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Why participants in The United Kingdom Rotator Cuff Tear (UKUFF) trial did not remain in their allocated treatment arm: a qualitative study

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Abstract

Objective The UKUFF trial was a three-way parallel group randomised trial comparing surgical and non-surgical treatments for people with rotator cuff tears of their shoulder.

High crossover between arms in the UKUFF led to the original trial design being reconfigured; 'Rest then Exercise' was halted. This study explored why participants recruited did not remain within allocated treatment arms and explored crossover and surgical decision making.

Design A qualitative phenomenological approach.

Participants Purposive sampling ($n = 18$) included participants randomised to 'Rest then Exercise' arm considered least likely to proceed to surgery but who had surgery, plus participants from all arms not having surgery.

Methods In-depth, semi-structured interviews were recorded and transcribed. Field-notes, memos, member-checking and a reflexive diary were used.

Data analyses In accordance with Interpretative Phenomenological Analysis. Peer review, code-recode audits and constant comparison occurred throughout.

Results 1. *Impact of symptoms and diagnosis:* these influenced crossover; long durations of severe pain and failed conservative treatment increased eagerness for surgery. 2. *Perceptions and expectations of treatment*: surgery provided hope for participants, especially when "Rest then Exercise" was perceived as having previously failed. Surgeons were perceived to believe "tears need repairing". 3. *Professionals know best: autonomy and communication*: patients deciding not to have surgery had to actively leave the surgical waiting list. Increasing age, carer role, self-employment, co-morbidity and improving symptoms were reasons described for declining surgery.

Conclusions Most participants had failed conservative treatment before trial entry and described strong preferences regarding treatment. Trials should demonstrate patient and clinician equipoise but participants' rarely described equipoise. If conservative treatments are usually provided sequentially in clinical practice, it may be inappropriate to include them as comparators in surgical trials.

This is a qualitative study and not eligible for trial registration since it was carried out independently of the UKUFF trial (UKUFF ISRCTN97804283 Date assigned 29/06/2007).

Keywords: Research design; Randomised controlled trial; Equipoise; Qualitative; Rehabilitation

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Introduction

The United Kingdom Rotator Cuff Tear Trial was a multicentred three-way parallel group randomised trial comparing arthroscopic rotator cuff repair surgery versus open/mini-open rotator cuff repair surgery versus Rest then Exercise (RtE) for rotator cuff tears of the shoulder [1]. Shoulder pain is common; estimations of prevalence range from 4 to 26%, and around one percent of adults aged over 45 years consult their General Practitioner (GP) for a new shoulder problem each year [2]. Rotator cuff problems account for more than two thirds of cases of shoulder pain [2] and the number of repairs carried out has dramatically increased [3]. Review of the indications for rotator cuff surgery concludes that good quality evidence is sparse. There is a lack of consensus regarding the optimal treatment of tears and limited, inconclusive evidence regarding effectiveness and harms [5,6]. A significant number (26%–39%) of rotator cuff tears demonstrated during radiological investigations are asymptomatic [7], though may become symptomatic over time [8]. In economic terms the burden of shoulder pain is large; in addition to consultation and treatment costs, work related upper limb disorders in the UK are now more prevalent than back pain [9].

The UKUFF RtE arm was halted because of the high rate of crossover of patients from RtE to surgery. Seventy seven of the first 214 participants (36%) did not complete the 10 week RtE program and underwent surgery, 88 (41%) completed the course before progressing to surgery and 36 (17%) completed the course and did not have surgery [10]. The trial was reconfigured to two arms of open versus arthroscopic rotator cuff repair [1]. Of 273 patients randomised to surgery, 162 (59%) participants underwent a rotator cuff repair; 59 (22%) withdrew and 52 (19%) underwent subacromial decompression without cuff repair [10].

Crossover, or treatment switching, may occur for many reasons, including when patients are responding poorly to treatment (e.g. oncology trials), and patients who crossover may have a different prognosis/outcome than those not switching [11,12]. There is literature assessing statistical methods to address crossover [11,12], but no previous studies have explored crossover from the patients' perspective. This study explored why participants recruited within UKUFF did not remain within their allocated treatment arm, and explored crossover and decisions about having/declining surgery from the perspective of trial participants.

Methods

Ethical approval: National Research Ethics Service, committee North East—Northern and Yorkshire ref no: 12/NE/0052.

Design

A qualitative study, including Interpretive Phenomenological Analysis (IPA) [13].

Participants

Potentially eligible patients were identified by the UKUFF team. Two hundred and fourteen participants were randomised to RtE and 273 to surgery [10]. UKUFF participants had a degenerative rotator cuff tear (diagnosed by ultrasound/MRI scan) [1]. The Oxford Shoulder Score (OSS) was a trial outcome and OSS data collected upon trial entry-were used to purposively invite participants from two groups (Fig. 1).

Group 1. Participants randomised to RtE considered least likely to proceed to surgery. 'Least likely' was defined by participants reporting no previous physiotherapy treatment and higher baseline OSS at trial entry (low pain and higher function). Most participants (six of seven) crossed over and had surgery (Fig. 1).

Group 2. Participants from surgical and non-surgical treatment arms who did not proceed to surgery. UKUFF participants with low OSS (higher pain and lower function; considered most likely to need surgery) at baseline were approached. All patients were placed on surgical waiting lists at randomization so the sample included both those randomised to RtE who did not have surgery (Group 2a in Fig. 1) and those randomised to surgery who did not have surgery (Group 2b in Fig. 1). By the time interviews were carried out, three of the four participants in Group 2a had crossed over and undergone surgery (Table A in supplementary material). The seven participants from Group 2b, randomised to receive surgery, did not have surgery. The sample was considered to achieve an appropriate balance between participants' crossing over to surgery and to no surgery.

Potential participants were posted an invitation by their local UKUFF investigator. Interested patients contacted the study team by prepaid reply slip/telephone/email. Written informed consent was obtained at the start of the interview visit.

Sample size

IPA recommends involving small numbers, from a fairly homogenous group for whom the research question is of significance, to gain a rich and in-depth account [13]. Sample sizes need to be sufficient to enable relevant data to be obtained, but not so overly large that detailed analysis is prevented [14]. Our protocol estimated 15–18 participants would be required. Recruitment ceased when the team believed that sufficiently rich data had been collected and the study aims achieved [15].

Interviews

A semi-structured interview guide was developed by researchers and a previous patient who had undergone treatment for diagnosed rotator cuff tear (Table A in supplementary material). Participants ($n = 18$) were invited to participate in in-depth semi-structured interviews with CML