Advice only versus advice and a physiotherapy programme for acute traumatic anterior shoulder dislocation: the ARTISAN RCT

Rebecca Kearney,[1*] David Ellard,[2,3] Helen Parsons,[2,3] Aminul Haque,[2] James Mason,[2] Henry Nwankwo,[2] Helen Bradley,[2] Steve Drew,[3] Chetan Modi,[3] Howard Bush,[3] David Torgerson[4] and Martin Underwood;[2,3] on behalf of the ARTISAN collaborators

[1]Bristol Trials Centre, University of Bristol, Bristol, UK
[2]Warwick Medical School, University of Warwick, Coventry, UK
[3]University Hospitals Coventry and Warwickshire NHS Trust, Coventry, UK
[4]York Clinical Trials Unit, University of York, York, UK

[*]Corresponding author Becky.kearney@bristol.ac.uk

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Scientific summary

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Scientific summary

Background

The shoulder is the most frequently dislocated joint; dislocation occurs in 8.2–23.9 per 100,000 people per year, and 95% of these are anterior dislocations [Brownson P, Donaldson O, Fox M, Rees JL, Rangan A, Jaggi A, *et al.* BESS/BOA Patient Care Pathways: Traumatic anterior shoulder instability. *Shoulder Elbow* 2015;**7**(3):214–26]. 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 [Brownson *et al.* 2015; Hanchard NC, Goodchild LM, Kottam L. Conservative management following closed reduction of traumatic anterior dislocation of the shoulder. *Cochrane Database Syst Rev* 2014;(4):CD004962; Berendes TD, Pilot P, Nagels J, Vochteloo AJ, Nelissen RG. Survey on the management of acute first-time anterior shoulder dislocation amongst Dutch public hospitals. *Arch Orthop Trauma Surg* 2015;**135**(4):447–54].

People with a traumatic anterior shoulder dislocation (TASD) may have ongoing pain, disability and substantial morbidity linked to high recurrence rates and subsequent need for repeated episodes of management (Brownson *et al.* 2015; Hanchard *et al.* 2014; Berendes *et al.* 2015). Re-dislocation following a first-time traumatic event typically occurs within 12 months of the index dislocation [Zacchilli MA, Owens BD. Epidemiology of shoulder dislocations presenting to emergency departments in the United States. *J Bone Joint Surg Am* 2010;**92**(3):542–9].

Rehabilitation may reduce ongoing 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 (Hanchard *et al.* 2014). However, a 2014 Cochrane review did not find an evidence base to support this (Hanchard *et al.* 2014). Dutch national guidelines explicitly state no referral to physiotherapy should be made, and UK guidelines cite referral 'may be helpful' (Brownson *et al.* 2015; Berendes *et al.* 2015). Consequently, the nature and extent of physiotherapy required for the management of patients following TASD are unclear.

A typical course of six physiotherapy sessions costs around £378; a single assessment and advice session costs £63 (NHS Reference cost). In addition to the cost of providing a 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, while 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 a positive impact on patient experience after TASD, lessening the burden on patients and their friends and families.

Consequently, a course of supervised, tailored physiotherapy needs to be of clear additional benefit, when compared to a single session of advice, 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 (Brownson *et al.* 2015).

Objective

The primary objective was to test a single session of advice and physiotherapy versus a single session of advice only, for adults with first-time TASD managed non-operatively at 6 months using the Oxford Shoulder Instability Score (OSIS).

Methods

Design

A UK multicentre, two-arm, parallel group, superiority, randomised controlled trial (RCT) with 1 : 1 treatment allocation, across 41 NHS sites, with embedded qualitative study. A protocol paper has been previously published [Kearney RS, Dhanjal G, Parsons N, Ellard D, Parsons H, Haque A, *et al.* Acute Rehabilitation following Traumatic anterior shoulder dISlocAtioN (ARTISAN): protocol for a multicentre randomised controlled trial. *BMJ Open* 2020;**10**(11):e040623]. The final protocol, statistical analysis plan and health economic analysis plan are publicly available.

Participants

People were eligible to be included in the trial if they were adults (≥ 18 years) with a first-time TASD confirmed radiologically. People were excluded if they had neurovascular complications or bilateral dislocations, were unable to adhere to trial procedures or unable to attend physiotherapy within 6 weeks of injury, or had been previously included in the trial. After potential participants were assessed, informed written consent was obtained by a site-based researcher trained in good clinical practice.

Intervention

All participating centres received an initial training session from an Acute Rehabilitation following Traumatic anterior shoulder dISlocAtioN (ARTISAN) trial research physiotherapist. Following this, a lead physiotherapist at each site was identified to complete subsequent training of additional physiotherapists. This training was supported with web-based materials and a trial intervention manual. A quality control programme ensured intervention fidelity. Fidelity was monitored by: (a) direct observations by a member of the trial team; (b) audio recordings, used to assess the success or failure of the therapist to introduce the aims/rationale of each component and consolidate participant learning at the end of each component; and (c) a therapist self-report form completed for every trial participant.

