ARTICLE

'Away Days' in multi-centre randomised controlled trials: a questionnaire survey of their use and a case study on the effect of one Away Day on patient recruitment

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Abstract

Objective 'Away Days' (trial promotion and training events for trial site personnel) are a well-established method used by trialists to encourage engagement of research sites in the recruitment of patients to multi-centre randomised controlled trials (RCTs). We explored the use of Away Days in multi-centre RCTs and analysed the effect on patient recruitment in a case study.

Methods Members of the United Kingdom Trial Managers' Network were surveyed in June 2013 to investigate their experiences in the design and conduct of Away Days in RCTs. We used data from a multi-centre pragmatic surgical trial to explore the effects of an Away Day on the screening and recruitment of patients.

Results A total of 94 people responded to the survey. The majority (78%), who confirmed had organised an Away Day previously, found them to be useful. This is despite their costs.. There was no evidence, however, from the analysis of data from a surgical trial that attendance at an Away Day increased the number of patients screened or recruited at participating sites.

Conclusions Although those responsible for managing RCTs in the UK tend to believe that trial Away Days are beneficial, evidence from a multi-centre surgical trial shows no improvement on a key indicator of trial success. This points to the need to carefully consider the aims, design and conduct of Away Days. Further more rigorous research nested within RCTs would be valuable to evaluate the design and conduct of Away Days.

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Introduction

Challenges of recruitment lead to many trials being abandoned (1, 2) with almost half failing to achieve even 80% of their recruitment targets (3). These delays or trial abandonment may incur increased costs to the funder, delay the implementation of findings about potentially ineffective or dangerous treatments (4) or risk drawing incorrect conclusions about the lack of an effective intervention. The importance of effective trial management is highlighted by an increasing body of literature exploring methods to improve trial recruitment and retention (3-7). Whilst methods to improve recruitment are often targeted at encouraging *patient* participation in trials, the *recruiting clinicians'* participation and level of engagement also presents a challenge. Often cited inhibiting factors include lack of time or institutional support, lack of knowledge of the study protocol or consent process and lack of interest in the study or understanding of how trial participation may benefit patients (8, 9). A review of randomised controlled trials (RCTs) of interventions aimed at this group found that none had demonstrated statistically significant effects on recruitment in the host trials (6). One well-established method that has not been evaluated in RCTs (6) is organising 'Away Days'. Unlike site initiation visits and other training events specific to one recruiting site, Away Days are organised events where recruiting clinicians and other stakeholders from multiple sites attend a training day. Such events provide an opportunity to promote the trial; facilitate cross-fertilization of ideas and good practice; provide training; and develop networks.

This study had two aims. First, to explore how Away Days are used in multi-centre RCTs and researchers' perceptions regarding the value of these events via a questionnaire survey. Second, via a case study, to examine the effects on screening and recruitment data before and after conducting an Away Day in a multi-centre surgical trial.

Methods

Questionnaire survey

1) Survey development: A questionnaire was developed through discussion with experienced Trial Managers to identify items to explore respondents' general views and experiences of undertaking Away Days. This included sections that identified the content and format of Away Days that had been organised by the respondents. Finally, the questionnaire explored respondents' opinions about the usefulness of Away Days in RCTs and collected data on other methods used to encourage trial recruitment.

A range of question types was included in the questionnaire, including selection of single and multiple response options and statements to be rated on a five point Likert scale (ranging from strongly disagree to strongly agree with a central 'neutral' category). Participants could provide further information for several questions using free text responses. The survey was developed using Surveymonkey.com for online completion. Where possible, skip logic was applied to make the questionnaire less cumbersome for respondents if questions were not applicable to them. Prior to dissemination, the questionnaire was user-tested by four external colleagues, whose feedback informed further modifications. The final survey took approximately 15 minutes to complete. The study was approved by the Department of Health Sciences Research Governance Committee, University of York, UK before dissemination.

