Acute Rehabilitation following Traumatic anterior shoulder dISlocAtioN (ARTISAN): A Multi Centre Randomised Controlled Trial

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TRIAL SUMMARY

Trial Title	*Acute Rehabilitation following Traumatic anterior shoulder dISlocAtioN: A Multi Centre RCT*	
Internal ref. number (or short title)	*ARTISAN*	
Clinical Phase	*Phase III*	
Trial Design	*Multi-centre randomised controlled trial with health economic evaluation*	
Trial Participants	*Adults with a first time traumatic anterior shoulder dislocation (TASD) will be screened for inclusion*	
Planned sample size	*478 people will be randomly allocated to receive a single session of advice or a course of physiotherapy.*	
Treatment Duration	*Maximum of six months post randomisation.*	
Follow-up Duration	*12 months post randomisation*	
Planned Trial Period	*01.06.18 – 30.11.21*	
	Objectives	Outcome Measures
Primary	*The primary objective is to test the addition of tailored physiotherapy to a single session of advice with a single session of advice only, for adults with first time TASD managed non-operatively at six months using the Oxford Shoulder Instability Score (OSIS).*	*Oxford Shoulder Instability Score (OSIS)*
Secondary	*1. To estimate comparative cost-effectiveness (cost/QALY) of the two trial treatments, from an NHS and personal social services perspective.* *2. To determine the difference in complication rate (e.g.*	*EQ-5D-5L* *Complications* *Resource use* *QuickDASH* *OSIS*

	shoulder re-dislocation) in the first 12 months between the trial treatment groups. *3. To quantify and draw inferences between the functional status (OSIS) of the trial treatment groups at six weeks, three and 12 months.* *4. To quantify and draw inferences on observed differences in the functional status (QuickDASH) of between the trial treatment groups at six weeks, three, six and 12 months.* *5. To quantify and draw inferences on observed differences of health related quality of life (EQ-5D-5L) between the trial treatment groups at six weeks, three, six and 12 months.*	
Qualitative	*To qualitatively explore the experience of receiving the trial treatments and facilitators and obstacles to adhering to them.*	*At a point soon after the return of the 12-month follow-up questionnaire a purposive sample informed by treatment allocation, gender, age, and outcome of up to 50 participants will be invited for, a one off face-to-face interview (telephone interviews will be our backup).*

LIST OF ABBREVIATIONS/GLOSSARY

Abbreviation	Explanation
AE	Adverse Event
BESS	British Elbow and Shoulder Society
BOA	British Orthopaedic Association
CI	Chief Investigator
CONSORT	*Con*solidated *S*tandards *o*f *R*eporting *T*rials
CRF	Case Report Form
CTU	Clinical Trials Unit
DMC	Data Monitoring Committee
GCP	Good Clinical Practice
HEAP	Health Economic Analysis Plan
HTA	Health Technology Assessment
ISRCTN	International Standard Randomised Controlled Trial Number
MCID	Minimally Clinically Important Difference
NHS	National Health Service
NIHR	National Institute for Health Research
OSIS	Oxford Shoulder Instability Score
PI	Principal Investigator
PIC	Patient Identification Centre
PPI	Patient & Public Involvement
PROM	Patient Reported Outcome Measure
QoL	Quality of Life
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
R&D	Research and Development
SAE	Serious Adverse Event
SD	Standard Deviation
SOP	Standard Operating Procedure

TASD	Traumatic Anterior Shoulder Dislocation
TM	Trial Manager
TMG	Trial Management Group
TSC	Trial Steering Committee
WCTU	Warwick Clinical Trials Unit

1. BACKGROUND

1.1 Epidemiology and burden of the condition

The shoulder is the most frequently dislocated joint; occurring in 8.2 to 23.9 per 100,000 people per year (1); 95% of these are anterior dislocations. They occur when excessive forces during a traumatic event displace the humeral head frontwards, out of the shoulder socket (glenoid fossa), resulting in the joint surfaces completely losing contact (1-3).

Traumatic anterior shoulder dislocation (TASD) has a bimodal distribution; males under 25 years during high impact incidents and females over 80 years during low impact incidents. This is an increasing health problem in the second peak because of our aging population (1).

Regardless of their age, people sustaining TASD may have ongoing pain, disability, and substantial morbidity linked to high recurrence rates and subsequent need for repeated episodes of management (1-3). Re-dislocation following a first time traumatic event typically occurs within 12 months of the index dislocation (4). An American study found a quarter of people with TASD had recurrent dislocations (4). Common reasons leading to re-dislocation include soft tissue damage surrounding the shoulder, such as a Bankart lesion in which there is damage to the glenoid rim, and bony injuries such as Hill-Sachs lesions whereby the humeral head sustains a compression fracture during the index event (5, 6).

Rehabilitation may reduce on-going re-dislocations and restore a functional, painless and stable shoulder through early restoration of joint movement, and promotion of exercises to retrain muscles to maintain stability (2). However, a current Cochrane review has not found an evidence base to support this (2). Dutch national guidelines explicitly state no referral to physiotherapy should be made (3) and UK guidelines cite referral 'may be helpful' (1). Thus, the nature and extent of physiotherapy required for the management of patients following TASD is unclear.

A typical course of six physiotherapy sessions costs around £330; a single assessment and advice session costs £55 [lead centre costs]. Hence, the choice of physiotherapy package after TASD has large resources implications for the NHS. Assuming, conservatively, an incidence of 10/100,000 of first TASD by 2020 there will be around 67,000 TASDs annually treated by the NHS. Providing a full course of physiotherapy for all of these will cost over £18M per annum.

In addition to the cost of providing physiotherapy service there was a clear message from our patient workshop that attending a typical course of six sessions of physiotherapy is burdensome. Younger people may need to take time from work or arrange care for dependents, older people may find travel challenging particularly if unable to drive following the dislocation. For both groups this can be time consuming and costly. If a single advice session were all that is required, it would have positive impact on patient experience after TASD, lessening the burden on patients and their friends and family.

Consequently, a course of supervised, tailored physiotherapy needs to be of clear additional benefit, when compared to a single session and an advice leaflet, if it is to be implemented as standard care in the NHS. There is no clinical consensus or high quality evidence on how best to manage TASDs (1). With increasing numbers, because of an aging population, and need to remain active in older age through continued participation in sporting activities, there is a pressing need for a trial to address this gap in the evidence-base. We will provide high-quality evidence regarding the nature and extent of what physiotherapy is required for the management of patients following TASD.

1.2 Existing knowledge

Joint British Elbow and Shoulder Society (BESS) and British Orthopaedic Association (BOA) guidelines, and two Cochrane reviews advocate non-operative management for people with a first TASD who are aged 25 years or over; and suggest further research on the possible benefits of surgery in the under 25 year group (1, 2, 7). Despite non-operative care being the predominant first line strategy there is no RCT evidence regarding what to do once the decision not to operate has been made (1, 2). Furthermore, there is conflicting national guidance, this evidence is summarised below:

1. 2014 Cochrane review (2) on methods of non-operative management concluded that there were no RCTs available in the literature comparing rehabilitation methods after the initial two weeks of immobilisation. The review also found no evidence of any on-going studies.

2. 2015 UK guidelines from BESS/BOA state '...referral to physiotherapy may be helpful...' (1).

3. Dutch Orthopaedic Association guidelines state '...physiotherapy is not recommended...' (3).

Robust evidence to inform the role of physiotherapy in TASD is absent, as demonstrated through the evidence in the above points. With more people receiving first line non-operative management, combined with the large personal and societal cost associated with this injury, the evidence gap in rehabilitation is a clear priority. With up to date reviews, recently published national best practice pathways and a growing TASD population now is the right time to establish best non-operative care for TASD. Crucially we need to know if resourcing an intensive physiotherapy package is clearly superior to a single advice session.

1.3 Hypothesis

That advice and a course of physiotherapy for first time TASD managed non-operatively is superior to a single session of advice.

1.4 Need for a trial

Addressing the increasing number of TASDs, combined with its short and long term burden on finances, health and healthcare resources, is an important research area. A Cochrane review has identified this need and Patient & Public Involvement (PPI) workshops and professional societies have recognised this as an important research question, the Orthopaedic Trauma Society have provided a letter of support.

1.5 Ethical considerations

The trial will be conducted in full conformance with the principles of the Declaration of Helsinki and to Good Clinical Practice (GCP) guidelines. It will also comply with all applicable UK legislation (including the Mental Capacity Act 2005) and Warwick Standard Operating Procedures (SOPs). All data will be stored securely and held in accordance with relevant UK data protection legislation.

Before enrolling people into the trial, each trial site must ensure that the local conduct of the trial has the agreement of the relevant NHS Trust Research & Development (R&D) department. Sites will not be permitted to enrol people into the trial until written confirmation of R&D agreement is received by Warwick Clinical Trials Unit (WCTU).

The trial staff will ensure that all participants' anonymity is maintained. The participants will be identified only by initials and a participant's ID number on the CRF and any electronic database. All documents will be stored securely and only accessible by trial staff and authorised personnel. The

study will comply with relevant UK data protection legislation, which requires data to be anonymised as soon as it is practical to do so.

Data will be collected on paper based CRFs at the time of clinic visits or surgery. Data will then be entered into a secure online study database provided by Warwick Clinical Trials Unit (WCTU). Paper based CRFs will be stored on site at WCTU under locked conditions for the duration of the trial, these will be considered source documents for this study.

Direct access to source data and documents: Direct access will be granted to authorised representatives from the sponsor, host institutions and the regulatory authorities to permit trial related monitoring, audits and inspections.

1.6 CONSORT

The trial will be reported in line with the CONSORT (*Con*solidated *S*tandards *o*f *R*eporting *T*rials) statement (Lancet 2001, **357**: 1191-1194).

1.7 Assessment and management of risk

Both advice alone and advice in addition to tailored physiotherapy are current practice across the NHS for the management of TASD. Consequently, both trial interventions reflect current standard practice and do not expose trial participants to any substantial risks over and above standard care currently received. In keeping with WCTU SOPs, a risk assessment and monitoring plan will be implemented

2. TRIAL DESIGN

2.1 Trial summary and flow diagram

A UK multi-centre, two-arm, parallel group, randomised controlled trial with 1:1 treatment allocation and internal pilot.

We propose an RCT to find out if a course of physiotherapy is of clear benefit when compared to a single session of advice. The proposed project is a superiority two-phased study. Phase 1 (Internal Pilot) will confirm the expected rate of recruitment in a large-scale multi-centre randomised controlled trial. Phase 2 (Main phase) will be the proposed randomised controlled trial in trauma centres across the UK.

In addition to the pilot and main trial we will also be conducting studies within the trial aimed at improving the way we conduct clinical trials. Examples include randomising trial participants to receive a brown envelope for follow-up return questionnaires or a white envelope. This will not impact on the main trial recruitment procedures, interventions, follow up time points or outcome measures collected as outlined for the main trial.

Internal pilot summary: Formative process measures will ensure the successful delivery of the main phase and will evaluate recruitment (50 participants, approximately 10% of the full sample) within a specified period (six months), amongst 12 pilot sites. At which point the decision to progress to the main trial will be made in collaboration with the trial steering committee and NIHR HTA programme based on pre-defined progression criteria.

The criteria for continuing will be achievement of 75-100% of the recruitment target; criteria for the need to review and amend trial procedures before continuing will be achieving 50-75% of the target; criteria for not proceeding will be achieving less than 50% of the target. These randomised patients

will be retained in the full trial analysis. The aim of this initial phase will be to determine the number of eligible and recruited participants in the trauma centres over the course of six months from the start of recruitment. We will keep screening logs at each site to determine the number of people assessed for eligibility and reasons for any exclusion. In addition, the number of eligible participants recruited, and the number of potential participants who decline consent/withdraw will be recorded. The pilot will also be used as a basis for testing the systems for collecting outcomes, including measures required for the economic evaluation.

Main RCT summary: Adults presenting at trial centres with a primary (first-time) TASD will be screened. In conjunction with their treating clinician, they will decide if they have surgery or not. Following identification of a potential participant with a TASD by the trauma team, a suitably trained member of the research team at each site will be contacted to undertake eligibility checks in conjunction with the trauma team, all eligibility checks will be confirmed by the clinician. Details will be entered on the monthly screening log. All eligible potential participants who are willing to be approached by a suitably trained member of the research team will be provided with verbal and written information about the study. For trial participation all participants are required to complete postal questionnaires in the English language.

If a potential participant is deemed eligible and is willing to take part in the study, a suitably trained member of the research team will then be responsible for completing consent procedures, baseline demographic data and pre and post injury functional outcomes using the validated Oxford Shoulder Instability Score (OSIS) (8). This is the primary outcome measure recommended by the joint British Elbow and Shoulder Society/British Orthopaedic Association's national guidelines. It is the only measure with adequate validation for this injury (1).

Participants will also be asked to fill out the QuickDash (9), which measures physical function and symptoms in people with any or multiple musculoskeletal disorders of the upper limb and EuroQol EQ-5D-5L health related quality of life questionnaire to indicate their typical pre-injury and current health status (10).

A computer generated randomisation sequence, performed by minimisation, using participant age, hand dominance and treating centre. It will be produced and administered independently by a secure web-based service, accessed by either a suitably trained member of the research team or treating physiotherapist. Randomisation will be on a 1:1 basis to either a course of tailored, supervised physiotherapy or a single session of advice.