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

All participants had an initial period where the injured arm was supported in a sling, and then received an appointment for a physiotherapy advice session within 6 weeks of their injury. At the first appointment, all participants received the same initial shoulder examination followed by advice to aid self-management, lasting up to 1 hour and administered by an ARTISAN-trained physiotherapist. This included core components on education, progressive exercises, and exercise planning to enhance self-management behaviours. These core components were available after the advice session via a password-protected website or via paper-based alternatives at the participants' preference. Details of the intervention development were first published in December 2021 [Liew Z, Mazuquin B, Ellard DR, Karasouli E, Drew S, Modi C, *et al.* Development of a single-session physiotherapy and self-management intervention for the treatment of primary traumatic anterior shoulder dislocation for the 'Acute Rehabilitation following Traumatic anterior shoulder dISlocAtioN (ARTISAN)' multicentre RCT. *Physiotherapy* 2021;**113**:80–7]. Following completion of the advice appointment, the participant was randomised, allocating them to this advice session alone or to this advice session plus the offer of additional physiotherapy. We defined the offer of additional physiotherapy to be the intervention.

Participants randomised to advice only were provided with a contact point to self-refer back to the clinical team if recovery did not occur. Participants who self-referred back to the clinical team were considered to be per protocol.

Participants randomised to receive additional physiotherapy were offered additional physiotherapy sessions. Each additional session lasted for up to 30 minutes, over a maximum duration of 4 months from the date of randomisation. The course of physiotherapy involved teaching and supervising the 'core set' of progressive exercises offered to the control arm in addition to being able to tailor treatment according to usual practice.

Outcome measures

Primary outcome measure

The primary outcome measure was the OSIS. The OSIS is a self-completed outcome measure containing 12 questions (0–4 points each), with possible scores from 0 (worst function) to 48 (best function) [Dawson J, Fitzpatrick R, Carr A. The assessment of shoulder instability. The development and validation of a questionnaire. *J Bone Joint Surg Br* 1999;**81**(3):420–6; Dawson J, Rogers K, Fitzpatrick R, Carr A. The Oxford shoulder score revisited. *Arch Orthop Trauma Surg* 2009;**129**(1):119–23]. These questions relate to activities of daily living particularly relevant to patients exhibiting shoulder instability.

Secondary outcome measures

The secondary outcome measures were as follows.

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 [Gummesson C, Ward MM, Atroshi I. The shortened Disabilities of the Arm, Shoulder and Hand questionnaire (QuickDASH): validity and reliability based on responses within the full-length DASH. *BMC Musculoskelet Disord* 2006;**7**:44].

EuroQol-5 Dimensions, five-level version (EQ-5D-5L): EQ-5D-5L is a well-validated, generic health-related quality of life measure consisting of five dimensions, each with five 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 [Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, *et al.* Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;**20**(10):1727–36].

Complications: Serious adverse events (SAEs) were reported through the following mechanisms: (a) participant reported during routine collection of follow-up data; (b) local research teams reported any additional investigations or treatment of participants; (c) local physiotherapists delivering the trial interventions reported any events occurring during treatment sessions; and (d) medical records of non-responding participants were retrieved by local research teams at site.

Serious adverse events not related to the intervention or TASD event were recorded on the SAE form but were not formally analysed or reported. SAEs that were predefined complications directly related to the trial interventions or directly caused by the primary TASD event were recorded as complications and were formally analysed and reported.

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

We used techniques common in long-term studies to ensure minimum loss to follow-up, such as collection of multiple contact addresses and telephone numbers, mobile telephone numbers and e-mail addresses. All outcome measures were collected at baseline, 6 weeks, and 3, 6 and 12 months following randomisation.

Qualitative interviews: One of the secondary objectives for ARTISAN was to qualitatively explore the participant experiences of receiving the trial treatments and facilitators and obstacles to adhering to them.

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 were invited for one-off face-to-face interviews [by telephone or via Microsoft Teams® (Microsoft Corporation, Redmond, WA, USA)]. The aim was to explore the participant experience of receiving the trial treatments, and facilitators and obstacles to adhering to them.

Results

Between 14 November 2018 and 14 March 2022 we recruited from 41 NHS Trusts, who screened 1551 adults with a traumatic shoulder dislocation, from whom 1069 were not randomised. Forty of the 41 NHS Trust teams randomised the remaining 482 to advice only (*n* = 240) or advice and a programme of physiotherapy (*n* = 242). Ten participants withdrew prior to the primary outcome point of 6 months; 354 participants completed the primary outcome OSIS (73%) and were included in the final analysis.

