



# Factors affecting patient participation in orthopaedic trials comparing surgery to non-surgical interventions



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## ARTICLE INFO

### Article history:

Received 24 January 2016

Received in revised form

25 April 2016

Accepted 11 May 2016

Available online 13 May 2016

### Keywords:

Orthopedic

Randomized controlled trials

Patient participation

### Abbreviations:

RCT

Randomized controlled trial

CROSSBAT

Combined randomized and observational

study of surgery for type B ankle fracture

treatment

OTA

Orthopedic trauma association

## ABSTRACT

**Background:** Randomized controlled trials (RCTs) are considered the most robust research design to determine the effectiveness of interventions. RCTs comparing surgery to non-surgical alternatives are particularly difficult to perform, partly due to difficulties with recruitment. Low recruitment rates can limit the internal and external validity of a trial thus understanding their causes may be important for avoiding protracted recruitment periods. This study aimed to report patient factors that influenced participation in a trial comparing surgery to a non-surgical treatment approach.

**Methods:** This study was a cross-sectional study nested within CROSSBAT (Combined Randomized and Observational Study of Surgery For Type B Ankle Fracture Treatment). Eligible participants willing to be randomized were randomized while those who declined randomization were offered participation in an observational cohort. Participants from both groups (randomized and observational) were asked to indicate their level of agreement on a 100 mm line with statements concerning reasons for acceptance or rejection of randomization. A subset were asked to state the primary reason for agreeing to participate or not in the trial.

**Results:** The nested study included 312 participants; 113 who accepted and 199 who declined randomization. Participants unwilling to be randomized (those in the observational arm of the study) predominantly received a non-surgical intervention. They were significantly more worried about receiving treatment by chance (55 mm vs. 33 mm;  $p < 0.0001$ ) and had a significantly higher preference for one particular treatment (less equipoise) (82 mm vs 43 mm;  $p < 0.0001$ ) compared to participants willing to be randomized. Influence from clinicians and risk avoidance were primary influences of participation. Participants' responses regarding protocol burden, study follow-up requirements and altruism did not significantly differ between groups.

**Conclusion:** Patient non-participation in an RCT comparing surgery to no surgery is related to concern about receiving a treatment through chance and the presence of a strong preference for a particular treatment, particularly a non-surgical one. To avoid protracted recruitment periods, investigators can increase the number of study sites and ensure personnel involved have equipoise and are trained to provide a balanced view of both treatment arms.

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## 1. Introduction

Randomized controlled trials (RCTs) are considered the most robust research design yet they are often arduous to perform [1].

Patient recruitment to RCTs in general is difficult, often because people have a preference for one treatment over another [2]. Surgical RCTs are reported to be more problematic than drug trials especially as the results of surgery are more permanent and may be associated with increased risks and costs. This issue is particularly highlighted in surgical vs. non-surgical RCTs [3–6]. Low patient recruitment can lead to a decrease in the scientific quality of an RCT in a number of ways, including loss of statistical power and poorer generalizability, and may lead to early termination [4].

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There are many factors affecting patient participation in RCTs. These can be related to the patient or to other factors such as clinician or systematic factors [6]. Patient factors including altruism, self-benefit, fear of chance depicting treatment and patient preference have been identified previously as they influence a patient's decision to participate in an RCT [7–9]. Clinician factors that can affect recruitment include time constraints, lack of staff and training, concern for patients, loss of professional autonomy, difficulty with the consent procedure, lack of rewards and recognition, or insufficiently interesting research question [6]. Institutional factors such as procedural, structural and infrastructural obstacles can also affect patient recruitment. Identifying and addressing these factors can improve patient recruitment and, thus, improve the quality of surgical RCTs. Although these factors have been studied in the medical RCTs, there is limited evidence on how these factors influence patient participation in surgical vs. non-surgical RCTs [4,6,8–10]. This study aimed to report patient factors that influenced participation in a trial comparing surgery to a non-surgical treatment approach.

## 2. Methods

CROSSBAT (Combined randomized and observational study of surgery for type B ankle fracture treatment) involved 22 hospitals across Australia and New Zealand that were a mix of rural, regional and metropolitan hospitals. It included a randomized group, and participants declining randomization were invited to participate in the observational cohort. CROSSBAT was designed to assess if surgical management was superior to non-surgical management for the treatment of type B ankle fractures with minimal talar shift. Consecutive adult patients presenting to a recruiting hospital during the study period with an isolated, closed OTA (Orthopedic trauma association) type 44-B1 distal fibula fracture without significant talar shift were screened for eligibility. Written, informed consent was obtained from all participants willing to participate.

