Journal of Clinical Epidemiology 76 (2016) 166−174

Journal of Clinical Epidemiology

A new simple six-step model to promote recruitment to RCTs was developed and successfully implemented

Alba Realpe[a], Ann Adams[a], Peter Wall[a], Damian Griffin[a,*], Jenny L. Donovan[b]

[a]*Warwick Medical School, University of Warwick, Coventry CV4 7AL, United Kingdom*

[b]*School of Social and Community Medicine, University of Bristol, Canynge Hall, 39 Whatley Road, Bristol BS8 2PS, Bristol, United Kingdom*

Accepted 12 February 2016; Published online 17 February 2016

Abstract

Objectives: How a randomized controlled trial (RCT) is explained to patients is a key determinant of recruitment to that trial. This study developed and implemented a simple six-step model to fully inform patients and to support them in deciding whether to take part or not.

Study Design and Setting: Ninety-two consultations with 60 new patients were recorded and analyzed during a pilot RCT comparing surgical and nonsurgical interventions for hip impingement. Recordings were analyzed using techniques of thematic analysis and focused conversation analysis.

Results: Early findings supported the development of a simple six-step model to provide a framework for good recruitment practice. Model steps are as follows: (1) explain the condition, (2) reassure patients about receiving treatment, (3) establish uncertainty, (4) explain the study purpose, (5) give a balanced view of treatments, and (6) Explain study procedures. There are also two elements throughout the consultation: (1) responding to patients' concerns and (2) showing confidence. The pilot study was successful, with 70% (n = 60) of patients approached across nine centers agreeing to take part in the RCT, so that the full-scale trial was funded.

Conclusion: The six-step model provides a promising framework for successful recruitment to RCTs. Further testing of the model is now required.

Keywords: Recruitment to randomized controlled trials; Orthopedics; Hip impingement; Femoroacetabular impingement; Consultation; Qualitative research

1. Introduction

Pragmatic multicentre randomized controlled trials (RCTs) are acknowledged to be the best design for evaluating the effectiveness of health care interventions but often encounter recruitment difficulties [1−4]. RCTs in surgery face particular challenges, including that many surgeons have limited experience of participating in RCTs, often face learning curves for particular surgical procedures, and sometimes develop individualized rather than standardized techniques. In addition, the comparator for a surgical procedure can often be a very different and more conservative option, such as physiotherapy in orthopedic trials, or no immediate intervention [5,6].

To participate in an RCT comparing surgery and physiotherapy, all clinicians involved need to accept the possibility that their usual preferred treatment is no more effective than the comparator; and it is particularly difficult for recruiting surgeons to accept this [7]. In addition, discussions about trials are difficult because they may be perceived as disturbing the usual expectations of both patients and clinicians surrounding routine diagnostic and treatment consultations, where shared decisions about best treatment are the intended aim. For patients, the idea that there is uncertainty over the comparative effectiveness of different treatments can also be very difficult to accept [8,9]. Discussions about trials are therefore awkward and may be avoided, leading to lack of accruals and insufficiently informed patients [7,10−12].

Qualitative research methods can be used to understand and inform the development of strategies to improve recruitment to RCTs [13−15]. For example, the results of an integrated qualitative study led to the rate of randomization of eligible participants rising from 30% to 70% over a 12-month period in the National

Conflict of interest: The authors declared no conflicting interests.

Funding: This program of research has been funded by the UK National Institute for Health Research, Health Assessment Technology (10/41/02). The trial registration number was ISCRCTN 09754699.

* Corresponding author. Tel.: +44-0-2476-968624; fax: +44-0-2476-968653.

E-mail address: Damian.Griffin@warwick.ac.uk (D. Griffin).

http://dx.doi.org/10.1016/j.jclinepi.2016.02.002

What is new?

Key findings

- This study presents a simple six-step model for achieving good recruitment practice, informed by previous research into successful recruitment strategies.
- Despite the challenging nature of the trial, with significant differences in risks and benefits associated with the different treatment arms, a 70% recruitment rate was achieved.

What this study adds to what was known?

- While there is an array of established good practice models to guide clinicians in conducting successful diagnostic and treatment consultations in routine clinical practice, the same is not true for trial recruitment consultations.
- The two types of consultations have very different aims and objectives. In routine practice, achieving shared clinician-patient decisions about what treatment is best is of paramount importance, but in recruitment consultations recruiters and patients have to achieve the opposite: equipoise regarding best treatment options, and willingness on the part of patients to become research participants and to receive random treatment allocation.

What is the implication and what should change now?

- The six steps are designed to guide how recruitment consultations are conducted.
- The model was developed and used in a pilot trial involving surgical vs. non-surgical treatments, of which few have been conducted.
- Differences between routine and recruitment consultations require an alternative skill set for which recruiters need training and support.

Institute for Health Research Health Technology Assessment–funded Prostate testing for cancer and Treatment (ProtecT) study [16]. An innovative approach to observing trial information exchange within clinician–patient consultations and giving formative feedback to recruiters based on those observations was among the strategies developed in this study and tested in other RCTs since [10,13,17]. Exploring patient preferences, presenting information while being aware of framing effects, and avoiding the use of loaded words were identified as practical actions that recruiters could take to improve recruitment [11,12,18–20].

In this article, we present the development and preliminary testing of a model for trial information delivery that was informed by the findings of the previously mentioned research, within a feasibility study of a trial of arthroscopic surgery for impingement compared with non-operative care study (UK FASHIoN—trial registration: http://www.controlled-trials.com/ISRCTN09754699, [21]). The conservative care arm comprised a detailed physiotherapy protocol developed specifically for the trial, named "Personalised hip therapy" [21]. The aim was to investigate the conduct of recruitment consultations that led to patients agreeing to participate in the pilot, including the order and manner in which the trial information is presented, and comparing this with the content and strategies used in consultations where they did not. Further, we aimed to derive a model from these findings, to offer a simple structure for a recruitment consultation that can be used in RCTs, and also inform the training of clinicians interested in conducting surgical RCTs.

2. Methods

The multicentre pilot UK FASHIoN RCT was undertaken in 10 National Health Service hospitals selected because they undertook a high volume of hip arthroscopic surgery. Details of the pilot design and characteristics are presented in Table 1. An integrated qualitative research study was set up to observe recruitment processes with the objective of understanding how any difficulties related to design or conduct could be addressed early, and solutions implemented [16].

2.1. Recruitment and data collection procedures

The chief investigator and trial management group (TMG) identified that the consultation where randomization was

Table 1. Pilot RCT design and characteristics

RCT acronym	UK FASHIoN
Type	Feasibility
Clinical centers	10
Sample size	60 patient approaches
Interventions	Hip arthroscopy vs. best conservative care
Specialities involved	Surgery and physiotherapy
Primary recruiters	Surgeons, nurses, and research associates
Inclusion criteria	• Age ≥16 • Symptoms of hip pain • Radiographic evidence of femoroacetabular impingement (FAI) on plain radiographs and cross-sectional imaging • Treating surgeon believed they would benefit from hip arthroscopic surgery • Ability to give written informed consent • Ability to participate fully in the interventions
Exclusion criteria	• Previous significant hip pathology • Existing osteoarthritis • Previous FAI surgery

Abbreviation: RCT, randomized controlled trial.