Across the groups there were high levels of adherence. Ninety-six physiotherapists delivered the interventions across the 41 sites. Two participants in the advice-only group (*n* = 240) crossed over to receive a programme of physiotherapy because in the opinion of the treating clinician a programme of further physiotherapy was needed. A further 42 participants self-referred to receive a programme of physiotherapy. A total of 194 participants received advice only, and there were missing data on two participants. In the group randomised to advice and further physiotherapy, 24 participants did not attend any additional appointments, 30 participants did not attend after one appointment, 167 had a complete programme of physiotherapy and 18 were receiving ongoing management after the 4-month period. There were three participants with missing data.

There was no evidence of a statistically significant difference in OSIS between advice only and advice plus a programme of physiotherapy in the 6-month primary outcome, for the primary intention-to-treat adjusted analysis [favours physiotherapy: 1.5, 95% confidence interval (CI) −0.30 to 3.5] or at earlier 3-month and 6-week time points. At each time point the direction of change favoured a programme of physiotherapy; however, the 95% CI at each time point excluded our target four-point difference on the OSIS. There were no statistically significant differences in the QuickDASH or consistent differences in the EQ-5D-5L secondary outcomes.

Secondary unadjusted and per-protocol analyses, and a sensitivity analysis accounting for missingness, were not materially different. Predefined subgroup analyses were undertaken to assess whether there was evidence that the intervention effect differed between age group (≤ 39 years old and ≥ 40 years old) and arm dominance. Our predefined subgroup analyses showed no evidence of clinically relevant effects from either age or arm dominance.

Predefined complications profiles were similar across the two groups. In the advice group, there were reports of 7 shoulder re-dislocations, 3 frozen shoulders, 8 compression fractures of the shoulder, 22 rotator cuff tears and 1 report of nerve damage. In the additional physiotherapy group, there were

3 shoulder re-dislocations, 7 frozen shoulders, 21 rotator cuff tears and 4 compression fractures of the shoulder.

Participants randomised to a programme of physiotherapy had non-significant increase in quality of life of 0.019 quality-adjusted life-years (QALYs) (95% CI −0.0005 to 0.0375) at a small, non-significant increased cost of £64 (95% CI −61 to 191) over the follow-up period. The probability of being cost-effective at a willingness-to-pay threshold of £30,000 was 0.946. Sensitivity analyses, including complete cases only and including broader societal costs, provided similar findings.

Thirty-one participants were interviewed from both arms of the trial: ARTISAN [*n* = 16, 8 male and 8 female, mean age 49 years (standard deviation 21 years)] and ARTISAN Plus [*n* = 15, 11 male and 4 female, mean age 59 years (standard deviation 17 years)]. Four interlinked themes emerged from the data: (1) feelings about their shoulder rehabilitation outcome; (2) judgement of ARTISAN rehabilitation materials; (3) assessment of shoulder rehabilitation services provision; and (4) experiences of involvement in ARTISAN. The data reveal that generally across both arms of the trial, participants' experiences were good. There are a number of areas where there are differences related to age and participants' requirements to return to sporting activities. In terms of recovery following their rehabilitation journey, there is a trend towards a more positive outcome reported by those in the ARTISAN Plus arm of the trial.

Conclusions

We found little difference in the primary outcome (OSIS) or other secondary outcomes. Advice with additional physiotherapy sessions is cost-effective at a £30,000/QALY threshold. However, the small imprecise health gains raise questions on whether it is the best use of scarce physiotherapy resources given current service demands.

The ARTISAN trial is the largest RCT for the common shoulder dislocation. The study recruited 482 participants, across 41 NHS Trusts and using 96 ARTISAN-trained physiotherapists, making the sample representative of NHS patients. Adherence to trial groups was high, with 99% in the advice group being offered advice only and 100% in the additional physiotherapy group being offered additional physiotherapy.

The advice-only intervention was delivered by physiotherapists and crucially did not prohibit patients from self-referring back to the service if recovery did not meet their expectations. With this mechanism in place, 18% (42/240) self-referred back to the service. Empowering people to make their own treatment decisions was acceptable to clinicians (99% adherence) and allows flexibility for patients to decide when additional supervised treatment is required. It is acknowledged that there will be circumstances where additional supervised physiotherapy is appropriate; however, as a default referral pathway, it is not clinically superior to an advice-only intervention.

The ARTISAN trial found evidence that there is little difference between referring people to a programme of physiotherapy or to a single session of advice with a physiotherapist. However, people who are not experiencing recovery as expected could self-refer for a supervised programme of physiotherapy. This will provide a balance between best use of NHS resources, empowering patients, and reducing unnecessary appointments for those who can self-manage. Further research should be directed towards optimising self-management strategies.

Study registration

This study is registered as ISRCTN63184243.

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