Functional outcome, health-related quality of life, complications and resource use questionnaires will then be collected via a postal questionnaire or by telephone at six weeks, three, six and 12 months following randomisation. Four hundred and seventy eight participants will be randomised in total, across participating centres. Both interventions are currently used in the NHS, consequently delivery of the randomised allocation will follow normal practice. All trial related follow up will be completed through postal follow up centrally from WCTU.

The local Principal Investigator and research team at each site cannot be blind to treatment as they will be delivering the interventions. None of these team members will have a role in the collection of follow up participant data beyond reporting serious adverse events.

A trial management group (TMG), trial steering committee (TSC) and data monitoring and ethics committee (DMC) will oversee the trial.

Figure 1 **Trial flow diagram**

2.2 Aims and objectives

The aim of the study is to test the hypothesis that advice and a course of physiotherapy for first time TASD managed non-operatively is superior to a single session of advice.

2.2.1 Primary objective

The primary objective is to test a single session of advice and physiotherapy with a single session of advice only, for adults with first time TASD managed non-operatively at six months using the Oxford Shoulder Instability Score (OSIS).

2.2.2 Secondary objective

Secondary objectives of the trial are:

- To estimate comparative cost-effectiveness (cost/QALY) of the two trial treatments, from an NHS and personal social services perspective.
- To determine the difference in complication rate (e.g. shoulder re-dislocation) in the first 12 months between the trial treatment groups.
- To quantify and draw inferences between the functional status (OSIS) of the trial treatment groups at six weeks, three and 12 months.
- To quantify and draw inferences on observed differences in the functional status (QuickDASH) of between the trial treatment groups at six weeks, three, six and 12 months.
- To quantify and draw inferences on observed differences of health related quality of life (EQ-5D-5L) between the trial treatment groups at six weeks, three, six and 12 months.
- To qualitatively explore participants' experience of receiving the trial treatments and facilitators and obstacles to adhering to them.

2.3 Outcome measures

2.3.1 Efficacy

Primary outcome:

Oxford Shoulder Instability Score (OSIS): The OSIS is a self-completed outcome measure containing 12 questions (0-4 points each), with possible scores from 0 (best function) to 48 (worst function) (8, 11). These questions relate to activities of daily living particularly relevant to patients exhibiting shoulder instability. The OSIS has been specifically designed to assess outcome of therapy (both surgical and non-surgical) by measuring activities of daily living and pain of patients exhibiting shoulder instability.

Secondary outcomes:

QuickDASH: The QuickDASH is a self-completed shortened version of the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire. Instead of 30 items, the QuickDASH uses 11 items to measure physical function and symptoms in people with any or multiple musculoskeletal disorders of the upper limb. The questionnaire was designed to help describe the disability experienced by people with upper-limb disorders and also to monitor changes in symptoms and function over time (9).

EQ-5D-5L: Is a well validated, generic health-related quality of life measure consisting of five dimensions each with 5-levels of response. Each combination of answers can be converted into a health utility score. It has good test-retest reliability, is simple for participants to use, and gives a single preference based index value for health status that can be used for broader cost-effectiveness comparative purposes (10).

Complications: Complications will be reported through the following mechanisms: a) Participant reported during routine collection of follow up data; b) Local research teams will report any additional investigations or treatment of participants c) Local physiotherapists delivering the trial interventions will report any events occurring during treatment sessions d) Medical records of non-responding participants may be retrieved by local research teams at site.

Complications will be defined into three categories: a) Pre-defined complications directly related to the trial interventions b) Pre defined complications directly caused by the primary TASD event not identified by the initial assessing clinician, but subsequently identified c) Complications not related to the intervention or TASD event and will subsequently not be formally analysed or reported.

Resource use questionnaires: The primary health-economic analysis will concentrate on direct intervention and healthcare/personal social services costs, while wider impact (societal) costs will be included within the sensitivity analyses. Participants will complete resource use questionnaires at baseline and all follow-up points, to collect resource use data associated with the interventions under examination.

We will use techniques common in long-term cohort studies to ensure minimum loss to follow-up, such as collection of multiple contact addresses and telephone numbers, mobile telephone numbers and email addresses. The trial team may keep in regular contact with participants using newsletters.

2.3.2 Safety

- See section 4 for details pertaining to adverse event (AE) and serious adverse event (SAE) data.

- Participants will be asked in follow-up CRFs at six weeks, three, six and 12 months if any complications or events have occurred. The PIs will also be asked to comply with the procedures for reporting AE and SAE data.

2.4 Eligibility criteria

People are eligible to be included in the trial if they meet the following criteria:

Adults with a primary (first-time) traumatic anterior shoulder dislocation will be screened against the eligibility criteria to take part in the trial. Broad eligibility criteria will ensure that the results of the study can readily be generalised to the wider patient population.

2.4.1 Inclusion criteria

- Provision of written informed consent

- They are aged 18 years or over

- They have a primary traumatic acute shoulder dislocation, confirmed radiologically.

2.4.2 Exclusion criteria

- Bilateral shoulder dislocation

- Having first line surgical treatment (Indications include a displaced greater tuberosity fracture for example)
- Cannot receive first session of physiotherapy within six weeks of injury
- In the opinion of the assessing clinician there is a significant neurovascular complication associated with TASD (e.g. brachial plexus injury)
- Unable to adhere to trial procedures or complete questionnaires; for example, a history of permanent cognitive impairment
- Previous randomisation in the present trial

If a trial participant were to sustain a contralateral TASD during the trial period, the second TASD would not be included in the study because the result of this intervention would not be independent from the first intervention.

2.5 Participant identification / Screening

People with a traumatic shoulder dislocation are typically referred to the secondary care orthopaedic team from either the emergency department or community/primary care. Potential participants will be identified by the usual treating orthopaedic clinical team in the secondary care site. Where appropriate, approved Patient Identification Centre (PIC) sites may refer patients. Following identification of a potential participant, a suitably trained member of the research team at each site will be contacted to undertake paper eligibility checks in conjunction with the treating clinical team. The research team member will complete the eligibility checklist and sign to confirm that eligibility checks were made in conjunction with and have been verified by a suitably qualified member of the clinical orthopaedic team, who will determine eligibility in keeping with their clinical training. The clinical team member will then document this on the participant's medical record, a quality assurance plan to check this process will be detailed further in the monitoring plan held at WCTU.

All potential participants meeting the entry criteria will be checked for eligibility and entered on the monthly screening log. Potential participants who are willing to be approached by a suitably trained member of the research team will be provided with verbal and written information about the study. They will then be asked if they wish to take part in the study. All new non-operatively managed potential participants will have a maximum of six weeks from date of injury to make a final decision and be randomised. If eligible and consenting, a member of the local research team will carry out the informed consent process, enrolment, baseline and pre-injury data collection.

Participants will be placed on the waiting list for physiotherapy, with a typical wait of up to two weeks. The eligibility will be re-confirmed by the treating physiotherapist at the first appointment and potential participants may be excluded at this stage if there has been a change in status. This allows someone who has consented to the study to be deemed not eligible at the point of randomisation to be excluded, using the pre-defined exclusion criteria.

To ensure all members of the trauma team are informed of the study, and to raise the profile of the study, where possible, publicity posters will be placed in clinical areas and sites will be supplied with other publicity materials (e.g. branded pens).

2.6 Site Staff Training

Members of the trial team will provide training prior to site activation to the local Co-Principal Investigator's (PI). The Co-Investigator team will comprise of one clinician and one physiotherapist,

to ensure that the complete participant pathway from identification through to management is overseen. Training will also include all research team members who will be responsible for conducting trial related procedures including for example confirming eligibility, obtaining consent, collecting baseline data, intervention fidelity procedures, randomisation and subsequent SAE reporting. The trial team will perform site initiation visits and will provide training tips via a presentation outlining the overview of the trial (key personnel, protocol, management and oversight) case report form completion, trial specific training (rehabilitation package with designated physiotherapists and fidelity procedures), SAE reporting, withdrawals, screening log and data clarifications. A training log will be used to document who has received training, research staff taking part in the study will sign the site delegation log and update the trial team when a new member joins the research team or the local PI changes.

This local team will then be responsible for distribution of the training materials across the wider trauma team using opportunities to present during clinical training and departmental meetings on an ad hoc basis. This wider training will occur throughout the recruitment phase due to the nature of rotating and changing trauma staff members.

Following site activation if a new research team member is appointed at local site the Trial Manager will be responsible for re-distributing trial-training materials and ensuring delegation logs are updated. If a new research team member is also responsible for delivering the physiotherapy intervention following this initial training, a lead therapist at each participating site will be identified to complete subsequent training of additional physiotherapists participating in the study at the trial site. This training will be supplemented with multi-media training materials accessible to the physiotherapists via a dedicated web-page and a comprehensive trial intervention manual.

2.7 Informed consent

Consent materials:

The orthopaedic team will undertake the initial approach, explaining that a study of shoulder dislocation rehabilitation is being conducted. If the potential participant is willing, the local member of the research team will then provide verbal and written information about the study. A list of information the research team should cover before consent is obtained will be provided to ensure that all essential information is discussed with the potential participant.

Participant's GPs will be informed by letter that they are taking part in this clinical trial.

Timing of consent:

Written informed consent will be obtained by a suitably trained member of the research team at each site as per the delegation log, after allowing sufficient time for the potential participant to consider their decision and ask questions about the trial. Sufficient time for some potential participants may result in a decision to take part in the trial immediately after receiving all relevant information; this is reflective of clinical practice. Alternatively, if potential participants would like to leave the clinic with the information and make a decision at a later date of their choosing, they will be free to do so within the time limits specified in the section entitled 'intervention'. The definition of 'sufficient time' is at the discretion of the potential participant being approached to take part.

Consent responsibility:

The Co-PI's retain overall responsibility for informed consent at their site and will ensure that any person delegated responsibility to participate in the informed consent process is duly authorised, trained, qualified and competent.

New information:

Any new information that arises during the trial that may affect participants' willingness to take part will be reviewed by the TSC; if necessary this will be communicated to all participants. A revised consent form will be completed if necessary.

Decline/withdrawal:

As there is a delay of a number of weeks before randomisation (due to the waiting list for physiotherapy), people who have entered the study will still have the option to withdraw before treatment starts if for any reason they change their mind.

The right of a potential participant to refuse participation without giving reasons will be respected, and recorded on the screening log. The participant will remain free to withdraw at any time without giving reasons and without prejudice to any further treatment, and will be provided with a contact point where he/she may obtain further information about the trial.

2.8 Randomisation

2.8.1 Randomisation

Pre-randomisation eligibility checks will be carried out to ensure that potential participants meet the eligibility criteria and are not randomised in error. Written informed consent for entry into the trial and baseline assessment must be obtained prior to randomisation. Subjects will be randomised once they have been registered as eligible for randomisation on the web based system and attended their physiotherapy advice session. Allocation concealment will be maintained by an independent randomisation team who will be responsible for generation of the sequence and will have no role in the allocation of participants.

The treatment group will be allocated by computer using a minimisation algorithm with a random element and stratification by participant age. There will be two groups 39 years old and under and 40 years old and over, hand dominance and treating centre following use of a secure web based randomisation service. The physiotherapist, following delivery of the control intervention, will randomise all trial participants. Physiotherapists will only be able to obtain the randomisation code after verifying that the initial control advice session is complete. By using this approach we have minimised any impact resentful demoralisation might have on people failing to engage with the control intervention.

Minimisation is a better option than conventional stratification with variable block sizes, due to the relatively small number of participants expected in some strata. The randomisation service will be available 24 hours a day, seven days a week to facilitate the inclusion of all eligible participants. The randomisation system will allocate each participant a unique trial number. A confirmation email will be automatically generated to the research site containing the randomisation details.

In an open trial of this nature it is impossible to completely control for the effects of demoralisation bias on engagement with the interventions. Failure to engage with an intervention is part of the reality of clinical practice regardless of the trial being conducted meaning that the effect size observed is likely to reflect real world effectiveness. We are cognisant of the risk of differential loss to follow-

up between the two groups. We will monitor this closely and maximise our collection of outcome data.

2.8.2 Post-randomisation withdrawals, exclusions and moves out of region

Withdrawal:

Participants may be discontinued from the trial treatment and/or the trial at any time without prejudice. Unless a participant explicitly withdraws their consent, they should be followed-up wherever possible and data collected as per the protocol until the end of the trial. For participants explicitly withdrawing consent for follow up procedures, trial data obtained up until the point of withdrawal will be included in the final analysis of the study. Participants will have the option to withdraw from the trial-related questionnaires, but continue to provide routine NHS data for the purposes of the trial e.g. hospital records of subsequent treatment for the shoulder dislocation.

Participants who withdraw will not be replaced in the trial and a corresponding withdrawal CRF will be completed.

Participants may be withdrawn from the trial at the discretion of the investigator and/or Trial Steering Committee due to safety concerns.

Follow up:

Core outcomes will be completed over the telephone, if postal copies are not returned. Text messages may also be sent to participants, text messages will only be sent to those participants who have given their prior consent to this by initialling the corresponding box on the consent form and providing their mobile telephone number. Details pertaining to the timing and nature of planned follow up procedure for telephone/post/text message are further detailed in the data management plan.

Multiple contact details will be recorded such as collection of addresses and telephone numbers, mobile telephone numbers and email addresses and contact details of next of kin to prevent loss to follow up. This information will be held separately from the trial data, on a password protected database, to uphold anonymisation, in line with current regulations. If the participant is lost to follow up at a certain time point, reasonable efforts (e.g phone calls) will be used to acquire outcome data at each time point.

