Contemporary Clinical Trials 32 (2011) 363–368

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

A questionnaire-based survey of participants' decisions regarding recruitment and retention in a randomised controlled trial — Lessons learnt from the SCoRD trial

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ARTICLE INFO

Article history:
Received 24 August 2010
Accepted 31 January 2011

Keywords:
Recruitment
Retention
Survey
Questionnaire

ABSTRACT

Successful recruitment and retention on trials is critical to ensuring that adequate power is conferred, results are generalisable and trials are completed within the allocated time and resources. Nested within an existing pragmatic randomised controlled trial a process evaluation was conducted to explore the reasons for a much higher than anticipated recruitment (120% of required sample size) and retention rate (96% completed follow-up).
A questionnaire was designed to ascertain patient's views on reasons affecting consent and retention. 148 patients still enrolled in the trial at their final follow-up were either given or mailed a questionnaire of which 102 were returned (69%). 96% rated the written information as very or somewhat important in their decision to consent. Verbal information given to them by the operating surgeon was considered very or somewhat important by 86% and the relative inconvenience was rated as important by 79% of patients. Reasons for consenting for a large proportion of patents were the wish to help in research which may benefit others in the future and the perception that this was an important and relevant study. There was also some evidence that patients weighed up the demands with the potential benefits to them. High levels of satisfaction were expressed with trial personnel and trial procedures.
The inclusion of a trial process evaluation such as the one presented here is an efficient method for gathering information of participants' decisions regarding recruitment and retention in a trial and can help to inform the successful planning of future trials.

1. Background

Successful recruitment and retention of participants in randomised controlled trials is of paramount importance to ensure that adequate power is conferred, results are generalisable and trials can be completed within the available time and resources. Yet it has been reported that less than a third of trials funded by the Medical Research Council (MRC) and UK Health Technology Assessment (HTA) between 1994 and 2002 achieved their recruitment target [1] with many requiring an extension. Increasing patient participation in research studies is also among one of the Department of Health's objective in their White paper 'Best Research for Best Health' [2] and since the inception of the National Institute for Health Research (NIHR) and the United Kingdom Comprehensive Research Networks (UKCRN) portfolio of studies the accrual of patients onto

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doi:10.1016/j.cct.2011.01.014

portfolio registered studies is also a means to accessing resources for service support costs through the local comprehensive research networks. All these factors make successful recruitment to target and retention an imperative for researchers.

A number of qualitative studies have been published in which factors affecting patients' decisions to consent and continuation to participate have been explored within the context of specific trials[3] [4,5]. The notion of 'conditional altruism' whereby participants consent but make this dependent on some perceived benefit or absence of any perceived disadvantage featured strongly in their findings.

The SCoRD (Splinting after contracture release for Dupuytren's disease) [6] trial was a multi-centre, pragmatic, open, randomised controlled trial designed to evaluate the effect of static night splints after surgical contracture release for Dupuytren's contracture. Patients undergoing fasciectomy or dermofasciectomy for contracture were randomised to one of two groups: i) one group received hand therapy as well as a static thermoplastic splint worn for up to 6 months at night-time; ii) the other group received hand therapy only. All patients were assessed at baseline, 3, 6 and 12 months after surgery by two research associates who visited patients at home. Outcome measures included a patient-reported questionnaire of upper extremity function and disability, range of motion measurements of operated digits and patient satisfaction. The trial aimed to recruit 128 patients from 5 centres over a period of 16 months informed by a sample size estimate using a power of 90% and 5% significance level and allowing for a 20% loss to follow-up.

A much higher than anticipated consent rate was observed after the first 6 months in which 79% of those invited consented. Given the existing resources it was decided therefore to increase the sample size by up to 20% to 154 patients. Loss to follow-up occurred in 6 patients (4%) representing also a much lower than anticipated drop-out rate.