2) Participants: A network of United Kingdom (UK) Trial Managers/Coordinators, which aims to facilitate knowledge exchange and promote effective trial management, was contacted via the National Institute for Health Research Trial Managers' Network (NIHR TMN). NIHR TMN members (443 in total) were invited in June 2013 via email to take part in an online survey exploring their attitudes towards and experiences of organising Away Days for RCTs. Trial Co-ordinators/Managers at York Trials Unit (32 in total) were also invited to participate. A reminder email was sent one week later.

Participation was voluntary and respondents were not asked to provide any personal information in order to take part. Participants were assured that information would remain confidential and non-identifiable. As an incentive to take part, participants were given the opportunity to enter a prize draw to win a luxury food hamper upon completion of the survey and provision of contact details.

3) Data analysis: Data were managed and analysed using SPSS® for Windows® version 18.0 (SPSS, Chicago, Illinois, USA) and Excel®. Descriptive statistics were used to describe the respondents' experiences of using Away Days in RCTs and opinions about the usefulness of

Away Days. Recurring themes in free text responses were identified following a period of familiarisation with the data; where comments were read and reread in response to the emerging thematic framework.

Analysis of surgical trial 'Away Day' data

1) Description of Away Day: Recruitment outcomes from a surgery trial, the ProFHER trial, were collated and analysed before and after an Away Day to examine the potential effect this event may have had on the screening and recruitment of patients into the trial. This was a retrospective observational study prompted by the lack of improvement in recruitment rates across sites following the Away Day event.

The ProFHER Trial is a national multi-centre pragmatic RCT that evaluated the effectiveness of surgical versus non-surgical treatment of displaced proximal humerus fractures in adults. Further information can be found in the published HTA monograph (10) or through the ISRCTN register (ISRCTN50850043).

An Away Day was organised during the trial, after a number of participating sites had been set up to recruit. The principal aim was to enhance recruitment through raising awareness of trial procedures, providing additional training (e.g. on the consent process) to Research Associates, such as Nurses and Physiotherapists, and encouraging networking and discussion between sites. Principal Investigators and Research Associates directly involved in recruitment at all the participating sites were invited to attend an Away Day on 6 October 2009, in York, UK. A central and convenient venue was used for the event, with re-imbursement of travel expenses. Where necessary, delegates' hotel expenses were provided. In total, 28 delegates from centres nationwide attended the Away Day, 20 of whom were Research Nurses/Physiotherapists, 2 were Principal Investigators, and 6 from the Trial Management Group. The total cost of the venue, travel and accommodation expenses (which did not include salaries) for the Away Day was £3290.

2) Data analysis: For eligible patients approached to take part in the ProFHER trial, the dates of screening and randomisation (of patients who agreed to join the trial) were collected and the numbers of screened and randomised patients were aggregated monthly by recruitment site. The profile of the average number of patients screened and/or recruited per site per month and the ratio between them before and after the Away Day was compared

descriptively between the sites that attended the Away Day and those that did not. This analysis covered the entire duration of the recruitment period for the trial. As the Away Day had not been designed to test its effectiveness with regard to recruitment, available patient numbers, centre variability and the retrospective nature of this analysis precluded formal statistical significance testing. Data were managed using Stata (version 13).

Results

Questionnaire survey

In total, 94 respondents completed the survey (20% response rate) all of whom were a Trial Co-ordinator/Manager who most had been in the role for up to 5 years (median: 5 years, Inter-Quartile Range (IQR): 3 – 10 years). The majority of respondents, 59%, had organised an Away Day for a trial they had worked on, whilst 12% had tried to organise an Away Day but there was not sufficient interest to take it forward and one third (34%) had no experience of arranging an Away Day (Figure 1). Nearly all respondents, 98%, indicated that they would consider organising an Away Day for a future trial.

1) Design and conduct of Away Days: Of those participants who had organised an Away Day, most indicated that these were undertaken to discuss the practical workings of the trial, provide training to centres on aspects of the trial, improve recruitment and to discuss trial progress. Related to this, most Away Day events were scheduled to take place during the recruitment phase, although some respondents reported undertaking these events before recruitment had commenced. The majority of respondents (79%) had organised Away Days in secondary care settings. There were a diverse range of secondary care specialities reported, including diabetes, mental health, midwifery, obstetrics, oncology, orthopaedics, renal medicine and stroke.

