telephone number and email address so they will be able to access the research team and discuss any questions over the course of the project. We will ask participants their preference for how we communicate with them i.e. telephone, email or post. For those that opt for post we will provide stamped addressed envelopes so they can return any study materials to us[53]. Participants will be sent a six-monthly newsletter, written with PPIE contributors to keep them informed and engaged about the progress of the study. Upon consent participants will be given a research pack with the contact details of the study team, a schedule of follow-up appointments and a flow chart of what being in the study involves, this includes being contacted for interviews. We will send participants reminders a week before follow-up outcomes are due and thank you messages once these are completed. Usual care participants will be sent a copy of the intervention resource handbook after 12-month follow-up post randomisation 2. Participant information sheets and intervention resources will be made available in English and the prevalent non-English native speaking languages spoken in our target recruitment areas[48]. Telephone and language line support will be available. Participants will have access to a study website where they can self-complete outcome measures. As part of the consent process all participants will be asked to consider sharing contact details for longer-term follow up. In addition, we will make materials (including trial materials such as PIS where possible) available in alternative formats (e.g. video). A plan will be followed to maximise completion of measures, and a fixed number of reminders will be sent as not to burden participants with reminders. Information shared by participants will also be taken into account when contacting e.g. holidays etc.

11 Process Evaluation

Our theory driven process evaluation will be underpinned by MRC guidance for process evaluations and Normalisation Process Theory. The evaluation will be comprised of multiple data collection activities, over multiple time points, and will aim to explore issues relating to the context, mechanisms and outcomes of the SPRING interventions and how they may differ to usual NHS care in a sub-set of participants who have received a combination of either the SPRING prehabilitation

intervention or early rehabilitation, and usual care. Specifically, the evaluation will aim to understand (1) deliverers' (healthcare professionals) and recipients' (people experiencing shoulder replacement) perceptions of and experiences with the SPRING interventions including training and ongoing delivery support, or usual NHS care (2) participants experiences of trial processes, including documentation, and communication about the research, (3) processes that facilitate and/or act as barriers to implementation, including contextual factors such as organisational, personal or professional issues, (4) indicators of intervention success (ways in which participants and intervention deliverers' recognise a successful coaching interaction or outcome) and the extent to which they match to outcomes of importance to participants, (5) knowledge, confidence and skills required to deliver the intervention and alignment with intervention fidelity, (6) the local context of site shoulder replacement pathways and (7) factors required to enable sustainability and spread within the wider context of the NHS beyond the project timeline. The process evaluation will be comprised of five data collection methods; intervention training survey, scenario-based fidelity self-assessment, fidelity observations, semi-structured interviews and focus groups. Data collected routinely as part of the trial on withdrawals, and reasons for withdrawals, will also be drawn upon to understand trial processes.

Training survey. Following the co-design SPRING intervention training, we will capture healthcare professionals' readiness to deliver the SPRING interventions. A pre-post training questionnaire, using a 5-point Likert scale, will be used to assess healthcare professionals' knowledge, skills and confidence to deliver a range of co-designed key principles of the intervention/s. All healthcare professionals who receive the training will be asked to complete the survey prior to training session 1 and within 2 weeks following completion of the final training session. The online survey is not expected to exceed 20 minutes for completion.

Fidelity assessments. Healthcare professionals delivering the SPRING prehabilitation and/or SPRING early rehabilitation one-to-one personalised self-management support sessions will be asked to participate in fidelity assessments. Fidelity assessments will explore whether the interventions are being delivered as intended and will be reviewed against a pre-defined criteria comprised of the co-designed core principles of each intervention – eight prehabilitation and nine early rehabilitation core principles. The number of sites, their geographic spread and differences in technological infrastructure and service provision means these assessments may need to be undertaken flexibly.

Two methods will be used to assess fidelity: 1) scenario-based assessments and 2) fidelity observations:

Scenario-based fidelity self-assessment. All healthcare professionals will be asked to complete a scenario-based fidelity self-assessment to explore their understanding and prospective application of the core intervention principles. The assessment will be comprised of scenarios which professionals might experience when delivering SPRING prehabilitation and/or SPRING early rehabilitation sessions to a participant. Healthcare professionals will be asked to select and/or rank statements in order of best SPRING practice in response to each scenario.

***Fidelity observations*.** Healthcare professionals will be asked to record sessions for the research team to observe. The research team will seek to observe the language and interpersonal skills of the healthcare professional and score these against the core intervention principles. Sessions will be recorded via teleconference (e.g., MS Teams) or by audio if sessions are undertaken via telephone or face-to-face. Some on-site, face-to-face observations may also be undertaken. Purposive maximum variation criterion-based sampling will be used for healthcare professional observations based upon site, number of intervention sessions delivered, scores from the scenario-based self-assessment and professional background. It is anticipated that at minimum, one healthcare professional from each site will be observed at least once. Observations will be initiated from each healthcare professional's second intervention session. This will enable healthcare professionals to gain familiarity with intervention delivery before being observed. Participants will be made aware if their sessions will be recorded, and each recording will be stored in a confidential space only accessible by the trial team, and the specific healthcare professional.

Following competition of the scenario-based self-assessment and/or observation, healthcare professionals will receive feedback and will be directed to materials to enhance their knowledge and skills to deliver the intervention if necessary.

Semi-structured interviews. A sub-set of participants (approx. 15%) receiving each or both SPRING interventions/and usual care will be approached for a remote (e.g., Zoom/MS Teams, telephone) or face-to-face interview. We will sample purposively with the aim of ensuring the sample reflects the current data on who is likely to experience shoulder replacement, as well as to capture a variety of different demographics (e.g., age, sex, gender, shoulder replacement type, dominant vs non-dominant arm). Within the sample, we will also seek to recruit participants who start but do not

complete SPRING interventions but who consent to follow-up. Interviews will be undertaken at two time points: 1) six-week post-surgery and 2) twelve-months post-surgery.

Participants will be invited to take part in an interview at 6 weeks post-surgery and/or 12-months post-surgery.

Interview topics for both interview time points will focus on a) the acceptability, feasibility and appropriateness of the interventions and/or usual care to meet participants needs, b) the content, frequency and type of any usual care services received, c) challenges faced in accessing or receiving SPRING interventions/usual care and how/if participants overcame such challenges, d) impacts from the SPRING interventions/usual care on participants day-to-day lives, and e) why participants felt these interventions/usual care had such impacts.