Specific factors associated with the trial question being addressed, the design and management of the SCoRD trial may have all contributed to this highly successful recruitment and retention rate. The trial management team decided that it was important to explore the reasons for the high recruitment and retention as this could inform the planning of future clinical trials.

2. Materials and Methods

Whilst the use of face to face interviews with participants would have yielded rich qualitative data it would also have required additional resources and imposed an additional burden on the participants' and research workers' time. Using a postal questionnaire had several advantages including complete anonymity of the respondents thus minimising bias. Another benefit of this method was that it could potentially include all participants and was inexpensive. Furthermore it offered an opportunity to develop a 'process evaluation' questionnaire which could be piloted and then adapted for use in future trials.

The questionnaire was designed with closed and open questions relating to factors influencing initial consent, ongoing participation and overall satisfaction with trial processes and personnel. It was important that the questionnaire did not exceed two pages and thus could be completed in a short time. In order to elicit honest responses complete anonymity was offered and therefore no demographic data were collected and neither were questionnaires numbered or coded ensuring therefore that returned questionnaires could not be linked to individual participants. Three lay members from the Norfolk Patient and Public Involvement in Research (PPIRes) group who were also members of the trial management committee were consulted over the layout and wording used in the questionnaire and their suggestions incorporated. A copy of the final questionnaire is presented in Appendix A. The questionnaire with a covering letter was either mailed to patients who had already been visited for their final 12 months follow-up or where this was still to be completed the researchers left the questionnaire with the patient at the end of their visit with a stamped addressed envelope. Only one copy of the questionnaire and stamped addressed envelope was left or sent to each patient thus ensuring only one reply per respondent.

Data from completed questionnaires were entered into an Excel spreadsheet. Closed questions were analysed by frequency counts and responses to the open-ended questions were analysed using thematic analysis by two authors. Each response was assigned to a code and these were organised into overarching categories and themes. CJH and SV read and analysed the data independently and any inconsistencies were resolved by discussion.

This process evaluation was approved as a substantial amendment by the multi-centre Research Ethics Committee as part of the main trial and the Research Governance Committees of all participating centres.

3. Results

A total of 148 patients (96%) were still enrolled in the trial at the time of their final assessment and each participant was either mailed or given a questionnaire to complete. 102 questionnaires were returned of which 101 were complete giving a 69% response rate.

3.1. Responses to closed questions

Table 1 gives a summary of the frequency of responses. 86 patients (86%) considered the verbal information they were given about the trial at their appointment with the surgeon as very or somewhat important in deciding to consent when invited at a later date. The participant information sheet and leaflet was posted to patients once the trial coordinators had been given eligible patients' names and addresses. This outlined the study aims and what participating would entail and was considered as very or somewhat important in obtaining consent by 96 (96%) of the respondents with only 4 rating it as somewhat unimportant.

When asked about the potential convenience that participating in the trial would mean 76 (79%) patients considered the convenience of the study a somewhat important or very important factor. The trial had been set up so that all additional assessments for the trial took place in the patients' home thus minimising the burden from additional visits and associated costs to the local hospital. However there were

Table 1
Frequency of responses on closed questions.

Consent and recruitment Please tell us how you would rate the importance of the following in deciding to give us your consent	Very important	Somewhat important	Somewhat unimportant	Not important at all	Not applicable (I was not told about the study by the surgeon)	N
1. The information you were given about the trial by the surgeon in clinic (n = 100)	54	32	3	0	9	100
2. The letter and leaflet explaining about the trial which you received by post	70	26	4	0		100
3. The convenience or inconvenience that participating in the study would mean for you	41	35	10	10		96
Once you consented, there are many factors which may have influenced your decision to continue participating in this trial. Please tell us what you think about the quality of the following aspects of the trial	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Somewhat dissatisfied	Very dissatisfied	N
5. Whenever you were contacted by the researchers by telephone, e-mail or post (e.g. to arrange appointments, answer questions, etc.) overall you felt	91	7	1	1	0	100
6. When the researchers visited you at home overall you felt	90	9	1	0	0	100
How relevant did you feel were the questionnaires you had to complete for each visit?	Very relevant	Somewhat relevant	Somewhat irrelevant	Completely irrelevant		N
	60	26	13	2		101

also 20 respondents who indicated that the convenience was either somewhat or completely unimportant.