A range of delegate numbers and budgets for Away Days were reported; events tended to be organised with at least 30 attendees and cost over £1500. In the majority of cases (87%) this was funded by a trial grant; a small number (13%) received sponsorship from a pharmaceutical or medical device company. Members of the trial management team (e.g. Chief Investigator and Trial Manager) and members from participating sites in multi-centre

trials (Principal Investigators and Research Nurses or similar) were invited to attend the Away Day. Sponsors and Funders were only invited in a few cases (17% and 15% respectively) and Comprehensive Local Research Network staff occasionally (6%). Most respondents indicated that they paid for attendees' travel costs and half indicated that they paid for attendees' accommodation costs. Some trialists reported restricting the number of attendees per site, partly to limit costs.

Conference centres and university campuses were the most popular venues; these tended to be influenced both by the convenience for attendees and budget constraints. The majority of respondents considered other key dates that may have impacted on attendees' availability when planning Away Day events and, in some instances, participants' free text comments indicated that Continuing Professional Development (CPD) points were awarded to encourage attendance. The majority of events were reported by respondents as being well attended by the collaborators at the participating trial sites responsible for recruiting patients into the trial. When asked about the format of the Away Day event, the majority (65%) responded that the Chief Investigator took the lead during the event and a range of activities were included: presentations (35% of responses), workshops (19%), panel sessions (13%), key note speakers (12%) and focus groups (10%). Free text comments indicated that a key aspect of an Away Day event was to facilitate discussions across research sites.

The majority (78%), who confirmed had organised an Away Day previously, found them to be useful. However, the outcome of the Away Day was only assessed informally through qualitative discussion, by reviewing feedback or based on observations of the impact on both recruitment figures and data completion. One respondent suggested, anecdotally, that "there was always a significant increase in numbers of trial patients recruited" immediately after an Away Day was held. Other comments suggested that communication and engagement with the coordinating centre and participating trial sites were improved.

2) Other Recruitment methods: The majority of respondents (87%) provided information about the various strategies used to encourage participating sites to recruit, regardless of whether or not they had organised an Away Day. The most frequently reported strategies included newsletters (31% of responses), visiting sites (28%) and recruitment incentives (e.g. payment, gifts) (19%). Responses suggest that these strategies were considered more

beneficial when used in combination but also the perceived benefits might depend on the type of trial.

Building relationships with site staff was considered to be important and was achieved by maintaining regular contact using informal emails, frequent telephone contact, regular meetings or teleconferences, text messages, Facebook and Twitter presence. Free text comments suggest that engagement with the trial could be achieved by requesting feedback on aspects of the trial as it was believed that this would encourage more ownership of the trial. Additionally, respondents highlighted the importance of prompt resolution of site queries.

Analysis of the multi-centre surgical trial 'Away Day' data

Of the 1250 patients screened for the ProFHER trial, 563 were considered eligible, and 250 patients gave consent and were recruited by 32 of the 35 participating sites. Recruitment took place from September 2008 until April 2011. When the Away Day was held, half (16) of the sites were open to recruitment and 47 patients had agreed to join the trial. Twenty eight sites were invited to the Away Day, and representatives from 18 sites attended; comprising 11 sites that were already open to recruitment and 7 sites opening subsequently.

Sixteen sites were open to recruitment by the time of the Away Day. For the 11 sites attending the Away Day, screening increased from 2.2 patients per month before the Away day to 2.4 afterwards. However, the 5 sites not attending the Away Day also increased screening from 1.4 to 1.7 patients per month before and after the Away Day. Interestingly, the number of recruited patients decreased marginally for attending sites by 0.05 patients randomised per month, whereas recruitment increased marginally for non-attending sites by 0.12 patients randomised per month. This before and after the Away Day pattern also applied for the consent ratio (3% decrease for attending sites versus 18% increase for non-attending sites).