Focus groups. We will further conduct up to 6 remote focus groups with healthcare professionals to explore (a) how training was delivered to staff and its acceptability to them, (b) how SPRING interventions were delivered and whether professionals perceived that they were able to deliver the intervention as intended and/or with any modifications required, (c) any contextual factors within community teams and the wider health service environment that affected intervention implementation and trial delivery and (d) any perceived outcomes from the interventions for participants. This will increase understanding of how the interventions align and be implemented and integrated within NHS services to foster sustainability and spread, should the intervention be shown to be effective and cost-effective. All healthcare professionals who were involved in intervention delivery will be invited to participate in focus groups which will be hosted at the end of the intervention delivery period.

We expect that through this process evaluation sampling and data collection, thematic saturation in will be reached. The topic guide for the interviews and focus groups will be designed jointly with our PPI panel who have lived experience of shoulder replacement surgery and will be informed by our co-design participants and clinical co-applicants on the study. The process evaluation will be carried out prior to knowledge of the final statistical analysis of primary and secondary outcomes to interpret findings without being influenced by knowledge of the results. The proposed methods will enable triangulation of multiple data sources and theory and provide an in-depth understanding of

the functioning of the trial, intervention, mechanisms and contextual factors and the implementation process to support SPRING beyond this study. Following the evaluation, a definitive logic model of change will be created to inform knowledge mobilisation, policy, practice and subsequent scale up.

Process Evaluation Analysis

All data from interviews and focus groups will be transcribed in full. All identifiable information, including names and locations, will be removed during the transcription process. De-identified files will be uploaded to and stored on Nvivo to enable initial coding and categorisation of raw data. Descriptive themes will be developed to identify emerging concepts and analysis. Further to the data-driven themes that emerge from the interviews with trial participants and focus groups with providers, Normalisation Process Theory (NPT)[54] and other theories will be applied to allow us to synthesise findings from an implementation perspective. NPT is a middle range sociological theory that conceptualises implementation, embedding and integration of innovation in healthcare settings. It emphasises the interactions between contexts (organisational and technical structures), individuals and groups (HPs, surgeons, patients) and objects such as clinical practices and procedures. Given the disparity and lack of consistency across shoulder replacement pathways a theoretic model which enables an understanding of 'the work' required by all stakeholders is vital to understand the translational gap between emerging evidence and practice as well as guiding recommendations for future implementation work. NPT and each of the four constructs has been previously used within Bridges Self-Management to pre-emptively plan for ways in which language, strategies and processes relating to self-management can be integrated into routine care and built into different aspects of training and sustainability support. It will not be possible to blind participants or practitioners to group allocation. Statistical and health economic analyses will however be conducted blind to group allocation.

Additional secondary analyses of the process evaluation data may be carried out by co-applicants at their respective institutions. These analyses will be undertaken on the de-identified data for the purposes of obtaining a richer understanding of specific aspects of the process evaluation, such as trial processes. These analyses should facilitate methodological learning for future trials with this population and comparable groups.

12 Patient and Public Involvement

In developing the proposal for this study, we engaged with ten people who have had a shoulder replacement or significant shoulder arthritis (eight female). These public and patient involvement (PPI) volunteers were from across England and Wales and from regions that vary in terms of population density, access to shoulder replacement surgical and rehabilitation services, and socioeconomic levels.

All volunteers were identified through adverts, charities, and word of mouth. The volunteers helped us with the prehabilitation early rehabilitation intervention co-design component (see co-design protocol), through individual online meetings and one small group meeting. In capturing their varying perspectives, we were able to identify key recommendations for the prehabilitation and early rehabilitation interventions, namely that they should:

- Ensure personalised support models to build knowledge, confidence and skills
- Support sourcing information that meets their needs
- Use other people's stories to guide their own realistic expectations
- Encourage the use of social networks
- Be accessible and seek to unify prehabilitation and rehabilitation
- Facilitate knowledge and confidence to engage in appropriate levels of shoulder movement, immobilisation and self-care based on pain and surgical factors
- Be delivered by knowledgeable Health Practitioners (HP's) that see the whole person, are empathetic, listen and provide reassurance and encouragement.

For ongoing PPI support, two of the volunteers that we spoke to have agreed to be co-applicants and have fed back on specific sections of our application including the lay summary, PPI activities if funded and strategies for retaining people to the trial. We will also form a 6-person public and patient involvement (PPI) group which will be co-chaired by our two PPI co-applicants alongside researchers from the Trial Team. We will seek to ensure representation from individuals from diverse backgrounds such as those from low socioeconomic and ethnic groups. We will achieve this both by linking with existing networks established by our team in other projects and working with site teams. The PPI group will meet every 3 months during the set-up and intervention co-design, piloting and refinement. During the main trial they will meet every 6 months or additionally if the need arises. An agenda will be prepared with the support of our researcher PPI lead before all

meetings and PPI will be given time to prepare/ read materials. Our PPI co-applicants will be members of the trial management group (TMG). The PPI within this study will adhere to the UK standards for patient and public involvement and reported and activities monitored within a standing TMG agenda item to ensure we are meeting these values-based principles. The PPI will work with key members of the study team to develop a recruitment and retention strategy to ensure that our research is accessible to groups that do not often take part in research. They will be asked to read and contribute to the development of all public facing materials such as adverts, participant information sheets and approach letters/ emails. To keep in contact and engage participants throughout the study -we will share a 6 monthly newsletter which will be co-designed with the PPI group. We will ask our PPI to help us develop short videos, sound bites and testimonials about the study that can be used to support recruitment and optimise retention. Early in the set-up we will ask the PPI to pilot our online system for completion of outcome measures and will ask for their input into the design of the study website. We will ask them to review the questions that will be used in the participant interviews. We will work together to raise public awareness of the study by linking with community, faith, charity or voluntary organisations that they have connections with. The PPI will be supported to help us develop and deliver our knowledge mobilization strategy. We will work with the PPI to ensure that the key messages from the study are communicated in a way that will reach the different target audiences and for them to present in our dissemination workshop. We will follow GRIPP2 guidance for reporting public and patient involvement in research and apply this in our final report and dissemination. Representatives will be made aware of other support that exists such as Health and Care Research Wales Public Involvement community and equivalent in other regions of the UK.

13 Trial Intervention

The SPRING study is formed of two interventions; one delivered before shoulder replacement surgery (prehabilitation) and one delivered after surgery (early rehabilitation). These prehabilitation and early rehabilitation interventions have been co-designed together with healthcare professionals and people who have experienced a shoulder replacement. These interventions are underpinned by Bridges Self-Management (Bridges), an approach to personalised supported self-management which has found to be effective in other health conditions. The Bridges approach is focused on enhancing individuals' self-efficacy through supporting them to acquire knowledge, build confidence, and

develop skills to manage and collaborate on actions to optimise preparation for surgery, and recovery after.