2.9 Trial treatments / intervention

Preparatory work:

Defining the trial arms:

We have performed an update to the Cochrane review (April 2018) entitled 'Conservative management following closed reduction of traumatic anterior dislocation of the shoulder'(2). Using the same search strategies we found one small ongoing RCT additional to those reported in the latest review. We also widened the search by not limiting to RCTs, but excluding case studies, which resulted in two further case series describing rehabilitation protocols.

As a second strategy, we obtained full papers included in the Cochrane review entitled 'Surgical versus non-surgical treatment for acute anterior shoulder dislocation' (7) to collate and summarise non-operative rehabilitation protocols from the non-operative trial arms. However, they were either absent from the research papers or not sufficiently defined to replicate.

We found that there is a consensus on a phased approach to rehabilitation based on the underlying mechanism of injury and healing time scales, beginning with simple range of movement exercises and progressing to strengthening exercises that are manipulated to be easier or more challenging by altering load, frequency and repetitions. We carried out consultations with clinicians via a telephone and/or email interview to ascertain if the published literature was reflective of current NHS physiotherapy rehabilitation delivery. This process was also key to planning an intervention that is acceptable and deliverable to clinicians.

Once an intervention approach was outlined we presented our findings to a PPI group who discussed their experiences and expectations of physiotherapy. The PPI group not only discussed the content of the rehabilitation being important but also the need to understand their injury and to receive a 'package of care' that would aid compliance, which the group all agreed was difficult, at times. Subsequently this led to the intervention being developed to include an additional behavioural component to enhance adherence.

PPI Involvement:

The clinical team talked to patients about the project and a subsequent focus group representing our potential participants was arranged where we discussed experiences and expectations of services and the plans for the trial. These perspectives were key in the development of the protocol to ensure trial processes, materials and interventions are feasible and acceptable.

This has ensured best practice is feasible and scientifically grounded. It is current UK practice to offer either advice alone or advice and a course of physiotherapy. This trial will reflect these variations.

2.9.1 Trial treatment(s) / intervention

All participants: Advice session

We will describe our intervention in line with the TIDIER and CERT checklists (12, 13). All participating centres will receive an initial face-to-face training session from a member of the trial team with a physiotherapy background. Following this initial training, a lead therapist at each participating site will be identified to complete subsequent training of additional physiotherapists participating in the study at the trial site. This training will be supplemented with multi-media training materials accessible to the physiotherapists via a dedicated web-page and a comprehensive trial intervention manual.

All participants will receive a period of initial immobilisation as per UK national guidelines, for a duration of up to two weeks from date of injury (1). Typically this involves the injured limb being placed in a sling following reduction of the dislocation. This usually occurs in the fracture clinic environment. The exact duration and brand/type of immobilisation will be at the discretion of the treating clinician as per their usual practice. This will ensure that the results can be generalised across the NHS. At this first encounter consenting participants will be provided with a web-link to Phase 1 of the advice materials and provided with a paper based booklet version of the same content. Phase 1 will cover the below information:

- What has happened to me?
- What can go wrong?
- How do I stop this happening again?
- How long do I have to wear my sling?

- Should I move my arm?
- How do I control my pain?
- When can I return to usual activities?
- What if something goes wrong?

The expectation is that all participants will receive an appointment for physiotherapy within two weeks of injury (i.e. the time point at which the immobilisation would be expected to be removed). However, to reflect that some clinicians/sites may recommend immobilisation to be worn for greater or lesser time and to offer achievable time frames for all physiotherapy services an upper time limit of six weeks from date of injury will be accepted. Six weeks was chosen as the upper period limit to reflect the time point at which a soft tissue injury is no longer considered acute.

All participants will receive a single session of advice to aid self-management. This will last up to one hour and will be administered by an ARTISAN trained physiotherapist. Following routine assessment, the physiotherapist will deliver a core set of intervention components that will include education and discussion on the following:

a. What has happened to me?
b. What can go wrong?
c. How do I stop this happening again?
d. How long do I have to wear my sling?
e. Should I move my arm?
f. How do I control my pain?
g. When can I return to usual activities?
h. What if something goes wrong?
i. Points of contact if complications occur or expected recovery times are not achieved
j. A core set of progressive phase 2 range of movement exercises and what they aim to achieve
k. Enhancing self-management behaviours through the addition of goal setting, exercise planning and diaries

The outlined participant information (a-i) will aim to improve understanding of the condition and its management, to counter any participant misconceptions. Points j and k will aim to agree with the participant an exercise (or other) goal (e.g. repetition, duration, frequency); prompt them to think of possible factors (barriers & facilitators) influencing the behaviour (e.g. controlling the pain) and come up with strategies to overcome them. They will also be prompted to make detailed planning of performance of the behaviour or behaviours (e.g. exercise or pain management) to include at least one of context, frequency, duration or intensity. (e.g. encourage to complete one set of exercises every day after work and as soon as they return home).

The physiotherapist will provide details of web based materials, which will include all the core components above in written and video format, and will include a dedicated area for participants to set goals and keep diaries. The physiotherapist will also discuss with the participant that the website resources also contain progression to a core set of progressive phase 3 strengthening exercises and what they aim to achieve and later stage information on phase 4 how to return to sports (Appendix

One). Participants will be offered paper based alternatives (Appendix Two). Offering different formats (e.g. written and digital resources) enhances adherence as it adapts to a variety of individual needs.

Following completion the physiotherapist will randomise the participant, allocating them to this intervention alone or to this intervention in addition to the comparator detailed below, which will be delivered by the same physiotherapist.

Table 1: Summary of advice session received by all participants:

Component	Method of administration	When
Phase 1 Advice	Website and booklet	Consent
Phase 1 Advice	Verbally by physiotherapist	At first physiotherapy appointment
Phase 2 Range of movement exercises	Verbally by physiotherapist, website and booklet	At first physiotherapy appointment
Goal setting and exercise diaries	Verbally by physiotherapist, website and booklet	At first physiotherapy appointment
Phase 3 Strengthening exercises	Website and booklet	Following first physiotherapy appointment at home
Phase 4 Return to sport advice	Website and booklet	Following first physiotherapy appointment at home

Comparator: Advice session and offer of additional physiotherapy sessions.

The course will consist of the offer of at least one additional physiotherapy session after the pre-randomisation session. Each additional session will last for up to 30 minutes, over a maximum duration of four months from date of randomisation. It will be tailored, supervised and taught incorporating common methods to increase adherence by a physiotherapist trained by the trial team or local lead trial therapist. The course of physiotherapy will involve teaching and supervising the 'core set' of progressive exercises offered to the control arm and published on the web based resources in addition to being able to tailor through offering additional exercise components from a trial manual menu which will provide a range of exercises at differing levels which the physiotherapist can then choose and set specified frequency, loads and number of repetitions at their discretion.

This injury has a bi-modal age distribution. Following literature reviews, clinical and PPI consultation there were no age specific protocols published or routinely used in practice identified. More commonly rehabilitation protocols follow a phased approach beginning with early range of movement exercises in the acute stage, progressing through to early and then more challenging strengthening exercises. By using this approach participants can choose what level of activity they would like to retrain to (e.g. return to normal every day activities or continue to advanced exercise phases aimed at returning people to high impact sports). This approach does not pre-determine exercises based on age. Therefore no amendments to the intervention will be made based on age. However, trial materials will be available in a number of formats to accommodate different needs, for example if a participant does not wish to use on-line systems, paper based alternatives will be

made available. This will be available in large print on request. The team will develop a breadth of options so as to not discriminate any one demographic.

2.9.2 Compliance/contamination

Following site set up the trial team will implement mechanisms to ensure treatment fidelity. This will be based on a standardised approach of evaluating fidelity (14):

a) Direct Observations: With additional permissions, a member of the trial team will observe trial related procedures and the delivery of the two intervention arms (permission will be sought from the trial participants to observe treatment sessions). An adherence evaluation form consisting of items that reflect the occurrence or non-occurrence of an event will form the basis of the assessment.

b) Audio Recordings: With additional permissions, and in addition to the adherence form the interactions between the therapist and trial participant will be recorded during the above observation (additional permission will be sought from trial participants to record treatment sessions). This will be used to assess success or failure of the therapist to introduce the aims/rationale of each component and consolidate participant learning at the end of each component. Assessment will be given a Yes/demonstrated, No/not demonstrated and Unsure.

c) Therapist Self Report: The adherence evaluation form will also be self-reported by the site therapist. Alongside this, Case Report Forms will be collected on intervention delivery including number of treatment sessions attended, materials provided and exercise components prescribed. This will be completed for every trial participant.

Points a) and b) will be evaluated twice annually for the duration of recruitment and intervention delivery. Any issues identified will be discussed by the trial management group on a case by case basis who will be responsible for recommending appropriate action. If issues with individual sites are not resolved following the recommendations they will be escalated to the trial steering committee.

The trial team will also collect data to establish how often web based resources are accessed via a password access system.

2.10 Blinding

As the type of rehabilitation used will be clear to the participant they cannot be blind to their treatment. In addition, the treating clinician will also not be blind to the treatment, but will take no part in the subsequent assessment of participants. The follow up questionnaires will be distributed by post and telephone; centrally from the Warwick CTU trial office, where participants will be directed to return responses that will be collected and entered onto the trial central database by the administrative team to reduce the risk of assessment bias.

2.11 Concomitant illness and medication

2.11.1 Concurrent illness

Details of any concomitant illness will be recorded at trial entry.

2.11.2 Concurrent Medication

Details of medications will be recorded at trial entry, as detailed in the baseline CRF.

2.12 End of trial

The trial will end when all participants have completed their 12 month follow-up.

The trial will be stopped prematurely if:

- Mandated by the Ethics Committee
- Following recommendations from the DMC
- Funding for the trial ceases

The Research Ethics Committee will be notified in writing within 90 days when the trial has been concluded or within 15 days if terminated early.

3. METHODS AND ASSESSMENTS

3.1 Schedule of delivery of intervention and data collection

Table 2: Trial assessments

Visit	1	2	3	4	5	6	7	8
Visit Window	Pre-Consent	Baseline	First Physio session	6wk (± 2 weeks)	3m (±1m)	6m (±1m)	12m (±1m)	Post12 m
Eligibility Check	✓		✓					
Written and verbal information provided	✓							
Written informed consent and registration		✓						
Baseline CRFs (Pre injury)		✓						
Phase 1 Advice – Website and booklet		✓						
Baseline CRF (Post injury)			✓					
Physiotherapy control			✓					
Randomisation			✓					
OSIS		✓	✓	✓	✓	✓	✓	
QuickDASH		✓	✓	✓	✓	✓	✓	
EQ5D5L		✓	✓	✓	✓	✓	✓	
Resource use				✓	✓	✓	✓	
Complications				✓	✓	✓	✓	
Interviews								✓

3.2 Qualitative assessments – Nested studies

Qualitative interviews: It is important within this trial to ensure that people who are receiving the interventions are given a voice. One of the secondary objectives for ARTISAN is to qualitatively explore the participant experiences of receiving the trial treatments and facilitators and obstacles to adhering to them. Through achieving this component, the ARTISAN team will elicit pertinent information to explore why the rehabilitation programmes succeed or not and are they of 'value' to the patient.

At a point soon after the return of the 12-month follow-up questionnaire a purposive sample informed by treatment allocation, gender, age, and outcome of up to 50 participants will be invited for, a one off face-to-face interview (telephone interviews will be our backup). Information will be provided to all participants as they are recruited to the trial. These information sheets will include

clear information about the interviews that would take place at the end of the study. At this point we would be asking all participants to indicate on their consent form an expression of interest or not to be contacted at the end of the project. It would be clear that we are looking for research partners/participants who would be willing to share their views and experiences of the intervention/service they received. Those chosen will be from those who indicate at consent to the study that they are willing to being approached. Written informed consent will be taken before the interview.

The interview schedule can be found in appendix three. In general terms the aim of the interviews is to explore the participant experience of receiving the trial treatments and enablers and obstacles to adhering to them. Experienced interviewers will work through the interview schedule where necessary probing deeper to get to the real evidence. Interviews will be arranged via telephone at mutually agreeable times and places. Interviews will be digitally recorded, subject to permission of each participant, and will be transcribed verbatim.

4. ADVERSE EVENT MANAGEMENT

4.1 Definitions

4.1.1 Adverse Events (AE)

An Adverse Event (AE) is defined as any untoward medical occurrence in a participant which does not necessarily have a causal relationship with this treatment/intervention. Foreseeable AEs related to the management of TASD occurring as a result of the trial intervention(s) will not be recorded as part of the trial because advice and physiotherapy are part of normal clinical practice, with a good safety profile. Examples of such AEs include pain and reduced shoulder movement.

4.1.2 Serious Adverse Events (SAEs) A Serious Adverse Event is an AE that fulfils one or more of the following criteria:

An AE is considered a SAE if it is an untoward medical occurrence that fulfils one or more of the following criteria:

- Results in death
- Is immediately life-threatening
- Requires hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability or incapacity
- Is a congenital abnormality or birth defect
- Is an important medical condition

In the context of this protocol hospitalisation refers to any hospital event including day surgery and single A&E attendances. SAEs that may be expected as part of the interventions will be pre-defined and recorded on the participant's CRF for routine return to the ARTISAN central office and reported to the relevant oversight committees. AE/SAEs that may be expected as part of the TASD are: damage to nerve or blood vessels, fractures, re-dislocation, torn ligaments or muscles, persistent exacerbation of shoulder pain, restriction of range of movement, adhesive capsulitis (frozen shoulder) and persistent instability. All participants will be followed-up as per protocol until the end of the 12 month follow up period, all AEs/SAEs will be collected during this 12 month period.