Nineteen sites were not open for recruitment by the time of the Away Day. The 7 of these sites that attended the Away Day screened and recruited fewer patients per month (1.3 screened, 0.3 randomised) than the 12 non-attending sites (1.6 screened, 0.4 randomised). Non-attending sites also had a better consent ratio (40% non-attending versus 28% for attending sites). The group differences were generally small and group averages were often

driven by particularly well or poor recruiting sites, as shown by the minimum and maximum values.

Figure 2 shows an initial surge in screening and randomisation of patients. This can be attributed to the lead site starting recruitment early, which had the motivation and experience of the Chief Investigator and an experienced Research Nurse. Following this initial phase, recruitment tended to follow a slightly seasonal pattern with an increased number of screened and randomised patients during the winter months. The profile of recruitment did not appear to differ consistently between sites that attended the Away Day and those that did not. A drop in recruitment but not screening (only one patient randomised of 30 screened) occurred in the month of the Away Day for attending sites. However, similarly low recruitment rates are observed in some other months.

Discussion

While there is an expanding evidence base investigating the use of different strategies to improve recruitment into RCTs (3-7), this is the first study that has explored the conduct and perceived value of Away Day events and quantified their effect on a key indicator of trial success in a case study. With nearly all survey respondents indicating that they would consider organising an Away Day in the future and viewing these as useful, the survey findings present a valuable overview of the organisational aspects that should be considered when planning these events. These include paying for the attendees' travel costs, considering key dates that may impact on availability of attendees, and feeding back the findings of the Away Day. Researchers should also consider the cost of undertaking an Away Day event when preparing funding applications, as the survey responses suggest that these costs tend to be met by the trial budget. However, whilst nearly all Trial Co-ordinators/Managers reported finding their Away Days useful, our descriptive analysis of recruitment data from the ProFHER Trial suggests that such an event did not increase the numbers of patient screened, randomised or the consent ratio. A possible explanation for this was that our Away Day was very much led and delivered by the Trial Management Group. On reflection, greater engagement with the Research Nurses/Physiotherapists could have been employed by involving them in the planning and content of the Away Day and on the day the use of nurse-led 'Question and Answer' sessions.

Our findings, however, do need to be interpreted with some caution. Whilst the majority of survey respondents found the Away Day useful and nearly all would consider conducting an Away Day in the future, 381 (80%) of those invited to take part in the survey did not respond. Although low response rates are common in survey research, it is possible that non-responders may not be as enthusiastic about Away Days. We targeted Trial Co-ordinators/Managers because they would more likely to be involved in organising an Away Day. It may also have been beneficial to explore the opinions of other stakeholders about the design, conduct and usefulness of Away Days. The evidence of the effect of the Away Day on the ProFHER Trial applies to the conduct of one trial for which the number of patients screened or randomised per site was relatively small. Although the trial team gained the impression that the Away Day had not improved recruitment within a few months of it taking place, we decided that any analyses of the trial data needed to be based on the final checked and approved dataset with priority given to the preparation of the main reports of the trial. The fact that attendance at the Away Day was not randomised means that there might be differences in the characteristics of sites that did or did not attend the Away Day, which could confound our findings. Examples of site differences include: catchment area; experience of the Principal Investigator and/or Research Nurse, which could influence the extent to which a site might have felt the need for further support and to attend the Away Day or not; and demographics of the patients. Furthermore, fatigue at trial sites over time or changes in local resources for a trial could confound the results. Since Away Days are designed to educate and train delegates in various aspects of the study, as well as encourage recruitment, it would not be desirable to simply randomise sites to either attend or not attend the Away Day in order to control for confounding factors. However, as all sites might need to be trained in aspects of the trial, sites could be randomised to attend an Away Day or receive training through other common strategies used to encourage trial recruitment in order to evaluate the costs and effects of the two different formats. Such comparator interventions could include the use of newsletters, visiting sites, teleconferencing, social media support or ‘webinars’; which may also prove less costly. A further possibility could be to use a stepped wedge design that involves the sequential conduct of the Away Day across a random geographical cluster of sites over a period of time. In addition to improving recruitment, other factors should be considered, such as fidelity in the delivery of the intervention or correct completion and improved return of Case Report Forms.