In addition to the above, inclusion criteria included patients with no other concomitant fractures/dislocations; aged between 18 and 65 years inclusive; mobilizing unaided/independently pre-injury and willing to be followed up for 12 months. Exclusion criteria included participants that were medically unfit for anesthesia/surgery; skeletally immature; previous trauma or surgery to the fractured ankle; inability to consent; pregnancy; the presence of other injuries or co-morbidities that impede mobilization; and non-English speaking. Eligible participants willing to be randomized were randomly allocated in a 1:1 ratio to either the surgical or non-surgical intervention. Those not willing to be randomized were invited to participate in the study as part of the observational cohort. Members of the orthopedic team recruited participants either in the emergency department or fracture clinics of the participating hospitals.

At baseline, along with demographics questions, all participants were asked to complete a survey indicating their level of agreement with a series of statements by placing an "X" through a 100 mm line (Fig. 1). The survey questions were based on common patient concerns regarding participation in RCTs that have been raised in other studies, such as uncertainty of treatment; lack of participant equipoise; protocol rationale, follow-up burden and altruism [6–8]. As the study progressed, it was evident that the majority of people who participated in CROSSBAT (almost 2:1), opted to become involved in the observational arm (and thus avoid the possibility of surgery). In order to understand further what was the primary reason for participation or not in the randomized arm, participants in the latter stage of recruitment were probed further at six weeks post-surgery via a telephone interview.

The primary outcome was participant level of agreement with

each statement expressed in millimetres. As this study was nested within the CROSSBAT study, the sample size was dictated by the CROSSBAT sample. Baseline characteristics of the two cohorts were compared using Student's t-test or chi-squared test. The survey data were compared using Student's t-test. Missing data were not imputed. The probed responses were categorized by two investigators (RM, JN) at the conclusion of the study. The number of participants in each category was calculated and expressed as a percent. The percentages in each study group were compared using chi-squared test.

The CROSSBAT protocol was approved by the relevant ethics committees associated with each site. Approval for the nested study was granted by the Hunter New England HREC covering the New South Wales participants.

## 3. Results

A total of 312 participants were recruited in the sub-study from August 2010 to October 2013; 113 in the randomized cohort and 199 in the observational cohort. The majority of people in the observational cohort received a non-surgical intervention (185 vs. 14) whilst, as expected, treatment distribution was balanced in the randomized cohort.

There were significantly more females in the randomized cohort. The observational cohort had a significantly higher number of participants with a tertiary level education. Other baseline characteristics were similar between the two cohorts and are shown in Table 1.

Participants in the observational cohort (i.e. those declining randomization) were significantly more worried about receiving treatment by chance (mean 55 mm, 95%CI: 50.0 to 59.7 vs. 36 mm, 95%CI: 30.3 to 40.8;  $p < 0.0001$ ) and had a significantly higher level of preference for non-surgical management, indicating they had less equipoise (mean 82 mm, 95%CI: 78.6 to 85.0 vs. 43 mm, 95%CI: 37.2 to 48.9;  $p < 0.0001$ ) when compared with the randomized cohort, respectively. Participants in both cohorts (observational and randomized) had similar levels of agreement with the protocol rationale (mean 77 mm vs. 79 mm;  $p = 0.41$ ), follow-up burden (mean 17 mm vs. 17 mm;  $p = 0.96$ ) and altruism (mean 16 mm vs. 13 mm;  $p = 0.17$ ). The results are shown in Table 2 and Fig. 1.

Of the subset ( $n = 84$ ) who were probed about their primary reasons for participation in the randomized or observational cohort, 25 were from the randomized arm, and 59 were from the observational cohort. The demographics details of these 84 participants were similar to the whole cohort as shown in Table 3.

The primary reasons for participation or not in the randomized arms were broadly categorized into two themes - health professional influence and risks of surgery. - A higher proportion of participants from the observational cohort preferred non-surgical management ( $n = 57$  (97%)) and identified influence from a health professional regarding their choice of participation (observational vs. randomized) compared to those in the randomized arm as shown in Table 4.

A higher proportion of participants from the observational cohort also identified risks of surgery as a factor that affected their choice of participation (observational vs. randomized) compared to those in the randomized arm as shown in Table 5.

## 4. Discussion

Recruiting for randomized controlled trials is challenging and recruiting for surgical randomized controlled trials is associated with particular barriers. These barriers have been broadly grouped into patient-, surgeon- and institutional-related factors. Within the context of an orthopedic trial, we provide some insights into

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