Subacromial spacers for adults with symptomatic, irreparable rotator cuff tears: the START:REACTS novel group sequential adaptive RCT

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Disclosure of interests of authors

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/TKJY2101.

Primary conflicts of interest: Andrew Metcalfe, Helen Parsons, Elke Gemperlé Mannion, Charles Hutchinson, James Mason, and Martin Underwood are co-investigators on two other NIHR-funded trials: Robotic Arthroplasty: A Clinical and cost Effectiveness Randomised controlled trial (RACER)-Knee and RACER-Hip (Andrew Metcalfe leads RACER-Knee), for which Stryker also fund treatment costs and some imaging costs. As with the presented study, the full independence of the study team is protected by legal agreements.

Andrew Metcalfe, Susanne Arnold, Helen Parsons, Nicholas Parsons, Elke Gemperlé Mannion, Aminul Haque, Charles Hutchinson, Rebecca Kearney, Iftekhar Khan, James Mason, Nigel Stallard and Martin Underwood all work on other NIHR-funded studies. Charles Hutchinson, Rebecca Kearney, James Mason and Martin Underwood are or have been members of funding panels in NIHR, although not on the EME programme. Rebecca Kearney is chair of the NIHR Programme Grants for Applied Research

(PGfAR) committee, a paid position in NIHR but unrelated to the trial. She is also a previous chair of the NIHR Research for Patient Benefit (RfPB) committee and previous member of the Health Technology Assessment (HTA) Clinical Evaluation and Trials Committee and NIHR Integrated Clinical Academic (ICA) doctoral committee. Martin Underwood was a member of the NIHR Journals Library Editors Group and HTA Commissioning Committee. Until March 2021 he was an NIHR Senior Investigator. Until March 2020 he was an editor of the NIHR journal series, and a member of the NIHR Journal Editors Group, for which he received a fee. Simon Gates was a member of the NIHR Clinical Trials Unit Standing Advisory Committee and EME – Funding Committee Members and currently part of the HTA General Committee. Stephen Drew held an educational consultancy with Wright from 1 April 2016 until it was acquired by Stryker in 2021, when it migrated to an educational consultancy with Stryker from 1 April 2022.

Outside of this study, the authors report no personal financial conflict of interest with Stryker or any other related commercial organisation.

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Plain language summary

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Plain language summary

Tears of the rotator cuff tendons of the shoulder are very common. Some people with a rotator cuff tear have pain and loss of function that is not improved by simple treatments, and they may undergo surgery.

Many people have the tear repaired. if this cannot be done, keyhole surgery can be used to clear space around the tendons and allow the shoulder to move better. This procedure is called an arthroscopic debridement.

The InSpace® (Stryker, Kalamazoo, MI, USA) balloon is a dissolvable device that is placed by the surgeon above the shoulder joint, after an arthroscopic debridement. We wanted to know if it improved results for patients and was good value.

We compared the standard operation, arthroscopic debridement, with the same procedure with the InSpace balloon inserted. We collected data from 117 people with rotator cuff tears from 24 NHS hospitals. Because of the COVID-19 pandemic, we could not directly measure strength or movement and used well-established questionnaires instead.

Twelve months after their operation, most people had improved. People who had the standard operation alone, without the balloon, had less pain and could use their shoulder more.

We calculated the costs of each treatment, including lost earnings. The InSpace balloon was more expensive and was poor value for money for the NHS.

We developed a new method for doing an early statistical analysis to decide whether we could stop the study early. Because of this, around half the number of people were needed in the study, compared with the number we would normally need to do this work. We did additional research and found that this new method would work for some other studies and would give much quicker results about which treatments work best.

We developed a new method for doing magnetic resonance imaging scans of the shoulder, although data collection was limited by the COVID-19 pandemic.

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This report

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