Both interventions are underpinned by nine core intervention principles which were developed from the intervention co-design process. These intervention principles comprise topics, language and skills that matter most to people with shoulder replacement, and which have subsequently informed two intervention components; two co-designed handbooks and a training and resource package for healthcare professionals who will be delivering one-to-one personalised self-management sessions.

Each of the two interventions, and their components, are described in more detail below:

Prehabilitation Intervention (before surgery)

The prehabilitation intervention comprises two components: A prehabilitation resource handbook (available electronically and in paper format) and up to four, one-to-one sessions with a SPRING trained healthcare professional.

The prehabilitation handbook is comprised of six main sections: stories of shoulder replacement, why people have the surgery, what usually happens when you have the surgery, how people can prepare, space to prepare and plan and take away messages and information.

People can also receive up to four, one-to-one sessions in the prehabilitation intervention dependant on their own needs. These can be delivered face-to-face, via telephone, or via video conferencing software, and can last up to 45 minutes per session. The duration and format of each session should be mutually agreed with the participant based upon their preference and site facilities. Ideally, people will receive all their sessions with the same healthcare professional; no more than two different healthcare professionals should deliver the four intervention sessions.

One-to-one sessions for prehabilitation will be delivered after a person has been waitlisted for surgery and after they have received their pre-operative assessment (approximately anytime between 6 months and 6 weeks prior to the surgery date). This will allow time for participants to mentally, emotionally and physically prepare for their surgery.

Early Rehabilitation Intervention (after surgery)

The early rehabilitation intervention is also formed of two components: An early rehabilitation resource handbook (available electronically and in paper format) and up to four, one-to-one sessions with a SPRING trained healthcare professional.

The early rehabilitation handbook is comprised of six main sections: stories of shoulder replacement, what happens after shoulder surgery, people's challenges and ways of coping, movements and exercises, space to plan and reflect on recovery and final messages and take away messages and information.

People can also receive up to four, one-to-one sessions in the rehabilitation intervention dependant on their own needs. In similarity with the prehabilitation sessions, these can be delivered face-to-face, via telephone, or via video conferencing software, and can last up to 45 minutes per session. The duration and format of each session should be mutually agreed with the participant based upon their preference and site facilities. Ideally, people will receive all their sessions with the same healthcare professional; no more than two different healthcare professionals should deliver the four intervention sessions.

One-to-one sessions will commence within 24 hours after a person has received their surgery. One session will happen within 24-hours of surgery and be delivered while the person is on the ward, before discharge. If a participant is discharged within 24 hours before they have received their first intervention session, they will receive a follow-up phone call within 48 hours of their surgery. If the person received their surgery on a Friday afternoon or evening and there are limited weekend staff, their first session can be on Monday. The remaining three sessions will be delivered across a six-week period following surgery. Participants will revert to the usual NHS care pathway in their site after the 6-week early rehabilitation delivery period.

Healthcare professional training

Prior to delivering any prehabilitation or early rehabilitation one-to-one sessions, all healthcare professionals must have completed the SPRING Bridges intervention training programme. This training programme will be eight hours long, comprised of four two-hour sessions. The sessions will be delivered remotely, in groups and be interactive. Healthcare professionals must attend, at minimum, three sessions live and are only permitted to attend one session by watching a recording. The training sessions will be rooted in the nine key principles of the SPRING interventions. In the training, healthcare professionals will learn about and have opportunities to practice the application of these nine principles which will include the language and skills they need to deliver the intervention as intended.

Intervention delivery and fidelity will be supported by the provision of an ongoing 'wrap around' support package, a method used in previous trials. This will provide healthcare professionals with

access to a suite of support, including exemplar sessions, crib sheets, exemplar language, FAQs and access to drop-in sessions.

Adherence

Intervention delivery and fidelity will be supported by ongoing 'wrap around support' a method used in previous trials. We will capture reflections from the intervention training team about methods used to engage and sustain fidelity of intervention delivery, through completion of on-line reflective questions. A pre-post training questionnaire addressing HP knowledge, skills and confidence on a 5-point Likert scale for a range of items relating to the key principles of Bridges Self-Management.

With regards to fidelity, we will carry out an independent analysis of 10-15% of 1:1 self-management support delivered in intervention sites. The number of sites and the geographic spread means these will need to be recorded via Zoom/Teams or telephone. Where possible we will include some on-site observations to assess intervention fidelity or ask HPs to do audio recordings of face-to-face sessions with consent from participants. This approach is underpinned by our experience of using these methods and contextualising to site setting and intervention. This approach will be refined after input from clinical co-apps during the pilot qualitative evaluation.

Our fidelity protocol will use a recruitment strategy that ensures each intervention delivery (prehab and early mobilisation support) are observed in each site at least once. Observations will be initiated after one participant has been recruited and completed their intervention. This will enable HPs to become familiar with intervention delivery before being observed. Fidelity observations will be reviewed against pre-defined fidelity markers generated through our previous trials and contextualised to core principles of SPRING through the co-design stages. Intervention HPs will receive detailed feedback about their alignment with fidelity and their use of language and strategies. Adherence will be measured by reviewing number and duration of sessions attended, key activities within each session (check list from physio notes).

Comparator

This will be usual care. Commonly there is no prehabilitation and when it does exist, it can take the form of information and exercise advice in a leaflet or singular information session or discharge planning questionnaire. Early rehabilitation post shoulder replacement is highly variable. It is HP

directed around the timing of how and when active shoulder movement starts, use of sling immobilisation and performance self-care tasks.

All randomised participants will receive the standard post-operative care offered at site for the first 24 hours post surgery.

All randomised groups will continue rehabilitation in the physiotherapy out-patient setting beyond early rehabilitation (approximately 6 weeks post-surgery) as required (normally 6-8 sessions but likely to be variable).

Usual care will be measured by CRFs completed by PIs to describe usual care in their area (quantitative, collected at baseline and pre surgery post-randomisation 1). This will also be measured as part of the process evaluation via focus groups (qualitative).

14 Trial Procedures

Participants will be involved on the RCT (including pilot and process evaluation) until 12 – month follow-up post randomisation 2. The timings of the data collection assessment are described below in Table 2.

14.1 Assessments

Table 2. Schedule of enrolment, interventions and assessments[1]

Procedures									
	Screening	Baseline	5 day follow-up post randomisation 1	Prehabilitation intervention	Pre surgery follow-up post randomisation 1	Surgery and early rehabilitation intervention	6-week follow-up post randomisation 2	6-month follow-up post randomisation 2	12-month follow-up post randomisation 2

[1] Taken from the HRA CTIMP protocol template (2016).