All participants experiencing non pre-defined SAEs related to the intervention or TASD injury will be entered onto the appropriate reporting form and reported to WCTU using a dedicated ARTISAN and QA resource account within 24 hours of the investigator becoming aware of them.

4.2 Reporting SAEs

SAEs that may be expected as part of the interventions, and are pre-defined, will be recorded on the participant's CRF for routine return to the ARTISAN central office and reported to the relevant oversight committees. SAEs will be entered onto a SAE form and once received, causality (Table 3) and expectedness will be confirmed by either the Principal Investigator or Chief Investigator.

SAEs that are deemed to be unexpected and possibly, probably or definitely related to the trial interventions will be notified to the Research Ethics Committee (REC) within 15 days. All such events will be reported to the TMG at their next meeting. All SAEs that occur between the date of randomisation and the end of 12 month follow up for the participant will be reported. For each SAE the following information will be collected:

- Details of event that occurred from participant CRF or direct from site

If the event is identified on the participant CRF this will result in site being contacted to collect:

- full details in medical terms and case description
- event duration (start and end dates, if applicable)
- action taken
- outcome
- seriousness criteria
- causality (i.e. relatedness to intervention), in the opinion of the investigator
- whether the event would be considered expected or unexpected.

If the event is identified by site this will result in the site contacting WCTU with the above details via a SAE form.

Any change of condition or other follow-up information should be communicated to the Sponsor as soon as it is available. Events will be followed up until the event has resolved or a final outcome has been reached. The research team will liaise with the investigator to compile all the necessary information. The trial coordinating centre is responsible for reporting any related and unexpected SAEs to the sponsor and REC within required timelines.

Table 3: Relationship to intervention

Relationship to intervention	Description
Unrelated	There is no evidence of any causal relationship
Unlikely to be related	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the trial intervention or device). There is another reasonable explanation for the event (e.g. the person's clinical condition, other concomitant treatment).
Possible relationship	There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after administration of the trial intervention or device). However, the influence of other factors may have contributed to the event (e.g. the person's clinical condition, other concomitant treatments).
Probable relationship	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.
Definitely related	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.

All SAEs will be recorded for inclusion in annual reports to the Research Ethics Committee.

The following process will be used to review individual SAEs:

- Clinical review of a line listing of all life-threatening SAEs or SAEs resulting in death within 1 week of their occurrence.
- Clinical review of a line listing of all other SAEs on a monthly basis at TMG meetings

The following process will be used to independently monitor trends in SAEs in addition to usual trial safety monitoring procedures:

- Cumulative review of all safety information by the DMC, timetable to be agreed by Chair.

A member of the Principal Investigator's trial team will be instructed to closely monitor each participant who experiences a SAE until the outcome of the SAE has been determined.

4.3 Responsibilities

Co-Principal Investigator (PI):

- Checking for SAEs when participants attend for treatment / follow-up.
- Using clinical judgement in assigning seriousness, causality and expectedness
- Ensuring that all SAEs are recorded and reported to the Sponsor within 24 hours of becoming aware of the event and provide further follow-up information as soon as

available. Ensuring that SAEs are chased with Sponsor if a record of receipt is not received within 2 working days of initial reporting.

- Ensuring that SAEs are recorded and reported to the Sponsor in line with the requirements of the protocol.

Sponsor:

- All SAEs will be reported to the trial team
- Central data collection and verification of SAEs, according to the trial protocol.
- Reporting safety information to the CI, delegate or independent clinical reviewer for the ongoing assessment of the risk / benefit according to the Trial Monitoring Plan.
- Reporting safety information to the independent oversight committees identified for the trial (DMC and / or TSC) according to the Trial Monitoring Plan.
- Expedited reporting of related and unexpected SAEs to the REC within required timelines.
- Notifying Investigators of related and unexpected SAEs that occur within the trial.

Trial Steering Committee (TSC):

In accordance with the Trial Terms of Reference for the TSC, periodically reviewing safety data and liaising with the DMC regarding safety issues.

Data Monitoring Committee (DMC):

In accordance with the Trial Terms of Reference for the DMC, periodically reviewing overall safety data to determine patterns and trends of events, or to identify safety issues, which would not be apparent on an individual case basis.

4.4 Notification of deaths

All deaths will be reported to the sponsor.

4.5 Reporting urgent safety measures

If any urgent safety measures are taken the CI/Sponsor shall immediately and in any event no later than 3 days from the date the measures are taken, give written notice to the relevant REC of the measures taken and the circumstances giving rise to those measures.

5. DATA MANAGEMENT

Personal data collected during the trial will be handled and stored in accordance with applicable UK data protection law.

Personal identifying information will be brought to WCTU for follow up purposes. Handling of personal data will be clearly documented in the participant information sheet and consent obtained.

Disclosure of confidential information will only be considered if there is an issue which may jeopardise the safety of the participant or another person, according to Warwick Standard Operating Procedures (WCTU SOP 15 part 1) and the UK regulatory framework. There is no reason to expect this situation to occur in this trial more than any other.

5.1 Data collection and management

The CRFs will be developed by the trial manager in consultation with chief investigator, statistician, health economist and other relevant members of the trial team to collect all required trial data. A suitably trained member of the research team will complete and return the CRFs to the ARTISAN trial office. The coordinating team will check and enter the data onto a secure trial database held at WCTU as outlined in the data management plan and in accordance with the WCTU SOPs.

Various methods will be used to chase missing data/ unreturned questionnaires including post, phone, text and email (see 2.8.2), the procedures for managing this will be outlined in the data management plan and appropriate consent will be sought to contact participants. Data will still be collected for participants who discontinue or deviate from the intervention protocol, unless they withdraw their consent (see section 2.8.2).

5.2 Database

The database will be developed by the Programming Team at WCTU and all specifications (i.e. database variables, validation checks, screens) will be agreed between the programmer and appropriate trial staff.

5.3 Data storage

All essential documentation and trial records will be stored at Warwick Clinical Trials Unit in conformance with the applicable regulatory requirements and access to stored information (paper and electronic) will be restricted to authorised personnel. All data will be stored in a designated storage facility within the University Hospitals Coventry and Warwickshire and/or Warwick Clinical Trials Unit. Electronic data will be stored on password protected university computers in a restricted access building.

5.4 Data access and quality assurance

All data collected will be pseudoanonymised after the collection of the baseline demographic data for each participant. Confidentiality will be strictly maintained and names or addresses will not be disclosed to anyone other than the staff involved in running the trial. Participants will be identified by ID number, initials and date of birth only where necessary. Identifiable participant data will be held in a locked filing cabinet and coded with the trial number to tag identifiable data to the outcome data.

Direct access to source data/documents will be available for trial-related monitoring or audit by UHCW or Warwick CTU for internal audit, regulatory authorities or ethics committees.

The principal investigator must arrange for retention of trial records on site in accordance with GCP and local Trust's policies.

5.5 Data Shared with Third Parties

Requests for data sharing will be managed in accordance with University of Warwick/WCTU policy on data sharing. The datasets generated during and/or analysed during the current study are/will be available upon request. The publication of a trial protocol, trial results and trial data will be in line with the NIHR standard terms and will follow WCTU SOP 22: Publication & Dissemination.

5.6 Archiving

Trial documentation and data held at WCTU will be archived for at least ten years after completion of the trial. Trial documentation and data held by recruiting NHS sites will be stored in line with their local trust policy.

6. STATISTICAL ANALYSIS

6.1 Power and sample size

The OSIS is the only patient reported outcome measure recommended by UK BESS/BOA guidelines and was used by the most recent Cochrane review (1, 2). The standard deviation (SD) of the OSIS six months after injury is around 10 points (15, 16), however, the literature has predominantly included a younger population. Given that we will recruit a wider range of ages, it is likely that a larger SD is expected for this study. We have estimated required sample size with two-sided significance set at 5% for various scenarios of MCID, power and SD (Table 4). The bolded figure of 191 participants per treatment arm represents the most likely scenario, based on our current knowledge, for 90% power to detect the selected MCID. This corresponds to a small standardised effect size of 0.3. This represents a conservative evaluation of the sample size required based on the above literature.

Table 4: Study sample size. (Figures are per treatment arm)

	MCID	80% power			90% power		
		3	4	5	3	4	5
Stand. Dev	10	176	100	64	235	133	86
	12	253	143	92	338	**191**	123
	14	343	194	125	459	259	166

Allowing a margin of 20% loss during follow-up, this gives a figure of 478 participants in total. Therefore, 239 participants randomised to each group will provide 90% power to detect a difference of 4 points in OSIS at 6 months at the 5% level (11, 15).

This is a rehabilitation trial and the research team recognise the theoretical possibility of therapy effects. All of our recent experience at Warwick CTU of therapist delivered is that therapist effects have minimal or non-existent (17-19) (BeST, BEAM and SARAH all reported ICC <0.001 or "lower than anticipated" at 12 months). Whilst this does not completely exclude the possibility of such an effect this gives us reassurance that it is unlikely. Any such effect, if it were to exist, would be of greater concern in a cluster randomised trial where individual participants were seeing different therapists in each arm of the trial; or where there was a group intervention.

In this case we are randomising by individual, it is the same therapist who will be seeing people in both arms of the trial, and the treatment is individually delivered ensuring there are no group effects. The initial therapist contact will be described in the study manual, coupled with the use of the supporting media that we will develop as part of this study, this will keep presentation of key information as standard throughout the study. We intend to recruit from 30 study sites over 23 months. There will be multiple therapists working at each site over the course of the study (for example, sickness and holiday coverage). The recently completed NIHR HTA funded FASHION study of physiotherapy vs surgery used 43 therapists over 24 sites which recruited. Assuming this study will have a similar pattern of study staff retention, this then gives the number of therapist levels clusters upwards of 60 and potential cluster sizes of around four participants in each arm of the trial. With such small cluster sizes, even if there were to be important therapist effects their effect on statistical power would be minimal.

Thus, it is unlikely that there will be a therapist effect of sufficient size to affect the validity of our analyses. However, to address the possibility that these might exist we will run an interim analysis to estimate the ICCs for both arms of the study when we have three month data available on around

200 participants. If there is a therapist effect present, we expect it would be maximal soon after the end of the treatment phase and for this to attenuate over longer term follow-up. Only values for ICC and SDs will be presented to study team who will re-visit sample size estimation in light of these additional data. This revised sample size estimate will be discussed with DMC and TSC and if appropriate, we will request permission from the funder to adjust the sample size. This adaptive design has the additional advantage that we will have actual data on the standard deviation of our primary outcome at three months which will allow us to further refine our sample size estimate.

The internal pilot will specifically inform and test the recruitment rate for the main trial. Recruitment will take place in 12 trial centres over a period of six months. The expected rate of recruitment is based on consultation with clinicians during presenting the trial at the Orthopaedic Trauma Society January 2017 and through individual consultation with clinicians during telephone interviews pertaining to refinement of the intervention. A conservative recruitment rate of one participant per month per centre is estimated for the six month pilot phase. Formative process measures will ensure the successful delivery of the main phase and will evaluate recruitment (50 participants, approximately 10% of the full sample) within a specified period (six months), amongst 12 pilot sites. At which point the decision to progress to the main trial will be made in collaboration with the trial steering committee and NIHR HTA programme based on pre-defined progression criteria. Decisions regarding stop-go criteria are given in table 5 below.

Table 5: Stop-go criteria

Target recruitment	Actual recruitment		
50 participants (100% or target)	50-38 participants *(75-100% of target)*	37-25 participants (75-50% of target)	< 25 participants (<50% of target)
Stop-go criteria	Recruitment feasible; proceed with study	Review recruitment strategies. Report to TSC/DMC. Continue but modify & monitor closely	Recruitment not feasible; decision not to proceed

We will retain these randomised participants in the final trial analysis. The aim of this initial phase will be to determine the number of eligible and recruited participants in the trauma centres over the course of six months. Screening logs will be kept at each site to determine the number of participants assessed for eligibility and reasons for any exclusion. In addition, the number of eligible and recruited participants, and the number of participants who decline consent/withdraw, will be recorded. We will also use this pilot as a basis for testing the systems for collecting outcomes, including measures required for the economic evaluation. We intend to recruit participants from a minimum of 30 centres. The proposed sample size of minimum 478 participants will then be recruited over a total of 23 months.

6.2 Statistical analysis of efficacy and harms

6.2.1 Statistics and data analysis

Unless otherwise stated, further details in relation to the planned analyses will be detailed in a statistical analysis plan (SAP), which will be agreed with the Data Monitoring Committee (DMC). All data will be analysed and reported in accordance with the CONSORT statement. All primary analyses are planned to be on an intention to treat basis with secondary per protocol analysis.

6.2.2 Planned recruitment rate

Recruitment from centres will be based on a staged roll out. The expected rate of recruitment is based on consultation individually with UK sites and at a national trauma conference (January 2017). Using a conservative estimate of 50% conversion rate from eligible patients to recruited participants; one participant per month per centre is estimated. We intend to recruit from approximately 30 centres over approximately 23 months.