On the two questions regarding the level of satisfaction with telephone, e-mail or postal contact made by researchers and the conduct of the home visits patients expressed an overall high level of satisfaction (91 very satisfied, 7 somewhat satisfied). One respondent was somewhat dissatisfied with the researchers contact but did not qualify this further. The same respondent also commented that he/she considered the whole trial a waste of time and money, however did remain in the trial.

With regard to the measures taken as part of the trial, this included a patient-rated questionnaire of hand function, the Disabilities of the Arm, Shoulder and Hand (DASH) [7] which is an upper extremity-specific measure for musculoskeletal disorders. Whilst overall most of the patients did consider the measures taken as very or somewhat relevant (86 out of 101) 13 respondents felt the questionnaire was somewhat irrelevant and 2 found it completely irrelevant.

3.2. Open-ended questions

Numbers placed in brackets behind quotes refer to the respondent's unique identifier.

As for reasons why respondents consented to participate in the trial this included a wide range of responses. Helping others, which included clinical staff, researchers, future patients with the condition and medical research in general was by far the most common reason and stated by 71 participants.

> 'to assist in the compilation of data so medical staff and patients can be better informed when deciding to splint and not to splint' (069);
> 'contribute some time to the well-being of others' (018);
> 'to help the surgeon' (004);
> 'hopefully others may benefit' (102).

Nine respondents said that they felt a 'duty' to help:

> 'the health system was doing something major and helpful for me — this was something I could give back' (022)
> 'duty to help … to give something back to the NHS' (099).

Eight respondents cited the importance of this research affirming that they considered the trial relevant and worthwhile

> 'I believe such trials are important' (011)
> 'SCoRD trial seemed a good idea' (056).

Personal interest and a perception that by participating some personal benefit, even if very small, could be derived also featured in 34 of the responses. Personal interest in finding out more about the condition, their own progress or how trials are run was expressed.

> 'it was beneficial to me' (082)
> 'knowing that my hand would be regularly checked' (017).

Others hoped to derive a more direct benefit such as the possibility of receiving 'preferential treatment' or other benefit from being in the trial.

> 'possibility I might benefit myself' (016)
> 'joining the trial reduces waiting times' (084).

Conversely some patients reasoned that they consented not because they would benefit but they perceived no disadvantage. Whilst for some these amounted to practical or logistical issues such as no added cost or extra time, some also expressed notions of equipoise and welcomed the fact that alternative treatment options were available.

The second open question asked participants why they continued to participate in the trial. Very similar themes to the reasons why they had consented in the first place emerged such as a desire to help research, helping future patients as well as an expectation that they would derive some personal benefit. However 22 respondents qualified their continued commitment by stating that they felt it was important to see things through.

'partial trial is no use' (047)
'having started it would waste everybody's time to drop out' (054)
'committed to the investigation/trial' (026).

Two further themes emerged, satisfaction with process/trial management and the fact that ongoing participation did not pose any inconvenience to them.

High satisfaction with the researchers had been expressed in the closed questions but several respondents also commented on the professionalism of the researchers and the overall trial process as reasons for continuing.

'the researcher was helpful and explained things well' (016)
'I felt the trial was well managed' (087)
'my researcher was caring and a delightful personality' (046)
'the researcher conveyed courtesy, enthusiasm and thoroughness which motivated me considerably' (052).

In order to minimise the burden on participants, data collection was undertaken in their own homes and patients commented positively on this aspect.

' it was no trouble' (021)
'no cost to me' (065)
'you came to me at my home. You came at a time and day which was good for me' (089).