Screening log completion	X								
Informed consent		X							
Eligibility assessment	X								
Randomisation		X				X			
Fidelity evaluation for prehabilitation		X							
Delivery of intervention				X		X			
Adherence				X		X			
Shoulder Pain and Disability Index (SPADI)		X	X		X		X		X
Global impression of change: Patient Global Impression Scale (PGI-C)		X			X		X	X	X
Additional shoulder disability items created by PPIE		X	X		X		X		X
Pain self-efficacy: Pain Self-Efficacy Questionnaire		X			X		X		X
Sleep: Patient Reported Outcome Measurement Information system (PROMIS) Sleep Disturbance Short Form 8a		X			X		X		X
Additional sleep disturbance items created by PPIE		X			X		X		X

Hospital Anxiety and Depression Scale (HADS)		X			X		X	X	X
Beliefs and priorities		X							
Length of stay							X		
Complications during and after surgery							X	X	X
Surgical (in hospital) outcomes						X			
Serious adverse events and trial-specific adverse events		X		X	X	X	X	X	X
Quality of life: EQ-5D-5L and EQ-5D-5L VAS		X			X		X	X	X
Healthcare resource use and costs (Resource Use Measure, RUM).		X			X		X	X	X
Demographics		X							
Process evaluation data collection				X		X			X
Fidelity evaluation for early rehabilitation							X		
Process evaluation Focus groups							X		

14.2 Follow-up

Data will be collected at 3-month follow-up post randomisation 1, and at 6week, 6-month and 12 – month follow-ups post randomisation 2. Data will be collected online. See table 2 for details.

15 Safety Reporting

The PI is responsible for ensuring that all site staff involved in this trial are familiar with the content of this section.

All Serious Adverse Events (SAEs) that meet requirements of an SAE must be reported immediately (and within 24 hours of knowledge of the event) by the PI at the participating site to the Trial team unless the SAE is specified as not requiring immediate reporting. .

a. Definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a participant or clinical trial participant administered an intervention which are not necessarily caused by or related to that product
Serious Adverse Event (SAE)	Any adverse event that - • Results in death • Is life-threatening* • Required hospitalisation or prolongation of existing hospitalisation** • Results in persistent or significant disability or incapacity • Consists of a congenital anomaly or birth defect • Other medically important condition***
Serious Adverse Reactions (SARs)	Any SAE occurring in a clinical trial participant for which there is a reasonable possibility that it is related to the intervention.
Suspected Unexpected Serious Adverse Reactions (SUSARs)	A SAR, the nature and severity of which is not consistent with the Reference Safety Information (RSI) for the intervention.

*Note: The term 'life-threatening' in the definition of serious refers to an event in which the trial participant was at risk of death at the time of the event or it is suspected that used or continued

used of the product would result in the subjects death; it does not refer to an event which hypothetically might have caused death if it were more severe.

** Note: Hospitalisation is defined as an inpatient admission, regardless of the length of stay, even if the hospitalisation is a precautionary measure for continued observation. Pre-planned hospitalisation e.g. for pre-existing conditions which have not worsened, or elective procedures, does not constitute an SAE.

*** Note: other events that may not result in death, are not life-threatening, or do not require hospitalisation, may be considered as an SAE when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

b. Trial Specific SAE Reporting Requirements

In addition to the SAE reporting requirements above, for the purposes of this trial the following events will also be considered SAEs and must be captured on the SAE reporting form and reported to the CTR with 24 hours of knowledge of the event:

Trial specific events[55]:

- Infection
- Implant loosening
- Instability
- Rotator cuff failure
- Periprosthetic fracture
- Neurological injury

c. Causality

Causal relationship will be assessed for the intervention and procedures:

Intervention: Emergent interventions for supported self-management prehabilitation and early rehabilitation in shoulder replacement patients.

Procedures: n/a

The PI (or another delegated medically qualified doctor from the trial team) will assess each SAE to determine the causal relationship and the Chief Investigator (CI) (or another appropriately qualified member of the Trial Management Group (TMG)) can also provide this assessment where necessary:

Relationship	**Description**	**Reasonable possibility that the SAE may have been caused by the intervention?**
Unrelated	There is no evidence of any causal relationship with the intervention	No
Unlikely	There is little evidence to suggest there is a causal relationship with the intervention (e.g. the event did not occur within a reasonable time after administration of the trial medication). There is another reasonable explanation for the event (e.g. the participant's clinical condition, other concomitant treatment).	No
Possible	There is some evidence to suggest a causal relationship with the intervention (e.g. because the event occurs within a reasonable time after administration of the trial medication). However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other concomitant treatments).	Yes
Probable	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.	Yes

Definite	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.	Yes

The causality assessment given by the PI (or delegate) cannot be downgraded by the CI (or delegate), and in the case of disagreement both opinions will be provided.

d. Expectedness

The CI (or another delegated appropriately qualified individual) will assess each SAE to perform the assessment of expectedness. The CI will escalate to a clinician on the TMG for further review or advice if needed.

SAEs which add significant information on specificity or severity of a known, already documented adverse event constitute unexpected events. For example, an event more specific or more severe than that described in the protocol is considered unexpected.

Expected events are[55]:

- Infection
- Implant loosening
- Instability
- Rotator cuff failure
- Periprosthetic fracture
- Neurological injury

e. Reporting Procedures

Participating Site Responsibilities

The PI (or delegated appropriately medical professional from the trial team) should sign and date the SAE CRF to acknowledge that he/she has performed the seriousness and causality assessments. Investigators should also report SAEs to their own health boards or trust in accordance with local practice.

A completed SAE form for all events requiring immediate reporting should be submitted via fax or email to the CTR within 24 hours of knowledge of the event. A separate form must be used to report each event, irrespective of whether or not the events had the same date of onset.

The participant will be identified only by trial number and partial date of birth (mm/yy) and initials. The participant's name should not be used on any correspondence.

It is also required that sites respond to and clarify any queries raised on any reported SAEs and report any additional information as and when it becomes available through to the resolution of the event. Additionally, the CTR may request additional information relating to any SAEs and the site should provide as much information as is available to them in order to resolve these queries.

Serious adverse events should be reported from time of signature of informed consent, throughout the treatment period up to, and including 12 months after the participant receives the intervention.

An SAE form is not considered as complete unless the following details are provided:

- Full participant trial number
- An Adverse Event
- A completed assessment of the seriousness, and causality as performed by the PI (or another appropriately medically qualified doctor registered on the delegation log).

If any of these details are missing, the site will be contacted and the information must be provided by the site to the CTR within 24 hours.

All other AEs should be reported on the CRF following the CRF procedure described in Section 16.

The CTR Responsibilities

Following the initial report, all SAEs should be followed up to resolution wherever possible, and further information may be requested by the CTR. For follow-up information, sites to update the initial copy of the SAE form and put a single line through the old information and new information added.