With nearly all survey respondents viewing Away Days as useful or potentially useful endeavour, it is important that trialists consider undertaking further research to evaluate, a priori, the design and conduct of Away Days and their potential costs and effectiveness (6). Such research has been enabled via the UK Medical Research Council 'Systematic Techniques for Assisting Recruitment to Trials' (START) initiative which provides a forum through which methodological trial designs can be advertised and facilitates the statistical pooling of findings across multiple RCTs (11). Evaluating the cost and effectiveness of Away Days across several RCTs in different clinical specialities would provide the data required to test formally whether this is an effective recruitment strategy.

In contrast to bringing together collaborators at an Away Day, an effective strategy to improve recruitment could be to visit a site and hold a scheduled meeting with key staff to discuss recruitment. This idea was proposed by the SWAT (Studies Within A Trial) programme, which is developing methods for evaluating aspects of trial methodology through the conduct of research within research RCTs (12). This study has been undertaken using a controlled before and after design where one site was chosen to be visited by the lead researcher who gave a presentation to key staff about site-specific and trial recruitment rates followed by a discussion. Two further sites did not receive the intervention and acted as controls. Recruitment rates were found to be increased at the site post-intervention (17% and 14% increases at 1 and 3 months respectively) with no differences in recruitment at the two other sites (13). The combined and cumulative evidence from initiatives such as START and SWAT will help to provide the evidence to underpin the successful conduct of trials.

Conclusions

In conclusion, nearly everyone who responded to the survey were interested in undertaking Away Day events in future RCTs and the majority had found them useful. However, evidence from an orthopaedic surgical trial shows no improvement in the screening and recruitment of patients. There is a need for further research nested within RCTs to evaluate the design and conduct of Away Days more rigorously across different settings.

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Ethical approval

Ethical approval was obtained for this study from a University Departmental Ethics Committee.

All authors had access to the data in the study and can take responsibility for the integrity of the data and the accuracy of data analysis.

Competing interests

The authors have no competing interests.

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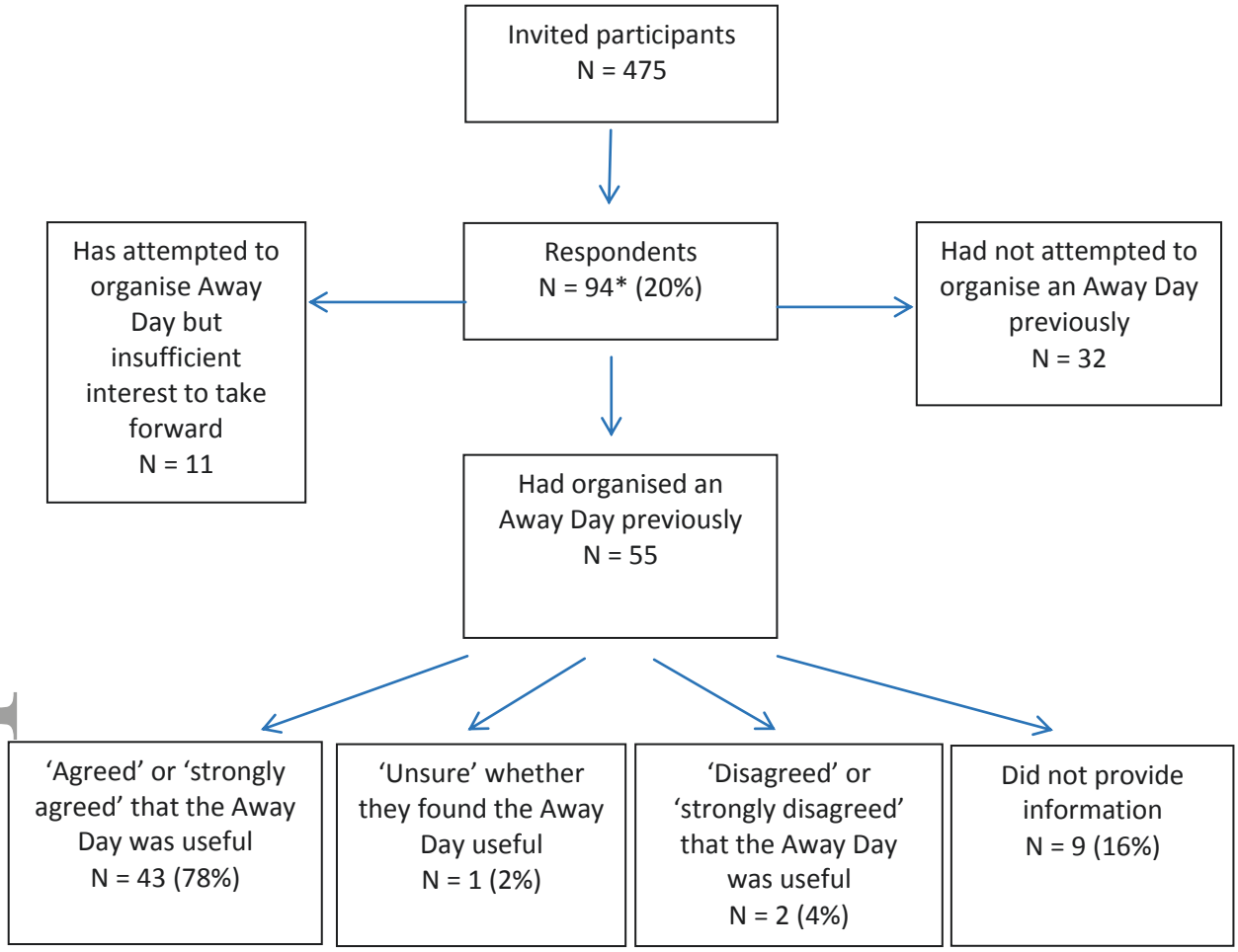
Table 1 Average monthly recruitment per site