6.2.3 Statistical analysis plan

Treatment effects will be presented, with appropriate 95% confidence intervals, for both the unadjusted and adjusted analyses. Tests will be two-sided and considered to provide evidence for a significant difference if p-values are less than 0.05 (5% significance level). All analyses will be conducted as intention to treat unless otherwise specified.

6.2.3.1 Summary of baseline data and flow of participants

Baseline data will be summarised to check comparability between treatment arms, and screening data will be checked to highlight any characteristic differences between those individuals in the study, those ineligible, and those eligible but withholding consent. A CONSORT chart illustrating participant flow throughout the study will also be produced. Standard statistical summaries will be presented for the primary outcome measure (OSIS) and all secondary outcome measures.

6.2.3.2 Primary analysis

The main analysis will investigate differences in the primary outcome measure, six months after randomisation, between the two treatment groups. Unadjusted and adjusted regression analyses will be used to estimate the between group difference. The adjusted analyses will adjust for the stratification variables, baseline scores and any other clinically important variables. More specifically, adjusted mixed-effects modelling will be used where the recruiting centre will be included as a random effect to allow for possible heterogeneity in participant outcomes due to the recruiting centre. Since individual clinicians will treat only a small number of participants enrolled in the trial, we do not expect clinician specific effects to be important in this study and hence will not be modelled unless shown otherwise by the interim analysis (see below in section 6.4). This adjusted mixed-effects linear regression analysis will be reported as the primary analysis, and will be used to assess evidence for differences in outcomes between intervention arms.

6.2.3.3 Secondary outcome analysis

Descriptive statistics of participant reported outcome measure (PROM) data (i.e. QuickDash and EQ-5D-5L) at each time point will be constructed with between group analyses following the method set out for the primary analysis above. Patterns of recovery will also be explored.

Secondary analyses will include chi-squared tests to compare the number of dislocations and other complications between allocation groups. For important complications (e.g. dislocations), Kaplan Meier curves of the time to complication will be constructed. If sufficiently large numbers of complication groups are observed, Cox regression models will be constructed to compare the time to complication in each arm. Other secondary functional and quality of life outcomes will also be modelled at each time point as appropriate. Temporal effects will be investigated using a multi-level model of all follow up data.

6.3 Subgroup analyses

Two pre-specified sub-group analyses will be undertaken to assess whether there is evidence that the intervention effect differs between whether:

• Hand dominance (injured shoulder dominant arm *v* injured shoulder is non-dominant arm)

• Age (younger participants *v* older participants)

Prior to starting this analysis, we will inspect the age distribution of the participants and, if possible, set our age cut off between 'young' and 'old' at the age point which best separates the observed older and younger age distributions. If this is not possible, the age groups used to stratify randomisation will be used. Furthermore, the data for each of the two age defined sub-groups will be summarised and reported, regardless of the presence of an interaction effect.

The subgroup analyses will follow the methods described for the primary analysis, with additional interaction terms incorporated into the mixed-effects regression model to assess the level of support for these hypotheses.

The study is not powered to formally test these hypotheses, so they will be reported as exploratory analyses only, and as subsidiary to the analysis reporting the main effects of the intervention in the full study population.

6.4 Interim analysis and criteria for the premature termination of the trial

The assessment of early recruitment and rules for the internal pilot are described in section 6.1. These will be reviewed at the scheduled TSC meeting to be held at the end of the internal pilot phase.

A single interim analysis is planned for this study to estimate the ICC to account for therapist effects (see section 6.1 for rationale). An estimate for the study ICC will be calculated, along with its 95% CI. This will be conducted after approximately 200 participants have completed the three month follow up questionnaires whilst recruitment is still open. The three month data will be used as if there is a therapist effect present, we expect it would be maximal soon after the end of the treatment phase and for this to attenuate over longer term follow-up. Only values for ICC and the combined study SD will be presented to study team, who will re-visit sample size estimation in light of these additional data. This revised sample size estimate will be discussed with DMC and TSC and if appropriate, we will request permission from the funder to adjust the sample size. This adaptive design has the additional advantage that we will have actual data on the standard deviation of our primary outcome at three months which will allow us to further refine our sample size estimate.

The trial statistician will prepare the interim analyses but will not be blind to the trial results. The incidence of AEs and SAEs in each group will also be collated for the interim analyses and will be presented to the DMC.

6.5 Subject population

The primary analysis and any applicable secondary analyses will be applied to an all-randomised population on an intention-to-treat basis. That is, any subject randomised into the study, regardless of whether they received study intervention and regardless of protocol deviations, unless specified above.

6.6 Procedure(s) to account for missing or spurious data

Whilst every effort will be made to ensure compliance and return of questionnaires, it is inevitable that some data will be missing and likely that cross-overs will occur (i.e. Physiotherapy sessions not attended or request for additional physiotherapy treatment). Careful monitoring of missingness and crossovers will be conducted. If judged appropriate, Multiple Imputation will be used to account for missing data, with all necessary assumptions reported. If large numbers of treatment cross-overs are observed, Complier-Average Causal Effect (CACE) models will be used. Similar to Per Protocol (PP)

methods, CACE models evaluate the average effect of the intervention in participants who comply with their allocated treatment. This preserves randomisation groups and eliminates introducing any potential confounders introduced by PP analysis.

It seems likely that some data may not be available due to voluntary withdrawal of participants, lack of completion of individual data items or general loss to follow-up. Where possible the reasons for data 'missingness' will be ascertained and reported. The nature and pattern of the missing-ness will be carefully considered, including whether data can be treated as missing completely at random. If judged appropriate, missing data will be imputed using the multiple imputation facilities available in the statistical analysis software.

If imputation is undertaken, the resulting imputed datasets will be analysed, together with appropriate sensitivity analyses. Any imputation methods used for scores and other derived variables will be carefully considered and justified. Reasons for ineligibility, non-compliance, withdrawal or other protocol violations will be stated and any patterns summarised. More formal analysis, for example using logistic regression with 'protocol violation' as a response, may also be appropriate and aid interpretation.

6.7 Health Economic Evaluation

Prospectively planned economic evaluation will be conducted from a NHS and personal social services perspective, in accordance with an agreed Health Economics Analysis plan (HEAP). The methods will adhere to the recommendations of the NICE Reference Case (20).

Costs of the intervention groups will be estimated, reflecting resource inputs associated with rehabilitation and broader healthcare resource utilisation. Resource use associated with the index condition will be captured through routine health service data collection systems and participant questionnaires administered at each follow up time point.

Unit costs will be estimated from local and national sources using established accounting methods, reflated to current prices. Health-related quality of life will be measured at baseline and at all follow time points using the EQ-5D-5L measure. Responses will be used to generate quality-adjusted life years (QALYs) using the UK time-trade-off (TTO) value set recommended by the EuroQol group(21).

Within-trial analysis using bivariate regression of costs and QALYs, with multiple imputation of missing data, will inform a probabilistic assessment of incremental treatment cost-effectiveness. Missingness mechanisms will be explored and multiple imputation methods will be used where appropriate to avoid biases associated with complete case analysis. Costs and outcomes arising during the trial will be undiscounted, reflecting the 12-month time horizon. Sensitivity analyses will be undertaken to explore uncertainty on the incremental cost-effectiveness ratios and to consider issues of generalisability of the study.

Although not anticipated to be necessary, more extensive economic modelling using decision-analytic methods may be considered to extend the time horizon and decision context if costs and benefit profiles are non-convergent at 12 months. Such modelling will draw upon best available information from the literature and stakeholder consultations to supplement the trial data. Parameter uncertainty in the decision-analytic model will be explored using probabilistic sensitivity analysis. Longer term costs and consequences will be discounted to present values using discount rates recommended for health technology appraisal in the UK (current discount rate: 3.5%).

6.8 Qualitative data Analysis

Following procedures for conducting interviews, as outlined in section 3.2, they will be digitally recorded, subject to permission of each participant, and will be transcribed verbatim. Data will be analysed using the Framework method [38], which is broadly as follows:

- Data familiarisation: reading of complete interview transcripts, listening to original audio recordings and use of field notes;
- Identifying a thematic framework: key issues, concepts and themes are identified and an index of codes developed;
- Indexing: whereby the index generated through identification of the thematic framework is applied to all data;
- Charting: a summary of each passage of text is transferred into a chart to allow more overall and abstract consideration of index codes across the data set and by each individual;
- Mapping and interpretation: understanding the meaning of key themes, dimensions and broad overall picture of the data and identifying and understanding the typical associations between themes and dimensions;

The charting process provides an opportunity to code data from numerous vantage points, by demographic factors, such as gender or age, by personality characteristics, such as looking specifically at people who are highly anxious compared to those who are not, or by medical aspects, such as those with a particular condition compared to those without.

The computer package NVivo 7 will be used to facilitate this process. Researcher bias will be minimised through regular crosschecking of data and findings by the members of Research Team. In addition, transcripts will be returned to participants (where necessary) providing them with the opportunity to check the transcripts for accuracy and authenticity and to offer any subsequent reflections. Quotes will be used as exemplars of key points in the writing up of these data.

The outcomes of the qualitative work will be reported as a separate chapter in the final report but results will also be incorporated in the discussion where we will be bringing together a synthesis of all the results helping to explore and explain the overall 'value' of the interventions

7. TRIAL ORGANISATION AND OVERSIGHT

7.1 Sponsor and governance arrangements

University Hospitals of Coventry and Warwickshire and University of Warwick co-sponsor the trial, although the lead contracting organisation is UHCW. The day-to-day running of the trial will be managed according to WCTU SOPs, with UHCW SOPs used for contracting.

7.2 Ethical approval

All ethical approvals for the trial will be sought using the Integrated Research Application System. The trial will be conducted in accordance with all relevant regulations and guidelines.

Before enrolling people into the trial, each trial site must ensure that the local conduct of the trial has the agreement of the relevant NHS Trust Research & Development (R&D) department. Sites will not

be permitted to enrol people into the trial until written confirmation of R&D agreement is received by the co-ordinating team.

Substantial protocol amendments (e.g. changes to eligibility criteria, outcomes, analyses) will be communicated by the trial team to relevant parties i.e. investigators, RECs, participants, NHS Trusts, trial registries, journals, as appropriate.

Annual reports will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the trial is declared ended. The REC and sponsors will be notified of the end of the trial (whether the study ends at the planned time or prematurely).

The CI will submit a final report to the required authorities with the results, including any publications within one year of the end of the trial.

7.3 Trial Registration

The trial will be registered with the International Standard Randomised Controlled Trial Number (ISRCTN) Register. A protocol paper will be published prior to completing recruitment.

7.4 Notification of serious breaches to GCP and/or trial protocol

A “serious breach” is a breach which is likely to affect to a significant degree –

(a) the safety or physical or mental integrity of the subjects of the trial; or
(b) the scientific value of the trial

If a serious breach occurs:

- the sponsor will be notified immediately of any case where the above definition applies during the trial conduct phase

7.5 Indemnity

NHS indemnity covers NHS staff, clinical academic staff with honorary contracts, and those conducting the trial. NHS bodies carry this risk themselves or spread it through the Clinical Negligence Scheme for Trusts, which provides unlimited cover for this risk. The University of Warwick provides indemnity for any harm caused to participants by the design of the research protocol.

7.6 Trial timetable and milestones

We propose a 42 month study starting June 2018. The planned trial timetable is shown below:

Month	By Date	Activity	Milestone	Responsibility
-2-2	July 2018	Ethic Submission	Approval	CI/TM
3-5	Oct 2018	Start Project Finalise Protocol & CRF's	1st TMG/TSC/DMC Final versions of all materials approved	CI/TM/TMG/TSC/ DMC
6-11	Nov 2018	Start recruitment at pilot sites	Initiate site opening	TM/CI/RF
	Dec 2018	Start 6 week follow-up	Initiate 6 week follow up phase	TMG
	Jan 2019	Start 3 month follow-up	Initiate 3 month follow up phase	TMG
	Apr 2019	Recruit 50 participants from 12 pilot sites Decision on trial progression	12 sites set up and recruiting to target Report to TSC and HTA	CI/TM/RF TMG/TSC
	Apr 2019	Start 6 month follow up assessments	Initiate follow up phase	TMG
12-28	Oct 2019	Start 12 month follow up assessment and interviews	Initiate 12 month follow up phase and interview phase	TMG/RF
	Nov 2019	Completion of site set up	30 sites set up and recruiting	TM/CI/RF
	Dec 2019	Data review of first 200 participants	DMEC report	DMEC via TSC to HTA
	Jan 2020	50% total recruitment	257 participants enrolled	TMG/TSC
	Sep 2020	End recruitment	478 participants enrolled	TMG/TSC
29-40	Mar 2021	Complete all primary 6 month follow up assessment. Statistical and health economic analysis of primary outcome data	Six week, three month and six month follow-up phase closed	TMG/TSC Lead Stat and HE
	Sep 2021	Complete all secondary 12 month follow up assessment Statistical and health economic analysis or secondary outcome data and analysis and reporting of qualitative interviews	12 month follow up phase closed 12 month interview phase closed	TMG/TSC Lead Stat and HE
41-42	Nov 2021	Data review all participants	Final DMC and TSC meetings	DMC-TSC-HTA

**CI Chief Investigator, RF Research Fellow, TMG Trial management group, TC Trial coordinator, TSC Trial Steering Committee, DMC Data monitoring Committee, Stat statistician, HE Health Economist*

7.7 Administration

The trial management team will be based primarily at UHCW in the Clinical Sciences Research Laboratories, but staff will work at WCTU, University of Warwick.