The CTR should continue reporting SAEs until 12 months after the participant receives the last part of the intervention.

Once an SAE is received at the CTR, it will be evaluated by staff at the CTR and sent to the CI (or their delegate) for an assessment of expectedness.

For all non-CTIMP studies such as SPRING, including clinical investigations of medical devices, only reports of related and unexpected SAEs should be submitted to the REC. These should be sent within 15 days of the CI becoming aware of the event. There is no requirement for Annual Safety Reports (ASRs) in addition to the information provided through the annual progress report.

Urgent Safety Measures

An Urgent Safety Measure (USM) is an action that the Sponsor, CI or PI may carry out in order to protect the participants of a trial against any immediate hazard to their health or safety. Any USM relating to this trial must be notified to the REC immediately by telephone, and in any event within three days in writing, that such a measure has been taken. USMs reported to the CTR will be handled according to CTR processes.

16 Statistical Considerations

16.1 Randomisation

Participants will be randomised using web-based randomisation embedded into the trial database hosted by the Centre for Trials Research (CTR). For logistical ease we will conduct two randomisations, given scheduling of surgery is outside our control. As such, participants will be randomised initially 1:1 to prehabilitation or usual care. The first randomisation will be stratified by recruitment site. Once participants have been admitted for surgery, we will then randomise 1:1 to early rehabilitation or usual care. The second randomisation will be triggered by completion of the post surgical CRF which should be completed in the first 24 hours post-surgery. If the surgery is completed on a Friday afternoon or evening and there are limited weekend staff, this CRF can be completed on the Monday morning. The second randomisation will stratify by recruitment site and allocation arm at randomisation 1. A partial factorial randomised design provides a pragmatic approach for sequenced interventions where drop out may occur after stage 1 and prior to surgery.

16.1.1 Timing of randomisation 2

If randomisation 2 has not occurred within six months from randomisation 1, the participant will go directly into follow up without receiving randomisation 2. The participant will continue to wait and then have the surgery as per NHS wait lists and scheduling. The database will regularly flag to the PIs and those delegated responsibility at sites if no surgery has been planned to take place within 12 weeks of randomisation 1. A partial factorial randomised design provides a pragmatic approach for sequenced interventions where drop out may occur after stage 1 and prior to surgery.

16.2 Blinding

It will not be possible to blind participants or practitioners to allocation. The primary statistical analyses will however be conducted blind to allocation. The primary outcome and the majority of the

secondary outcomes are reported by the participants, so are provided with unblinded to the interventions.

16.3 Sample Size

We will recruit 392 participants to this 2x2 factorial design to provide at least 90% power for each of our two main comparisons (prehabilitation vs. usual care, and early rehabilitation vs. usual care). This is based on the total Shoulder Pain and Disability Index (SPADI) score as primary outcome using a mean of 84.3 and SD 22.3 with an expected mean difference of 8[56]. That gives an effect size of 0.359 and at a power of 90%, the required sample size for the two comparisons is 165 at significance level of 0.05 based on a two-sided t-test. This will be increased to an initial recruitment target of 196 per arm to allow for 15% drop out for reasons such as cancelled operations and medically excluded from early mobilisation. This design assumes no between intervention interaction effect. However, if a small antagonist interaction were present, the study would maintain 80% power for a difference as large as 2.2 on the SPADI scale but if synergistic, power would be increased.

16.4 Missing, Unused & Spurious Data

The study database will have inbuilt warnings which will flag missing responses and mandatory data input will be specified for core outcome data (SPADI). Regular central monitoring will ensure missing data collection is minimised for all PROMs and CRFs. Spurious data should be identified using validations and eliminated from the database at source, but data checks will be performed at regular intervals blinded by arm. Further detail on handling missing PROM items will be provided in the Statistical Analysis Plan (SAP). Any methods and assumptions for imputation will also be detailed in the SAP.

16.5 Procedures for Reporting Deviation(s) from the Original SAP

These will be submitted as substantial amendments where applicable and recorded in subsequent versions of the protocol and SAP.

16.6 Termination of the Trial

Beyond the internal pilot, there will be no formal 'stopping rules' or 'discontinuation criteria' for individual participants, parts of trial or the trial as a whole. Any concerns with participant well-being will be referred to the Trial Steering Committee (TSC) and Data Monitoring Committee (DMC) (if

required). Continuation from internal pilot to main trial will be decided by the TSC, DMC (if required) and funder (see section 25).

16.7 Inclusion in Analysis

The primary and all key secondary analyses will include all randomised participants regardless of intervention receipt (as we will be using a treatment policy strategy for handling intercurrent events).

17 Analysis

17.1 Main Analysis

Summary recruitment and flow of participant data will be collated and presented in a CONSORT flowchart. Data completeness at each timepoint of the factorial design will be tabulated and baseline demographic data summarised. Baseline data for those completing the trial compared with those lost to follow-up will be assessed for any possible bias due to loss to follow-up. A comprehensive Statistical Analysis Plan (SAP) will be approved by the TSC and Trial Data Monitoring Committee prior to database lock and commencement of analysis. We will incorporate the estimand framework[57] with estimands based on a treatment policy strategy (see below), i.e. we are interested in evaluating the effect of prehabilitation and early rehabilitation regardless of whether participants are able to fully adhere[47, 53]. For each comparison (prehabilitation vs. usual care, and early rehabilitation vs. usual care) we will estimate an "at the margins" effect by comparing all patients assigned to prehabilitation vs. those assigned to usual care, and all patients assigned early rehabilitation vs. all assigned to usual care.

Estimand statement following the treatment policy strategy

Objective: to estimate the effect of prehabilitation compared to usual care, and also early rehabilitation compared to usual care, on SPADI total score, regardless of adherence to the assigned treatment or occurrence of intercurrent events.

Estimand for prehabilitation compared to usual care:

- **Treatment:** assignment to prehabilitation versus usual care at randomisation 1.

- **Population:** all participants allocated to an arm at randomisation 1 meeting the inclusion and exclusion criteria at baseline.
- **Primary Outcome:** SPADI total score at 12-month follow-up post randomisation 2.
- **Intercurrent Events:**
  all intercurrent events (e.g., intervention discontinuation, protocol deviations, etc.) are handled using the **treatment policy strategy**, meaning the outcome is measured and included regardless of these events.
- **Summary Measure:**
  Difference in mean SPADI total score between treatment groups at 12-month follow-up post randomisation 2 analysed using an intention-to-treat approach.

The primary analysis comparing rehabilitation to usual care will include all participants allocated to an arm at randomisation that have SPADI total score at 12-month follow-up post randomisation 2 using a linear mixed-effects model. This will include the SPADI total score at baseline and follow-ups with time-point and time-point-by-randomisation interactions, along with variables in the randomisation process (sex at birth and recruitment site (with site as a fixed effect)).