		Total recruitment		Average monthly recruitment per site					
		Sites	Months[2]	Patients screened (n=1250 total)		Patients randomised (n=250 total)		Consent ratio (patients randomised /screened) [3]	
		n	n	Mean (SD)	(Min, Max)	Mean (SD)	(Min, Max)	Mean (SD)	(Min, Max)
All sites		35	32	1.82 (1.52)	(0.00, 5.29)	0.38 (0.31)	(0.00, 1.34)	0.29 (0.24)	(0.00, 1.00)
1. Sites attending the Away Day		18	32						
a) Sites open for recruitment by time of away day	Before Away Day	11	13	2.18 (1.52)	(0.00, 4.08)	0.45 (0.53)	(0.00, 1.69)	0.20 (0.19)	(0.00, 0.50)
	After Away Day	11	19	2.44 (1.39)	(0.47, 5.00)	0.40 (0.38)	(0.05, 1.11)	0.17 (0.12)	(0.02, 0.40)
b) Sites not open for recruitment by time of away day (data after away day only)		7	18	1.29 (1.78)	(0.00, 4.88)	0.28 (0.37)	(0.00, 1.00)	0.23 (0.15)	(0.00, 0.41)
2. Sites not attending the Away Day		17	25						
a) Sites open for recruitment by time of away day	Before Away Day	5	6	1.39 (1.03)	(0.50, 2.75)	0.30 (0.31)	(0.00, 0.75)	0.22 (0.27)	(0.00, 0.67)
	After Away Day	5	19	1.72 (1.67)	(0.42, 4.63)	0.42 (0.18)	(0.26, 0.68)	0.40 (0.22)	(0.07, 0.63)
b) Sites not open for recruitment by time of away day (data after away day only)		12	19	1.64 (1.57)	(0.00, 5.29)	0.39 (0.26)	(0.00, 0.80)	0.40 (0.33)	(0.05, 1.00)

[1] All figures include three sites that did not randomise any participants; [2] Date of recruitment commencement varied by site, months of recruitment may be shorter for individual sites than the maximum figure given; [3] Consent ratio only calculated for sites that screened at least one patient

Figure 1 Diagram of participant responses



*Percentages are not indicated where responses relate to multiple questions in the survey (total N for these responses is greater than 94)

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Figure 2 Average monthly recruitment by sites