When asked hypothetically what may have prompted them to withdraw from the trial 22 respondents did not offer any comment and a further 24 stated 'nothing' thus reaffirming that they had a strong commitment to the trial and were unlikely to withdraw. Amongst the possible reasons for withdrawing were changes in personal circumstances such as ill health, work commitments or relocation. 27 respondents stated that had the researchers not kept appointments, displayed a less than courteous attitude, if the participants had not perceived any ongoing benefit, a lack of information or not feeling valued may have led them to reconsider their ongoing participation.

Finally all participants were asked to comment on how any aspects of the trial could have been improved. 24 respondents did not offer any comments and 34 stated there was nothing they felt needed to be improved. 18 respondents used the question to affirm their high level of satisfaction with the conduct of the trial, including clinical and research staff. One participant considered the trial a 'waste of money and time', two expressed some dissatisfaction with the appointments and the trial team's failure to change appointments. Aspects that could have been improved included more information, though it was not always clear whether this was information about the trial or about their clinical care. Four respondents expressed some dissatisfaction with their clinical aftercare and a further four respondents commented that the DASH questionnaire did not seem specific to the problems experienced by individuals with Dupuytren's contracture. Some respondents also used this question to express their overall satisfaction or dissatisfaction with the outcome of surgery rather than the trial.

'surgery did not improve the use or function of the finger, I believe it worse now than before the operation' (050)
'my surgeon made such a good job of my finger' (069)

4. Discussion

As a result of the excellent recruitment (120% of the target sample size) and retention rate (96%) in the SCoRD trial, participants were surveyed to ascertain the reasons for this and to inform the design and planning of future trials.

A good response rate (69%) was obtained suggesting that the questionnaire was relatively quick and easy to complete. It was also time and resource efficient for the researchers conducting this process evaluation.

A much higher proportion of those invited consented (79%) than had been anticipated especially when considering that SCORD did not use active 'recruiters'. The surgeons acted as information givers to prime patients about the trial but the actual recruitment was done by post and patients self-consented. This more 'passive' approach made it very easy for patients to refuse without giving a reason. The much greater than anticipated number of consents suggests that other factors are likely to have played a role in patients' decisions to participate. Some of these may be specific to this study population such as age and occupational status.

The mean age of the SCoRD trial participants was 68 years and given that surgery is often not advocated in patients with other serious comorbidities these patients are mostly fit and healthy. The majority of trial participants were retired (65% of trial sample) and in fact many stated that because they had time or no other commitments this made trial participation easy.

Dupuytren's disease often affects several digits, is bilateral and recurrence of contracture is common. As a result many patients return for repeated operations and have an 'ongoing' involvement with the specialist hand service, perhaps feeling some gratitude for the professional help they have had in past. This was certainly the case for some patients who were having their 2nd or 3rd operation and talked about 'giving back', although the proportion of patients who had previous surgery was small (15% of trial sample). Finally the role of the surgeon in telling patients about a trial that they were involved in themselves should not be discounted as previous research has shown that patients are more likely to enrol in a trial if their own doctor is part of the research team [8].

The participant information sheet was considered as important or very important by 96% of respondents indicating that both the content and presentation may have played an important part in securing consent especially as the SCoRD trial was an open trial in which patients knew which intervention they were receiving, a factor that has been found to improve

recruitment [9]. Following randomisation only 1 patient refused the allocated intervention and there were no other post-randomisation withdrawals. One possible explanation for this very low withdrawal rate is that experimental and control interventions were acceptable and that patients accepted the clinical equipoise on which this trial had been founded. Moreover both groups were receiving treatment, that is post-operative hand therapy with only the addition of a splint given to the experimental group. It has been suggested that the concept of randomisation is often poorly understood and even reviled as unethical, however the notion of being allocated 'by chance' to one of two treatments has been shown to be more acceptable if patients have a strong belief in clinical equipoise [5].

Although the wish to help research and the future care of other patients was the most common reason for consenting we also found evidence of what McCann et al [3] has termed 'conditional altruism', a notion that participation in a trial is not driven solely by consideration for others and that participants expect some personal benefit.