Estimand for early rehabilitation compared to usual care:

- **Treatment:** assignment to early rehabilitation versus usual care at randomisation 2.
- **Population:** all participants allocated to arms at both randomisation 1 and randomisation 2 meeting the inclusion and exclusion criteria at baseline.
- **Primary Outcome:** SPADI total score at 12-month follow-up post randomisation 2.
- **Intercurrent Events:** all intercurrent events (e.g., intervention discontinuation, protocol deviations, etc.) are handled using the **treatment policy strategy**, meaning the outcome is measured and included regardless of these events.
- **Summary Measure:** difference in mean SPADI total score between treatment groups at 12-month follow-up post randomisation 2 analysed using an intention-to-treat approach.

The primary analysis comparing rehabilitation to usual care will include all participants allocated to an arm at randomisation that have SPADI total score at 12-month follow-up post randomisation 2 using a linear mixed-effects model. This will include the SPADI total score at baseline and follow-ups with time-point and time-point-by-randomisation interactions, along with variables in the randomisation process (sex at birth and recruitment site (with site as a fixed effect)). The primary analyses of early rehabilitation vs usual care will only participants allocated to an arm at randomisations 1 and 2.

The assumption that interventions do not interact will be formally tested via the inclusion of interaction terms in an analysis model including just those participants receiving an allocation at both randomisations 1 and 2. Appropriate sensitivity analyses will be listed in line with the CONSORT extension for factorial trials[58]. Continuous secondary outcomes (SPADI pain subscale, SPADI disability subscale, HADS Depression, HADS Anxiety, Pain Self-efficacy Questionnaire and Patient Reported Outcome Measurement Information system (PROMIS) Sleep Disturbance Short Form 8a, EQ-5D-5L health utility , ED-5D-5L VAS) will utilise a similar modelling strategy to that of the primary analyses. Generalised linear mixed modelling will be used in this case and for count and binary outcomes. The final report will disaggregate the recruitment data as well as the primary and secondary outcomes outcome by gender in accordance with the MESSAGE (Medical Science Sex and Gender Equity) framework[59].

Multiple imputation will be considered for the two primary analyses where there is missing 12-month follow-up post randomisation 2 primary outcome data. Delta-based sensitivity analyses will be carried out to examine the mechanism of missing data . Additional supplementary analyses will be carried out to examine the effect of non-compliance to both interventions. Analyses of the partial factorial design will account for any loss to follow-up before the second randomisation. All these analyses will be detailed in the Statistical Analysis Plan.

Numbers of participants with adverse events, and the details of these, will be analysed descriptively.

17.1.1 Sub-group & Interim Analysis

Exploratory subgroup analyses will be hypothesis-generating in nature and be used to study the extent to which the primary outcome may differ across the following subgroups:

- Sex at birth;
- Planned replacement type.

Like for the primary analyses of early rehabilitation vs usual care, participants not allocated to an arm at randomisation 2 will not be included in these sub-group analyses.

17.2 Cost Effectiveness Analysis

The health economic evaluation will comprise within-trial cost consequence analysis (CCA), comparing the relative costs and outcomes of the intervention with usual care from an NHS and Personal Social Services perspective, and a wider perspective including personal costs and impact on productivity. We will include all outcomes of interest that are feasible, and where data are of adequate quality,

including the total SPADI score (the primary outcome) and utilities (to inform a cost-utility analysis). Since the trial has been designed to adequately power the primary outcome and not costs or utilities, we will conduct an "inside-the-table" approach, which treats each combination of the 2x2 factorial design as a separate group, allowing us to construct a four-arm decision analytic model that will allow for the presence of interactions in both costs and outcomes[60, 61] . This type of model will not bring unnecessary bias into the results which could occur if we do not deal adequately with the interaction term for costs and utilities. The model will be built according to best practice standards[62].

The within-trial CCA will use the scores from the primary and secondary outcome variables at baseline and follow-up (subject to intervention design) to calculate the change in each of these variables over the trial period. The within-trial CUA will use the EQ-5D-5L health utility score at baseline, and follow-up to calculate the number of quality-adjusted life years (QALYs) gained (or lost) using an area-under-curve approach[63]. Intervention development and implementation costs will be recorded in Phases 1 and 2. Healthcare resource use will be collected at baseline and the follow-up points. To provide efficiency and consistency in data collection we have aligned the collection of participant level self-reported resource use data to the time-points of other outcome measures. This could present a risk as there is potential for the immediate post-operative period to not collect accurate hospital data, and that a longer recall period (6 months) may result in recall bias. To mitigate these risks, we will work to develop a suitable resource use measure (RUM) during the trial set-up, based on good practice in design[64]. Hospital data will be collected at the 6-week post-surgery follow-up point within the CRF to maximise data quality of expected main cost drivers during this period, with attention to ensuring this does not overlap with the RUM collected at 6-months post-surgery. We will produce a participant diary based on the RUM to enable participants to record their resource use during follow-up as a recall support to completing the RUM. We will examine completion of the RUM in the internal pilot and work with our PPIE panel and the SPRING team to resolve any issues before progression into the full trial. Published unit costs will be used to value healthcare resource use at the most current price year[65-67]. The incremental cost-effectiveness ratio (ICER) of the intervention will be calculated using the intention-to-treat population as the base case and multiple imputation commensurate with the statistical analysis as sensitivity analysis. Deterministic and probabilistic sensitivity analysis will be performed to address uncertainty in the analysis and its key inputs. Reporting of analysis methods, results and discussion will conform to the CHEERS 2022 standards[68].

18 Data Management

Source data is where the data are first captured (either written or electronically). Depending on the complexity of the trial design and number of data points required, the source data requirements are likely to vary. Examples of source documentation include the CRF, hospital records, clinical and office charts, laboratory notes, memoranda, subject's diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files etc.

Trial data	*Source Data*									
	CRF	*Electronic or telephone Consent form*	*Participant Diary*	*Electronic System*	*Site file*	*Questionnaire*	*SAE form*	*Audio/Video recording*	*Telephone, email, website*	*Withdrawal form*
Eligibility	X									
Informed Consent		X			X ~~(2)~~					
Case Report forms	X		X							
Outcome data				X		X				
Health Practitioner session notes	X									
Qualitative								X		

interviews										
Intervention fidelity								X		
SAEs (initially reported by participant)									X	
SAEs (initially reported by site)							X			
Participant withdrawal										X

Source Data is defined as *"All information in original records and certified copies of original records of clinical findings, observations or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents."* There is only one set of source data at any time for any data element, as defined in site source data agreement.