7.8 Trial Management Group (TMG)

The Trial Management Group, consisting of the project staff and co-investigators involved in the day-to-day running of the trial, will meet regularly throughout the project. Significant issues arising from management meetings will be referred to the Trial Steering Committee or Investigators, as appropriate.

7.9 Trial Steering Committee (TSC)

The trial will be guided by a group of respected and experienced personnel and trialists as well as at least one 'lay' representative. The TSC will have an independent Chairperson. Face to face meetings will be held at regular intervals determined by need but not less than once a year. Routine business is conducted by email, post or teleconferencing.

The Steering Committee, in the development of this protocol and throughout the trial will take responsibility for:

- Major decisions such as a need to change the protocol for any reason
- Monitoring and supervising the progress of the trial
- Reviewing relevant information from other sources
- Considering recommendations from the DMC
- Informing and advising on all aspects of the trial

The membership of the TSC will be approved and appointed by the NIHR.

The full remit and responsibilities of the TSC will be documented in the Committee Charter which will be signed by all members.

7.10 Data Monitoring Committee (DMC)

The DMC will consist of independent experts with relevant clinical research, and statistical experience. The DMC meeting frequency will be guided by the DMC chair, but will be suggested to be six months into the recruitment phase and regularly thereafter, as directed by the DMC chair. Confidential reports containing recruitment, protocol compliance, safety data and interim assessments of outcomes will be reviewed by the DMC. The DMC will advise the TSC as to whether there is evidence or reason why the trial should be amended or terminated. The membership of the DMC will be approved and appointed by the NIHR.

DMC meetings may also be attended by the Chief Investigator and Trial Manager (for non-confidential parts of the meeting) and the trial statistician.

The full remit and responsibilities of the DMC will be documented in the Committee Charter which will be signed by all members.

7.11 Essential Documentation

A Trial Master File will be set up according to WCTU SOP 11 and held securely at the coordinating centre. The coordinating centre will provide Investigator Site Files to all recruiting centres involved in the trial.

7.12 Financial Support

The trial has been funded by a research grant from the National Institute for Health Research, Health Technology Assessment programme, following researcher led call.

8. MONITORING, AUDIT AND INSPECTION

The study will be monitored by the Research and Development Department at UHCW as representatives of the lead Sponsor and by the Quality Assurance team at WCTU as representatives of the co-sponsor, to ensure that the study is being conducted as per protocol, adhering to Research Governance and GCP. The approach to, and extent of, monitoring will be specified in a trial monitoring plan determined by the risk assessment undertaken prior to the start of the study. A Trial Monitoring Plan will be developed and agreed by the Trial Management Group (TMG) and TSC based on the trial risk assessment, including on site monitoring if applicable. Processes to be considered in the monitoring plan will include participant enrolment, consent, eligibility, and allocation to trial groups; adherence to trial interventions and policies to protect participants, including reporting of harm and completeness, accuracy, and timeliness of data collection. This plan will be available from the trial coordination centre and will also be lodged with the sponsors. Whilst the monitors work in the same institution as the CI and trial team (WCTU), they will act independently of the trial team in this role. Sites persistently late in reporting SAEs, receipt of multiple late/poorly completed CRFs, or evidence from CRFs that the trial protocols and procedures are not being adhered to (as assessed by the CI or the TMG) may be considered triggers for on-site monitoring visits. The co-sponsors will ensure investigator(s) and/or institutions will permit trial-related monitoring, audits and REC review, providing direct access to source data/documents as required. Monitoring will be performed by exploring the trial dataset or performing central monitoring procedures and/or site visits, as defined in the trial monitoring plan.

Recruitment sites are obliged to assist the sponsor in monitoring the study. These may include hosting site visits, providing information for remote monitoring, or putting procedures in place to monitor the study internally.

9. PATIENT AND PUBLIC INVOLVEMENT (PPI)

Patient and public involvement is at the heart of this study. Clinical co-applicants at UHCW consulted patients during appointments to ascertain if the research gaps highlighted in the literature were of high importance to them. These same people were asked if they would be interested in a consultation role for further development of the study and future roles in management of the research and dissemination of findings.

Those interested were directed to UNTRAP (Universities/User Teaching and Research Action Partnership) at Warwick University. UNTRAP ensures there are mechanisms in place for academics and patient/public members to meaningfully engage. Subsequently a discussion was held with two patient representatives and two lay persons from UNTRAP. In this group we discussed experiences and expectations of services and the plans for the trial.

These perspectives were key in the development of the protocol to ensure trial processes, materials and interventions are feasible and acceptable.

Key inputs from this group into the protocol were to ensure that the intervention employed a holistic approach not just focusing on physical well-being. A member of this lay group has agreed to join the co applicant team.

The lay co-applicant who contributed during our development work, will be a member of the TMG. They will contribute to trial processes and paperwork, such as Patient Information Leaflets. They will take a lead in the development of the information, training materials and resources used within the study.

To ensure representation of the bi-modal distribution of this injury we will develop and grow the current PPI representatives across the range of ages who will form a PPI panel. This panel will support the team with a range of duties including representation on the TSC and DMC and acting as critical reviewers for materials developed by the TMG. In the later stages our PPI support will be key to us ensuring that we disseminate our findings to a wider audience.

The Lay representatives will be supported by the CI and the trial coordination team. They will have access to training and advice through the UNTRAP network, an organisation which promotes the engagement and involvement of service users and carers from the local community in research and teaching in Health and Social Care at the University of Warwick.

10. DISSEMINATION AND PUBLICATION

The results of the trial will be reported first to trial collaborators. The main report will be drafted by the trial management team, and the final version will be agreed by the Trial Steering Committee before submission for publication, on behalf of the collaboration. It is our intention to simultaneously prepare a manuscript for a high impact peer-reviewed journal, which will allow for the results to be disseminated across the orthopaedic and rehabilitation communities, the wider medical community and policy makers.

The success of the trial depends on the collaboration of doctors, nurses and researchers from across the UK. Equal credit will be given to those who have wholeheartedly collaborated in the trial.

The trial will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines (www.consort-statement.org).

In addition, the findings of the study will be presented at the following international meetings:

- European Federation of Orthopaedic and Trauma Associations
- World Confederation for Physical Therapy

This will be in addition to UK conferences which include:

- British Elbow and Shoulder Society
- Orthopaedic Trauma Society
- British Orthopaedic Association
- Chartered Society of Physiotherapy

The lay co-applicants will lead on the dissemination of the trial results to participants and the wider public. To inform patients and the public, we intend to produce a lay summary, which will be made available in the trial hospitals and to trial participants via an end of trial letter. In addition, we will publicise the work through social media outlets (e.g. Facebook and twitter) as well as websites such as Patient.co.uk.

The outcome of this trial will provide clear evidence for the optimal rehabilitation strategy for people with traumatic anterior shoulder dislocation, providing the best results in terms of functional outcomes, with the fewest complications. This in turn will offer cost savings for the NHS. The team will take an active stance to encourage the optimal intervention into practice and provide real measurable impact on patient care. The team including our PPI representatives would take a number of approaches to achieve this:

- We will work with our trial sites, clinicians, managers and commissioners to encourage the adoption of the ARTISAN approach to the care of shoulder dislocations within the 30 Trusts that recruit to ARTISAN.
- We will seek implementation research funding so we could encourage others to adopt the approach and measure real impact. With impact being a change in practice as a result of the trial that has benefited the patient and the NHS.

We would expect the results of this trial to be incorporated into the next iteration of the Cochrane review on 'Conservative management following closed reduction of traumatic anterior dislocation of the shoulder' and national BESS/BOA' Patient Care Pathways: Traumatic anterior shoulder instability'.

HRA guidance on information for participants at the end of a trial will be followed:

https://www.hra.nhs.uk/about-us/consultations/closed-consultations/guidance-participant-information-end-study-consultation/

The publication of a trial protocol, methodology papers, trial results and trial data will be in line with the NIHR standard terms and will follow WCTU SOP 22: Publication & Dissemination.

12. APPENDIX ONE: OUTLINE OF WEB BASED MATERIALS

Phase one: Outline of voice over script, final version will be subject to minor amendments

Script Text:	(animation of Jess walking into physio department wearing a sling and goes into meet Martin) *Narrator:* You have dislocated your shoulder, and you probably have a few questions, but don't worry, we have put together some information about these early stages. So grab a cup of tea, sit back and let us help you understand the steps to recovery. We'd like you to meet Jess who dislocated her shoulder a few days ago and she is on her way to meet Martin, her physiotherapist. (animation of Jess sat opposite Martin in a physiotherapy consultation room wearing a sling) *Jess:* What has happened to me? *Martin:* You've had a shoulder dislocation which is when the bone in the upper arm bone is forced out of its joint at the shoulder. (animation of shoulder joint dislocating) Your shoulder joint is now back in place and you will have had an x-ray to check it is ok. (animation of shoulder going back in) *Jess:* What can go wrong? (animation of Jess sat opposite Martin in a physiotherapy consultation room wearing a sling) *Martin:* Usually once the shoulder joint is back in place there are no major problems. Occasionally your physiotherapist or doctor might identify damage to the nerves, muscles or bone around the shoulder that might need further investigation. *Jess:* How do I stop this happening again? *Martin:* Whilst things are healing you should avoid holding your arm in a 'surrender' position or putting your hands behind your head. But sometimes it will happen again, whatever you do. (animation of surrender position - arm away from side with fingers pointing to ceiling and/or hand behind head) *Jess:* How long do I have to wear my sling? (animation of Jess sat opposite Martin in a physiotherapy consultation room wearing a sling)

Martin: The sling is to keep you comfortable in the early days. You should remove it from time to time as soon as is comfortable. It is usually not used for more than two weeks.

Jess: Should I move my arm?

Martin: Yes. You should move your hand, wrist and elbow frequently to prevent stiffness.

(animation of taking sling off and moving elbow up and down and moving wrist up and down)

You should also practice moving your shoulder forwards and out to the side. If it is difficult to move you can use your other arm to support it.

(animation of moving arm out to side and forwards)

Jess: How do I control my pain?

Martin: You can use ice packs wrapped in a cloth around your shoulder, but no more than 20 minutes at a time and do not put ice directly on the skin. Common painkillers like paracetamol or ibuprofen may also help with pain. It's best to talk to your pharmacist to get advice on how much and how often.

(animation of frozen peas in tea towel on shoulder)

Even if your shoulder is uncomfortable it is important to keep it moving. If you are having a lot of trouble with pain talk to your GP who may give you a prescription for stronger painkillers, but these are not usually needed.

(animation of Jess moving shoulder forwards and out to side)

Jess: When can I get back to doing my usual stuff?

Martin: You can get back to doing most activities as soon as you feel comfortable. If you need to do anything heavier like helping a mate move some heavy boxes or a burning desire to rugby tackle someone on a grassy pitch then you should usually wait until after six weeks.

(animation of Jess rugby tackling)

Jess: What if something goes wrong?

Martin: If you think your shoulder has come out of joint again or if you experience a sudden change in symptoms then you should get that checked out urgently by the emergency department.

(animation of Jess feeling sudden pain and going back to A&E)

If your shoulder is just not getting better then contact the clinic you attended when you first injured it or see your GP.

	Jess: Thank you for your time, your advice has been very useful and I will make sure I follow it because I want to get back to my usual self a soon as possible. (animation of Jess leaving the physiotherapy consultation room) *Narrator:* We have given you some top tips about your shoulder. To help with your recovery there are some shoulder exercises that your physiotherapist will show you at your first appointment. Doing these exercises will help with your recovery.