Fearn et al. [10] conducted a similar questionnaire based survey of older participants (aged 65 years of over) in the MAVIS trial (Mineral and Vitamin Intervention Study). They report that the desire to help research, advance medical knowledge and thus help future patients were the most important reasons for consenting and that good communication and trial organisation were also valued by patients. But, Fearn and colleagues also found that participation was contingent upon potential demands and personal benefits. McCann et al. [3] and Canvin et al. [4] in their qualitative exploration of reasons for participation in trials identified similar themes of 'weak altruism' or 'conditional altruism' suggesting that trial participation involves weighing up of demands and potential benefits.

Some of the potential demands or burden on participants could be minimised through careful planning and adequate resources. For example, in our study we chose to visit patients for their baseline and follow-up assessments at home and in the case of those working often accommodated requests for evening visits. However this is not always feasible especially in trials where screening or assessment requires access to special equipment and facilities and visits to hospital may be unavoidable.

With regard to the perceived personal benefit, there were some patients who believed that participation would lead to improved or faster treatment, yet there is no evidence from our study that surgeons, therapists or researchers promised or indeed provided any preferential treatment to trial participants. Even if benefit was not offered, which would be regarded as coercive, some believed they would benefit from knowing more about the disorder and its treatment — especially for those who had only recently been diagnosed. Other welcomed the extended follow-up and detailed assessments of function compared to the normal clinical practice where patients are often discharged by 3 months.

5. Conclusions

The use of a brief postal questionnaire to ascertain factors affecting recruitment and retentions was piloted as part of the SCoRD trial. The high response rate and completeness of data indicate that this instrument is an efficient and easy method of nesting process evaluations within existing trials. The data generated very useful information regarding key factors affecting participants' decisions to consent and continue to participate in the SCoRD trial. The wish to help others and belief in the importance of the research featured strongly as a reason to consent. There was also evidence that some patients weighed up the demands of the trial with potential benefits to themselves. Minimising the burden to patients by visiting them at home together with a high satisfaction with trial personnel and the overall trial management were the main reasons why patients continued in the trial and led to a high retention rate at 1 year follow-up (96%). Future trials need to take into account the multiplicity of factors which are likely to impact on an individual's decision to participate. No single factor alone affects recruitment or retention however researchers should consider carefully the way in which trial information especially clinical equipoise, the relevance and importance of the research question are conveyed through verbal and written communication. Other important considerations are the demeanour and professionalism of the research personnel who have direct contact with patients and how the demands and costs to participants can be minimised.

By including an end of trial evaluation such as the one developed for the SCoRD trial researchers can gather very useful information about participant's views on why they participated and continued in the trial. This in turn can inform the design of trial procedures which maximise recruitment and retention rates thus increasing the validity of the research and ensuring efficient resource use.

Funding

Action Medical Research Charity funded the SCORD trial through a project grant. The National Institute for Health Research (NIHR) funded CJH through a Career Development Fellowship from January 2009.

Neither funding source has had any involvement in the study design, collection, analysis and interpretation of data, the writing of the article or the decision to submit it.

Declaration of conflict of interest

The authors declare that they have no conflicts of interest.

Acknowledgements

The authors would like to thank all members of the SCoRD trial group who assisted in the planning and implementation of the trial: P Chapman, A Logan, M Meyer, A Patel (Norwich); G Cormack, M Hayden, J Hopkinson-Woolley, I Grant (Cambridge); L Smith, M Wood (Bury St Edmunds); J Frusher, J Jones, A White, A Doran (Peterborough); P Crossman, J Dinley, C Roberts, M Shanahan (Ipswich). *Independent Trial Steering Committee members*: DGI Scott, S Spooner. *Local PPIRes members*: C Handford, V Hawes, C Williams and all the patients who participated in this evaluation.

Appendix A. Questionnaire

Supplementary data to this article can be found online at doi:10.1016/j.cct.2011.01.014.

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