18.1 Data Collection

All data collection for this trial will be completed using an online system using electronic CRFs, via individual log-in, either by the participant, or the CTR or site team on behalf of the participant. A full data management plan will accompany this protocol and will be stored on the TMF.

18.2 Completion of Case Report Forms (CRFs)

Once consent has been given, baseline data collection will involve completion of questionnaires via the study website at home, in clinic, or over the telephone with a member of the study team,

depending on individual preference. Data collection and data management will be developed using the 'ASSISTANT' system which combines the REDCap database and a secure website database designed by Baseline Software Ltd. The website database acts as a user interface, with participant data entered via forms linking straight into the REDCap database to be stored and managed securely. The participant's nominated support person can assist them with completion of primary and secondary outcomes if needed. Participants will be asked to complete questionnaires at Baseline and pre surgery post prehabilitation, and post randomisation at 6 weeks, 6 months, and 12 months post-surgery. Staff at sites will be asked to keep a log of eligible participants and intervention appointments. The research team will keep a log of numbers consenting, numbers being randomised, completion rates of outcome measures and mode of completion. We will monitor ethnicity, age, socioeconomic status and multimorbidity within our trial population.

Participants will be followed-up post randomisation one pre surgery, and post randomisation two at 6 weeks, 6 months and 12 months

PIs at Sites (or delegate(s)) will be required to complete a CRF to capture participants length of stay, surgical complications and surgical (in hospital) outcomes. The completion of the surgical CRF must be done within 24 hours post surgery and will trigger the second randomisation. PI at site (or delegate(s)) will also complete separate CRF to track participants flow through the study.

18.2.1 Paper CRFs

Paper CRFs will not be used for the SPRING trial. CRFs will be electronic. If participants are unable to complete outcome measures online, they will be assisted by staff at site or the trial team. Participants will also be encouraged to find a nominated person (a family member or friend) to assist them with online completion.

18.2.2 Electronic CRFs

It is intended to develop data recording for this trial as a web-based system. This is a secure encrypted system accessed by an institutional password and complies with the General Data Protection Regulation 2016. The system can be accessed on: [provide URL]

Data collection and data management will be developed using the 'ASSISTANT' system which combines two secure databases: REDCap and a secure website ASSISTANT database designed by Baseline Software Ltd. The website ASSISTANT database acts as a user interface, with participant data entered via forms/questionnaires linking straight into the REDCap database to be stored and managed securely.

Participants can register online via the study website [insert link/URL], or in person or over the telephone. Upon completion of the Expression of Interest/Eligibility questionnaire, participants are deemed eligible or not eligible for the study. REDCap creates a participant record/PID, the next sequential number for each EOI/Registration questionnaire submitted. Participants will be emailed directly from the ASSISTANT system if eligible or not eligible. If eligible, participants are directed to sign in and create a password to access their record, for consent and questionnaires.
All Site and Study staff will access the ASSISTANT system to be able to view and manage their participants. A user password will be supplied to investigators upon completion of all processes required prior to opening. Individual site staff, i.e. health practitioners, will also be provided with their own user access. User rights/access will be determined by the role assigned on the Sites' delegation log. Details can be found in the Data Management Plan, upon request.

<Insert Web address/URL for CRFs, and the ASSISTANT URL Here>

Details of data management procedures can be found in the Data Management Plan.

19 Protocol/GCP non-compliance

The PI should report any non-compliance to the trial protocol or the conditions and principles of GCP to the CTR in writing as soon as they become aware of it.

20 End of Trial Definition

The end of the trial is defined as the date of final data capture to meet the trial endpoints. In this case end of trial is defined as the date of the last follow-up data collection.

The end of the trial is defined as the date of final data capture to meet the trial endpoints.

Sponsor must notify the REC of the end of a clinical trial within 90 days of its completion or within 15 days if the trial is terminated early.

21 Archiving

The Trial Master File (TMF) containing essential documents will be archived at an approved external storage facility for a minimum of 15 years. The CTR will archive the SMF on behalf of the Sponsor. The Principal Investigator at each site is responsible for archival of the Site file on approval from the Sponsor. Essential documents pertaining to the trial shall not be destroyed without permission from the Sponsor.

22 Regulatory Considerations

22.1 Ethical &Governance Approval

This protocol has approval from a REC that is legally "recognised" by the UK Ethics Committee Authority for review and approval (Wales REC 6).
This trial protocol will be submitted through the relevant permission system for global governance review by HRA for the lead site (Cardiff and Vale University Health Board). This trial protocol will be 'linked' to previous REC applications from the SPRING study (the co-design and pilot process evaluation work).

Approval will be obtained from sites who will consider local governance requirements and site feasibility. The Research Governance approval from sites must be obtained before recruitment of participants within that host care organisation.

We will attempt to have this trial adopted onto the NIHR Clinical Research Network (CRN) Portfolio of studies which would bring some additional support from the RDN in England (e.g., additional support for gaining participant consent).

The trial will be registered on the International Standard Randomised Controlled Trial Number (ISRCTN) website.

22.2 Data Protection

The CTR will act to preserve participant confidentiality and will not disclose or reproduce any information by which participants could be identified, except where specific consent is obtained. Data will be stored in a secure manner and will be registered in accordance with the General Data Protection Regulation 2016. The data custodian for this trial is the Sponsor, Cardiff University.

Participants receiving joint replacement surgery are invited to consent for their personal details to be recorded in the National Joint registry (name, address, NHS number/national patient ID, contact details).
Participants will always be identified using a unique Participant identification number (PID) and additional identifiers. All other identifiable information will not be stored with collected data.

22.3 Indemnity

- Non-negligent harm: This trial is an academic, investigator-led and designed trial, coordinated by the CTR. The CI, local Investigators and coordinating centre do not hold insurance against claims for compensation for injury caused by participation in a clinical trial and they cannot offer any indemnity. The Association of the British Pharmaceutical Industry (ABPI) guidelines will not apply.

- Negligent harm: Where studies are carried out in a hospital, the hospital continues to have a duty of care to a participant being treated within the hospital, whether or not the participant is participating in this trial. Cardiff University as Sponsor does not accept liability for any breach in the other hospital's duty of care, or any negligence on the part of employees of hospitals. This applies whether the hospital is an NHS Trust or not. The Sponsor shall indemnify the site against claims arising from the negligent acts and/or omissions of the Sponsor or its employees in connection with the Trial (including the design of the Protocol to the extent that the Protocol was designed solely by the Sponsor and the Site has adhered to the approved version of the Protocol) save to the extent that any such claim is the result of negligence on the part of the Site or its employees.

All participants will be recruited at NHS sites and therefore the NHS indemnity scheme/NHS professional indemnity will apply with respect to claims arising from harm to participants at site management organisations.