Phase two and three: Outline of animated exercises:

Title of exercise:	**Animation required:**	**Descriptive text to accompany the animation on the webpage:**
Insert relevant text for scapula setting advice for all exercises on website		
Exercise 1:	Animation of standing character moving their arm forwards (flexion).	Forwards Movement: • Remove your sling • Stand up • Put your arm by your side • Move your arm forwards as far as pain allows • Move your arm back down to your side • Repeat little and often as pain allows If forwards movement is too difficult, repeat as above, but you can use your unaffected arm to help support your affected arm during the forward movement.
Exercise 2:	Animation of standing character moving their arm out to the side (abduction).	Out to the side movement: • Remove your sling • Stand up • Put your arm by your side • Move your arm out to the side as far as pain allows • Move your arm back down to your side • Repeat little and often as pain allows If moving your arm out to the side is too difficult, repeat as

		above, but you can use your unaffected arm to help support your affected arm during the movement.
Exercise 3:	Animation of standing character moving their arm out to the side and back across tummy with the elbow bent (internal and external rotation)	Rotation movement: • Remove your sling • Put your arm by your side • Bend your elbow to 90 degrees (right angle) • Keeping your elbow tight to your side and bent, move outwards (no more than 90 degrees) and inwards across your tummy. If this movement is too difficult you can repeat as above but you can use your unaffected arm to help support your affected arm during the movement.
Exercise 4:	Animation of standing character moving their arm into internal and external rotation against a door but not moving (isometric rotation exercise)	Static Strengthening for rotation movement: • Stand up • Bend your elbow to 90 degrees (right angle) • Place your hand against the edge of a door • Attempt to move the arm outwards towards the edge of the door, keeping your elbow by your side • Repeat attempting to move the arm inwards towards the edge of the door • Repeat little and often as pain allows
Exercise 5:	Animation of standing character pushing their fist into a wall and standing with back to wall pushing backwards (isometric flexion and extension exercise)	Static strengthening forwards and backwards movement: • Stand up • Bend your elbow to 90 degrees (right angle) • Face a wall • Attempt to move the arm towas the wall • Repeat facing with your back to the wall attempting to move the

		arm backwards into the wall • Repeat little and often as pain allows
Exercise 6:	Animation of standing character pushing their whole arm into a wall with elbow bent and repeating the movement into the body (isometric abduction and adduction)	Static strengthening out to the side movement: • Stand up • Bend your elbow to 90 degrees (right angle) • Stand next to a wall • Attempt to move the whole arm towards the wall • Repeat moving the arm towards the body • Repeat little and often as pain allows
Exercise 7:	Animation of standing character moving their arm forwards (flexion) and backwards (extension) with a tin of beans in their hand.	Dynamic Strengthening for Forwards Movement: • Stand up • Put your arm by your side • Hold a tin of beans • Move your arm forwards and backwards • Repeat little and often as pain allows To make the exercise more difficult progressively increase the weight (you can use heavier tins/bottles) and gradually increase the number of repetitions.
Exercise 8:	Animation of standing character moving their arm out to the side (abduction) with a tin of beans in their hand.	Dynamic Strengthening for out to the side movement: • Stand up • Put your arm by your side • Move your arm out to the side • Move your arm back down to your side • Repeat little and often as pain allows To make the exercise more difficult progressively increase the weight (you can use heavier tins/bottles) and gradually increase the number of repetitions.

Exercise 9:	Animation of standing character moving their arm out to the side and back across tummy with the elbow bent (internal and external rotation) with a tin of beans in their hand	Dynamic Strengthening for Rotation movement: • Put your arm by your side • Bend your elbow to 90 degrees (right angle) • Keeping your elbow tight to your side and bent, move outwards and inwards across your tummy. • Repeat little and often as pain allows To make the exercise more difficult progressively increase the weight (you can use heavier tins/bottles) and gradually increase the number of repetitions.

Phase four: Outline of voice over script, final version will be subject to minor amendments

Script Text:	(animation of Jess entering a physiotherapy consultation room) *Narrator:* Not all of you will need to take this last step; it is just for those of you who like to do a bit of sport. Sports that involve overhead activities or contact carry a higher risk of further re-dislocation, however many people wish to continue with what they enjoy, and this next information will help you get there. I'll re-introduce you to Jess, she's off back to meet her physio Martin because she enjoys playing rugby and is keen to get back to her former sporting self. (animation of Jess playing rugby) *Jess*: I'm really looking forward to getting back to my sports but I'm really worried that my shoulder may come out again. (animation of Jess sat in consultation room opposite Martin) *Martin*: The exercises you have been doing will help you get back to full activities. There is always a chance it might come out again, especially if you take part in high risk sports that involve contact, like rugby, or over head force, like tennis. (animation of jess playing rugby again) *Jess*: I want to go back to these sports so how do I phase back in? (animation of Jess sat in consultation room opposite Martin) *Martin*: Go back to some training sessions first and gradually introduce more contact and overhead activities. For example in rugby you would

first do passing drills, footwork, kicking and agility and then progress to overhead throwing, tackling, scrums and line-outs. Once you've practiced the full range of skills in a training environment you can progress to a competitive environment. When you do this it would be good to plan to do the last part as a substitute, towards the end of the game and then build up each week depending on how you feel.

(animation of drills in rugby)

Jess: How will I know if I am ready for each new progression?

(animation of Jess sat in consultation room opposite Martin)

Martin: We usually expect that a full return within six months of the injury. If you feel you are not progressing then we advise that you get back in touch with your GP or treating hospital site.

Jess: What should I do if I take the next steps and it becomes painful?

Martin: You can expect the shoulder to ache a little bit as you gradually increase the demands you place on it. If it becomes painful then you should step back to the stage before until it settles and then gradually phase forwards again.

Jess: What should I do if it comes out of the joint again?

Martin: You should go back to emergency department. Once relocated you will usually be referred back the orthopaedic team for review.

(animation of Jess to going to A&E)

Jess: Thanks a lot for all your help, you have been great, hopefully I will not see you again!

(animation of Jess leaving the physiotherapy department)

Narrator: Well that is it! All done! Back to your usual self! Nothing more to say other than all the best and well done for seeing it through to the end.

13. APPENDIX TWO: OUTLINE OF PAPER BASED MATERIALS

Phase one: Outline of booklet, final version will be subject to minor amendments

Front Cover:	Logo's Images: Still image of Jess sat opposite Martin in physiotherapy consulting room wearing a sling Title: Your recovery begins here
Page 1:	Images: Still image of shoulder dislocating and still image of shoulder going back in Title: Introduction Text: You have dislocated your shoulder, and you probably have a few questions, but don't worry, we have put together some information about these early stages to help you understand the steps to recovery.
Page 2:	Images: still image of surrender position - arm away from side with fingers pointing to ceiling and/or hand behind head under '*how do I stop this happening again'* Title: Common Questions Answered Text: What has happened to me? You've had a shoulder dislocation which is when the bone in the upper arm bone is forced out of its joint at the shoulder. Your shoulder joint is now back in place and you will have had an x-ray to check it is ok. What can go wrong? Usually once the shoulder joint is back in place there are no major problems. Occasionally your physiotherapist or doctor might identify damage to the nerves, muscles or bone around the shoulder that might need further investigation. How do I stop this happening again? Whilst things are healing you should avoid holding your arm in a 'surrender' position or putting your hands behind your head. But sometimes it will happen again, whatever you do.
Page 3:	Images: Still image with sling off and moving elbow up and down and moving wrist up and down and still image of arm out to side and forwards under heading '*should I move my arm'* Title: More Common Questions Answered Text: How long do I have to wear my sling?

	The sling is to keep you comfortable in the early days. You should remove it from time to time as soon as is comfortable. It is usually not used for more than two weeks. Should I move my arm? Yes. You should move your hand, wrist and elbow frequently to prevent stiffness. You should also practice moving your shoulder forwards and out to the side. If it is difficult to move you can use your other arm to support it.
Page 4:	Images: Still image of frozen peas in tea towel on shoulder under heading *'how do I control my pain'* Title: Even More Common Questions Answered Text: How do I control my pain? You can use ice packs wrapped in a cloth around your shoulder, but no more than 20 minutes at a time and do not put ice directly on the skin. Common painkillers like paracetamol or ibuprofen may also help with pain. It's best to talk to your pharmacist to get advice on how much and how often. Even if your shoulder is uncomfortable it is important to keep it moving. If you are having a lot of trouble with pain talk to your GP who may give you a prescription for stronger painkillers, but these are not usually needed. When can I get back to doing my usual stuff? You can get back to doing most activities as soon as you feel comfortable. If you need to do anything heavier like helping a mate move some heavy boxes or a burning desire to rugby tackle someone on a grassy pitch then you should usually wait until after six weeks.
Page 5:	Images: Still image of feeling sudden pain and going back to A&E under heading '*What if something goes wrong'* Title: Last Common Question Answered What if something goes wrong? If you think your shoulder has come out of joint again or if you experience a sudden change in symptoms then you should get that checked out urgently by the emergency department. If your shoulder is just not getting better then contact the clinic you attended when you first injured it or see your GP.
Page 6:	Images: Title: Final words Text: We have given you some top tips about your shoulder. To help with your recovery there are some shoulder exercises that

	your physiotherapist will show you at your first appointment. Doing these exercises will help with your recovery.
Back Page:	Logo's

Phase two and three: Outline of booklet, final version will be subject to minor amendments

Front Cover:	Logo's Images: Still image of character at home doing an exercise Title: Your ARTISAN Exercise Programme
Page 1:	Images: Still of shoulder in joint Title: Moving your shoulder Text: The exercises on the next pages will help you get your shoulder moving. To help you keep track of what you have done there are pages at the end of this section to record your goals and how many and how often you do these exercises.
Page 2:	Title: Moving your arm Forwards Image: Still image of standing character moving their arm forwards (flexion). Text: Forwards Movement: • Remove your sling • Stand up • Put your arm by your side • Move your arm forwards as far as pain allows • Move your arm back down to your side • Repeat little and often as pain allows If forwards movement is too difficult, repeat as above, but you can use your unaffected arm to help support your affected arm during the forward movement.
Page 3:	Title: Moving your arm out to the side Image: Still image of standing character moving their arm out to the side (abduction). Text: Out to the side movement: • Remove your sling • Stand up • Put your arm by your side • Move your arm out to the side as far as pain allows • Move your arm back down to your side • Repeat little and often as pain allows

	If moving your arm out to the side is too difficult, repeat as above, but you can use your unaffected arm to help support your affected arm during the movement.
Page 4:	Title: Rotating your arm Image: Still image of standing character moving their arm out to the side and back across tummy with the elbow bent (internal and external rotation) Text: Rotation movement: • Remove your sling • Put your arm by your side • Bend your elbow to 90 degrees (right angle) • Keeping your elbow tight to your side and bent, move outwards (no more than 90 degrees) and inwards across your tummy. • Repeat little and often as pain allows If this movement is too difficult you can repeat as above but you can use your unaffected arm to help support your affected arm during the movement.
Page 5:	Title: My Goals Text: In this section please write down your goals during these early phases, an example might be to be able to brush your hair or reach into a cupboard. It's important that your goal is personal to you and you acknowledge when you have achieved it. Image: Insert a text box with dotted lines for goals to be recorded.
Page 6:	Title: Record of Progress Text: In this section please keep a record of the movement exercises you have done. Once you are comfortable moving your arm you can progress to the exercises on the next page that will begin to strengthen your shoulder. Image: Insert of exercise diary
Page 7:	Images: Still of shoulder in joint Title: Starting to Strengthening your shoulder Text: The exercises on the next pages will help you start getting your shoulder stronger. To help you keep track of what you have done there are pages at the end of this section to record your goals and how many and how often you do these exercises.

	It would be good if you could do the next three exercises (p.8-p.10) comfortably before moving onto the more dynamic strengthening exercises (page 11 onwards).
Page 8:	Title: Static Strengthening for Shoulder Rotation Image: Still image of standing character moving their arm into internal and external rotation against a door but not moving (isometric rotation exercise) Text: Static Strengthening for rotation movement: • Stand up • Bend your elbow to 90 degrees (right angle) • Place your hand against the edge of a door • Attempt to move the arm outwards towards the edge of the door, keeping your elbow by your side • Repeat attempting to move the arm inwards towards the edge of the door • Repeat little and often as pain allows
Page 9:	Title: Static strengthening forwards and backwards movement Image: Still image of standing character pushing their fist into a wall and standing with back to wall pushing backwards (isometric flexion and extension exercise) Text: Static strengthening forwards and backwards movement: • Stand up • Bend your elbow to 90 degrees (right angle) • Face a wall • Attempt to move the arm towards the wall • Repeat facing with your back to the wall attempting to move the arm backwards into the wall • Repeat little and often as pain allows
Page 10:	Title: Static strengthening out to the side movement Image: Still image of standing character pushing their whole arm into a wall with elbow bent and repeating the movement into the body (isometric abduction and adduction) Text: Static strengthening out to the side movement: • Stand up • Bend your elbow to 90 degrees (right angle) • Stand next to a wall • Attempt to move the whole arm towards the wall • Repeat moving the arm towards the body • Repeat little and often as pain allows
Page 11:	Title: Dynamic Strengthening for Forwards Movement

	Image: Still animation of standing character moving their arm forwards (flexion) and backwards (extension) with a tin of beans in their hand. Text: Dynamic Strengthening for Forwards Movement: • Stand up • Put your arm by your side • Hold a tin of beans • Move your arm forwards and backwards • Repeat little and often as pain allows To make the exercise more difficult progressively increase the weight (you can use heavier tins/bottles) and gradually increase the number of repetitions.
Page 12:	Title: Dynamic Strengthening for out to the side movement Image: still image of standing character moving their arm out to the side (abduction) with a tin of beans in their hand. Text: Dynamic Strengthening for out to the side movement: • Stand up • Put your arm by your side • Move your arm out to the side • Move your arm back down to your side • Repeat little and often as pain allows To make the exercise more difficult progressively increase the weight (you can use heavier tins/bottles) and gradually increase the number of repetitions.
Page 13:	Title: Dynamic Strengthening for Rotation movement Image: Still image of standing character moving their arm out to the side and back across tummy with the elbow bent (internal and external rotation) with a tin of beans in their hand Text: Dynamic Strengthening for Rotation movement: • Put your arm by your side • Bend your elbow to 90 degrees (right angle) • Keeping your elbow tight to your side and bent, move outwards and inwards across your tummy. • Repeat little and often as pain allows To make the exercise more difficult progressively increase the weight (you can use heavier tins/bottles) and gradually increase the number of repetitions.
Page 14:	Title: My Goals

	Text: In this section please write down your goals during these late phases, an example might be to be able to lift your child or lift bags of shopping. It's important that your goal is personal to you and you acknowledge when you have achieved it. Image: Insert a text box with dotted lines for goals to be recorded.
Page 15 and 16	Title: Record of Progress Text: In this section please keep a record of the movement exercises you have done. Once you are comfortable moving your arm you can progress to the exercises on the next page that will begin to strengthen your shoulder. Image: Insert of exercise diary
Back Page:	Logo's

Phase four: Outline of booklet, final version will be subject to minor amendments

Front Cover:	Logo's Images: Still image of Jess playing rugby Title: Your recovery ends here
Page 1:	Images: Still image of rugby drills Title: Introduction Text: Not all of you will need to take this last step; it is just for those of you who like to do a bit of sport. Sports that involve overhead activities or contact carry a higher risk of further re-dislocation, however many people wish to continue with what they enjoy, and this next information will help you get there.
Page 2:	Images: Still image of consultation room with physiotherapist Title: Common Questions Answered Text: I'm really looking forward to getting back to my sports but I'm really worried that my shoulder may come out again. The exercises you have been doing will help you get back to full activities. There is always a chance it might come out again, especially if you take part in high risk sports that involve contact, like rugby, or over head force, like tennis. I want to go back to these sports so how do I phase back in? Go back to some training sessions first and gradually introduce more contact and overhead activities. For example in rugby you would first do passing drills, footwork, kicking and agility and

	then progress to overhead throwing, tackling, scrums and line-outs. Once you've practiced the full range of skills in a training environment you can progress to a competitive environment. When you do this it would be good to plan to do the last part as a substitute, towards the end of the game and then build up each week depending on how you feel.
Page 3:	Images: Still image of playing rugby Title: More Common Questions Answered Text: How will I know if I am ready for each new progression? We usually expect that a full return within six months of the injury. If you feel you are not progressing then we advise that you get back in touch with your GP or treating hospital site. What should I do if I take the next steps and it becomes painful? You can expect the shoulder to ache a little bit as you gradually increase the demands you place on it. If it becomes painful then you should step back to the stage before until it settles and then gradually phase forwards again. What should I do if it comes out of the joint again? You should go back to emergency department. Once relocated you will usually be referred back the orthopaedic team for review.
Page 4:	Image: Still image of brand characters and ARTISAN logo Title: Final words Text: Well that is it! All done! Back to your usual self! Nothing more to say other than all the best and well done for seeing it through to the end.
Back Page:	Logo'

14. APPENDIX THREE: ARTISAN INTERVIEW SCHEDULE

Introduction

- Introduce self

- As you are aware a research team at Warwick Medical School are currently doing some research into dislocated shoulder and its treatments in which you were involved. Your involvement in this study has recently come to an end and the research team would like to ask you to reflect on your experiences in the ARTISAN study.

- We would like to ask you some questions about your experiences in the study.

- This takes about one hour. An information sheet about the study has already been sent to read. Do you have any questions about the study? Before we continue with the interview are you still happy to participate?

- Go through this and the consent form to ensure the participant is OK about participating, cover the points about audio recording, data protection, confidentiality and anonymity.

Topic Guide

- **Topic One - Background**
  Background information about the interview, their general lifestyle and their dislocation.

- **Topic Two – Study recruitment**
  Explore reasons for becoming involved, explore contacting protocol and documentation. Suggestions for improvement.

- **Topic Three – Informed consent**
  Process, ease of completion.

- **Topic Four – Completion of study paperwork**
  How did they find completing the relevant paperwork including questionnaires?

- **Topic Five – The programme**
  Explore what aspects they found useful and why and conversely what wasn't useful and why. Physiotherapy sessions, Online content. Explore any attendance issues. Enquire about duration, location. How would they make it better?

- **Topic Six – Outcome of the programme**
  What has been the outcome, would they change anything? Would they recommend to others, or not and why
  What advice/education/influences have they found particularly helpful and unhelpful. Really explore what has motivated them and what hasn't.

- **Topic Seven – Ongoing support**
  Explore what they thought about the support and its availability.

Thank the participant for their valuable contribution and explain the next stage in the process of research and how their involvement will contribute.

15. APPENDIX FOUR: SWAT PROTOCOL

Do courtesy telephone calls or postcards to trial participants following enrolment increase future retention rates in the 'Acute Rehabilitation following Traumatic anterior shoulder dISlocAtioN' (ARTISAN) trial? Study Within A Trial (SWAT) protocol

Name and title of SWAT lead applicant
Ms Amna Shah

Names and titles of SWAT Co-applicants
Ms Jaclyn Brown, Dr Helen Parsons, Dr Rebecca Kearney

Applicant affiliations
Mrs Amna Shah

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Ms Jaclyn Brown

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Dr Helen Parsons

Warwick Medical School, University of Warwick

Dr Rebecca Kearney

Warwick Medical School, University of Warwick

SWAT Registration
This SWAT will be registered on the MRC SWAT Repository.

Host trial Registration
ISRCTN63184243

Background

The courtesy telephone call intervention
Randomised controlled trials (RCTs) are the bedrock of testing healthcare treatments. However, achieving high retention of participants in RCTs can be difficult. Trial teams often experience difficulties with maintaining follow-up and questionnaire response rates from participants, which can introduce bias, reduce the sample size and statistical power and affect the validity, reliability and generalisability of findings [1-5].

There is therefore a need to develop and test interventions to improve retention of participants. One method is to 'embed' trials of retention interventions in ongoing randomised trials. Testing interventions in ongoing trials ensures causality of intervention effectiveness is assessed [4] and avoids limitations associated with testing in a quasi-randomised controlled trial, or non-randomised setting such as the feasibility of intervention implementation.

In the UK as of 2017, 89 percent of households owned a landline telephone [6], whilst 95 percent of households owned a mobile telephone [7]. With wide prevalence of telephone use, courtesy telephone calls are routinely used in commercial and service settings to engage customers and are perceived to be 'good customer service'. Courtesy calls are perceived to be a good method by which to remind customers of upcoming appointments or to check on the arrival of products.

In clinical research settings there is evidence that telephone calls offer an effective method of data collection [8]. Advantages of speaking with research participants on the telephone include developing positive relationships between research teams and participants [8]. Some trial teams also routinely telephone newly recruited participants as a courtesy or introduction to thank them for participating in the trial, and to remind them that they will be followed up at pre-specified times. It is unclear however, what impact these courtesy telephone calls make, whether they are cost effective and how they compare with a written thank you card with a reminder about subsequent follow-ups.

The host trial

The SWAT will be hosted in the 'Acute Rehabilitation following Traumatic anterior shoulder dISlocAtioN (ARTISAN): A Multi Centre Randomised Controlled Trial' (ARTISAN). ARTISAN aims to establish if a course of physiotherapy is of clear benefit when compared to a single session of advice following a first time traumatic anterior shoulder dislocation. 478 consenting participants will be randomly allocated (randomised) to receive a single session of advice or a course of physiotherapy. The primary outcome will be the Oxford Shoulder Instability Score (OSIS) at 6 months after randomisation. Complications resulting from treatment and implications on resources for participants and the NHS will also be studied up to 12 months after randomisation. Follow up of participants will be by postal questionnaires at 6 weeks, and then at 3, 6 and 12 months.

Objective of this SWAT

The objective of this SWAT is to evaluate the impact of making a courtesy introductory telephone call to newly recruited participants in the ARTISAN trial on response rates to subsequent follow-up questionnaires compared with a written card with equivalent information.

Methods

Interventions and comparators

Participants will be randomised in a 1:1 ratio to receive one of the following:

1. A courtesy introductory telephone call [within two weeks] of being randomised into ARTISAN. This telephone call will include the following content: 1) Participants will be thanked for taking part in the ARTISAN trial; 2) Participants will be reminded how valuable their contribution is; 3) Participants will be reminded that they will be contacted by post initially at 6 weeks, and then at 3, 6 and 12 months post randomisation, which is just as important as their first visit; 4) Participants will be informed when the trial results are expected; 5) participants are asked to contact the ARTISAN team if they have any queries.
2. A postcard-sized written card, with similar content as above, signed by the Chief Investigator and Trial Manager posted in an envelope to participants' homes within one week of being randomised.

Eligibility criteria for the SWAT

Participants recruited into the ARTISAN trial who consent to being contacted by telephone and by post will be eligible for the SWAT. There are no additional inclusion or exclusion criteria.

Method for allocating to intervention or comparator

Minimisation with a random factor will be used to avoid imbalance between the SWAT intervention arms. The allocation ratio will be 1:1 and will be stratified by the ARTISAN allocation arm. Allocation concealment will be maintained by an independent randomisation team who will be responsible for generation of the sequence and will have no role in the allocation of participants.

Outcome measures

The primary outcome is the questionnaire response rate at 6 months. This is defined as the proportion of participants who return the questionnaire in the post at the 6-month time point within the response window (see ARTISAN main study protocol).

Secondary outcomes will include:

1. Time to response to the questionnaires at all time points, i.e. 6 weeks, 3 months, 6 months, and 12 months (date of first posting to date of questionnaire received by study team)
2. Response rates at 6 weeks, and then at 3 and 12 months (as for primary outcome)
3. Response rates at 6 weeks, 3 months, 6 months and 12 months (return of questionnaire data at any point, including via telephone)
4. Completeness of responses. This will be counted as the number of missing items in the PROMS (OSIS, QuickDASH and EQ5D) and the complications section.
5. Number of reminder notices required
6. Cost of intervention (phone call or postcard) per participant.

Sample size calculations

As is common with SWATs, the sample size is limited by the host trial sample size. ARTISAN aims to recruit 478 participants and the SWAT will be opened to recruitment after the pilot phase (approx. 50 participants). We therefore expect an analysable sample size of approximately 428 participants for the SWAT (214 per group). Analysed independently, this sample would give 90% power and 5% significance to detect differences in retention rates from the anticipated 80% to around 91% (i.e. approximately 11%).

Analysis plans

All eligible participants will be included in the analysis on an intention-to-treat basis, using two-sided statistical significance at the 5% level. All statistical analyses will be conducted in R or SPSS. We will summarise baseline characteristics of participants by the type of SWAT intervention sent. For the primary outcomes of questionnaire response rates, the difference in proportions will be calculated with 95% confidence intervals, and the primary analysis will be a chi-squared test to assess statistical association. Additionally, a logistic regression adjusting for age, gender and host trial treatment allocation will be performed to investigate the effects of these variables. A per protocol analysis will also be performed.

For the secondary outcomes:

The secondary outcome of time to questionnaire return will be assessed by a Kaplan Meier curve and the SWAT interventions compared by log rank test. Cox regression will be applied adjusting for participant age, gender and host trial treatment allocation, and the effect of the intervention reported. The requirement for any questionnaire return reminder will be analysed in the same way as the primary outcome).

An average cost per participant will be estimated for each SWAT intervention arm.

Project timetable

Date	Action
12/12/2018	Peer review of SWAT protocol
01/01/2019	Documentation for the SWAT agreed & signed off
01/02/2019	Submission to REC of application

01/05/2019	Recruitment to the SWAT begins
01/09/2020	Recruitment to the SWAT ends
01/09/2021	Data cleaning and submission of data set to PROMETHEUS team
01/09/2021	Collation of results and analysis, begin write up of trial level paper

Level of funding required

We estimate the proposed SWAT will cost £5,000 this is comprised of;
30 hours of a senior statisticians time, Dr Helen Parsons
100 hours of a data entry clerk's time, Phil Moss
£750 for Trial Manager, Amna Shah to attend MRC methodology conference and present results
£725 postage, printing and consumable costs

Expertise of team

Ms Amna Shah is a Clinical Trial Manager with particular experience is managing the day-to-day running of large multi-centre randomised controlled trials.

Ms Jaclyn Brown is an experienced Senior Project Manager with a demonstrated history of working on multi-centre randomised controlled trials in trauma and orthopaedics.

Dr Helen Parsons is a senior statistician within Warwick Clinical Trials Unit with particular experience of developing and managing large multi-centre NIHR funded orthopaedic trials.

Dr Rebecca Kearney is currently Chief Investigator for a series of multi-centre randomised controlled trials underpinned by NIHR and musculoskeletal charity funding and jointly leads the trauma and orthopaedic team within Warwick Clinical Trials Unit.

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16. APPENDIX FIVE: SWAT CALLING PARTICIPANTS

Telephone Guidelines Script – Introductory phone call

Hello. Please may I speak to XXX

My name is XXX and I am calling from the University of Warwick regarding a study you have agreed to take part in, following your shoulder dislocation.

On behalf of the ARTISAN study team at the University of Warwick, I would like to thank you for your participation and introduce myself. I will be in contact with you over the next 12 months and send you out postal questionnaires which will track your progress after treatment in the ARTISAN study, and I will send them at 6 weeks, 3 months, 6 months and 12 months post-randomisation in the ARTISAN study. The questionnaires will take approximately 5-10 minutes to complete and will be similar to the questionnaires you completed at the hospital when you agreed to take part.

At the end of the study we will publish the findings in medical journals and at medical conferences. You will not be identified in any reports or publications resulting from the study. Once all participants have been followed up and the results analysed, we will make a copy of the study results available which will outline what was found during the study and make them available for you by post via an end of study letter and also on the trial website.

We realise that participating in this study may be time consuming but we appreciate your contribution to try and find out the best treatment for patients with shoulder dislocations. We also realise that your circumstances may change over time, so please feel free to contact me if you change address or if you have any concerns or questions regarding the study. Do you have a pen and paper handy <<give phone number and ARTISAN email address>>

Do you have questions you would like to ask regarding the ARTISAN study?

Thank you very much again for your participation and for your contribution to the ARTISAN study.

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