22.4 Trial Sponsorship

Cardiff University will act as Sponsor for trial. Delegated responsibilities will be assigned to the sites taking part in this trial.

- Conditions and principles of Good Clinical Practice.
- Declaration of Helsinki (1996)
- UK Policy Framework for Health and Social Care Research.
- Data Protection Act (2018)
- Other regulatory requirements as appropriate.

The Sponsor has/will be delegating certain responsibilities to Cardiff University/CTR(CU), the CI, PI, host sites and other stakeholder organisations as appropriate in accordance with the relevant agreement that is informed by regulation and trial type.

22.5 Funding

The trial is funded by the National Institute of Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme. Sites will meet the costs of intervention delivery through funding the programme.

23 Trial Management

23.1 Trial Management Group (TMG)

The TMG will normally meet monthly during the trial. TMG members will consist of all Co-investigators, collaborators and the trial team and will oversee all aspects of the trial. The role of the TMG will be to help set up the trial by providing specialist advice, input to and comment on trial procedures and documents (information sheets, Protocol, etc.). They will also advise on the promotion and running of the trial and deal with any issues that arise. TMG members will be required to sign up to the remit and conditions as set out in the TMG Charter.

23.2 Trial Steering Committee (TSC)

A TSC, consisting of an independent chair with expertise in rehabilitation trials, an independent shoulder expert, and independent statistician, a health economist, representatives from the PPIP panel, will meet every nine months and will oversee all aspects of the trial. Ideally, at least 75% of the TSC should consist of independent members. Non-independent members will include the joint CIs, trial statistician, senior trial manager and other members of the trial management team may attend in an observer capacity at the request of the Chair.

The first meeting will be as soon as possible, to review the Protocol and arrange the timelines for the subsequent meetings. If necessary, additional/more frequent meetings may occur. The TSC will provide overall supervision for the trial and provide advice through its independent chair. The ultimate decision for the continuation of the trial lies with the TSC and funder. TSC members will be required to sign up to the remit and conditions as set out in the TSC Charter which will be filed in the TMF.

23.3 Data Monitoring Committee (DMC)

The TSC will be responsible for determining if a DMC is required for this trial, or if the TSC will take on DMC responsibilities. If a DMC is deemed necessary, DMC members will be required to sign up to the remit and conditions as set out in the DMC Charter. If a DMC is required, then it should consist of at least three independent members.

24 Quality Control and Assurance

24.1 Monitoring

The trial risk assessment has been used to determine the intensity and focus of central and on-site monitoring activity in the SPRING trial. Low monitoring levels will be employed and are fully documented in the trial monitoring plan.

Investigators should agree to allow trial related monitoring, including audits and regulatory inspections, by providing direct access to source data/documents as required. Participant consent for this will be obtained. Where electronic health records (EHR) are being used, trial teams and monitors should check EHR process early in trial and periodically thereafter.

Findings generated from on-site and central monitoring will be shared with the Sponsor, CI, PI and local R&D offices.

24.2 Audits & Inspections

The trial is participant to inspection by regulatory bodies. The trial may also be participant to inspection and audit by Cardiff University under their remit as Sponsor.

25 Publication Policy

All publications and presentations relating to the trial will be authorised by the TMG. We will develop a broad reaching, accessible knowledge mobilisation strategy. We will create intervention manuals for practitioners, infographics, podcasts, blog posts for patient and public audiences, materials and policy briefings for the Department of Health and Social Care, NHS bodies and NICE. We will publish results in journals and host knowledge mobilisation events to discuss findings and implementation factors. We will work with our PPIE committee, organisations such as Versus Arthritis, British Association of Shoulder and Elbow Surgeons, Chartered Society of Orthopaedic and Trauma Physiotherapists Special Interest Group and project team to fully develop a dissemination strategy and ensure key findings are clear and accessible to participants, members of the public, NHS organisations and policy makers. We will raise the profile of the study by creating a study website, releasing social media posts, press releases, linking with Health and Care Research Wales and NIHR research networks and community networks in underserved communities through relationships we have established in our previous research. The impact will be to create a wider audience to increase reach of interim and full study findings. We will produce quarterly study newsletters for participants and study sites alongside researcher blogs that will highlight study progress.

We will develop a publication policy that will ensure that all team members can contribute to the publication process to ensure timely dissemination of the research outputs in an equitable, efficient, and transparent manner. We will use social media and the study website to disseminate findings to the wider public. Posters will be produced to disseminate findings at the locations that were involved in recruitment. Anonymised trial data will be made openly available on request to the TMG so that it can be used by other research groups to evaluate pain, function, quality of life and recovery in this population. At the end of the study if the interventions demonstrate clinical and cost effectiveness, we will translate the co-designed books into the 4 most common non-English

languages used across the UK. The potential impact will be increasing accessibility of the interventions to underserved populations.

If successful, we would expect to see the SPRING interventions adopted within the NHS. This would be based on the availability of evidence-based guidelines (e.g. NICE), and we would lobby policy makers and commissioners to ensure rapid review of any current guidance to reflect the emerging evidence delivered through this research. We will work with global collaborators to explore the adaption and inclusion within global solutions for total shoulder replacement.

26 Milestones and Piloting

See piloting section.

27 SWAT

There is evidence to suggest that SPADI measures two separate constructs of pain and disability, which cannot be added, and also that the disability sub-scale contains redundant items. This has been highlighted in two Rasch measurement theory analyses[69,70]. We will thus design a Study Within A Trial (SWAT) to replicate previous findings and explore options for modifying the SPADI disability sub-scale for future use in practice and research. This SWAT (called BLOSSOM) will be lead by an Early Career Researcher (Physiotherapist) from the NHS who is working up a funding application for institutional funds. The application for the BLOSSOM study has gone to H&CRW. A set of additional disability items, defined and designed by PPIE collaborators, will be asked in addition to SPADI at all relevant timepoints. Participants will be asked to voluntarily complete SPADI and additional disability items at 1-week follow-up post randomisation 1, which will allow assessment reliability and measurement error. Additional analyses will include correlations with other outcome measures, correlations of change in subscales from baseline to follow-up with change in other outcome measures from baseline to follow-up and calculation of effect sizes. Additionally, and only if we can secure further funding.

If additional funding is secured (in addition to the agreed funding), a sample of participants will be invited to cognitive interviews relating to the comprehensiveness, comprehensibility and relevance of the items in each subscale to provide evidence for content validity.

Despite the evidence above, SPADI total score was chosen as the primary outcome due to availability of evidence for it minimal clinically important difference. The other options considered for outcome measures of the same construct, such as Oxford Shoulder Score, lacked this evidence.

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29 Appendices

None.