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Short report: How often do UK primary care trials face recruitment delays?

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Bower P, Wilson S and Mathers N. How often do UK primary care trials face recruitment delays? *Family Practice* 2007; **24**: 601–603.

Recruitment to trials is often viewed as problematic but data are scarce. This study surveyed authors of published primary care trials to assess the scale of recruitment problems. Seventy trial authors were surveyed with a response rate of 56%. Less than one-third of trials recruited to their original timescale. Recruitment requiring GPs to gain patient consent was significantly associated with recruitment problems. The data may be useful in the wider drive to improve recruitment in primary care.

Keywords. Randomized controlled trails, recruitment.

Introduction

Trials need sufficient patients to ensure statistical power and validity, but recruitment remains problematic.[1] A previous study of UK trials found that less than one-third recruited to target, but reported few significant factors associated with success.[2] Although recruitment in primary care is always viewed as a particular challenge, data concerning the exact magnitude of difficulties are scarce.

We surveyed authors of published trials to examine:

(a) the extent of recruitment difficulties;
(b) responses to recruitment problems; and
(c) the relationship between trial characteristics and recruitment.

Methods

We identified randomized trials through an online search of three medical journals which publish primary care trials routinely (*British Medical Journal*, *Family Practice* and *British Journal of General Practice*) and included trials from UK primary care requiring individual patient consent, published during 2000–2005.

We emailed a questionnaire to the corresponding authors, with two reminders. Where authors had published more than one eligible trial, we chose one randomly.

Analysis was largely descriptive. We identified potential predictors of recruitment success from a previous study (see Table 1).[3] Factors associated with recruitment success were analysed using cross-tabulations, comparing study characteristics with a dichotomous measure of recruitment 'success' (defined as recruiting to time or overrunning by less than 50% of the planned time).

Results

We identified 213 trials and excluded 125 trials on one or more exclusion criteria: outside the UK ($n = 71$); no patient consent ($n = 45$) and not in general practice ($n = 36$). We removed 18 trials by the same author, leaving 70 eligible, and the response rate was 56% overall ($n = 39$), although data on the main dependent variable was reported for 34. Responders were involved in larger trials, although the difference was not significant (mean difference 399, 95% confidence interval –214 to 1011). Table 1 shows key trial characteristics.

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TABLE 1 *Trials organizational characteristic and associations with recruitment (n = 34)*

Theme	Characteristic	*n* (%)	Percentage recruiting within 50% of planned duration
Planning	Piloted recruitment methods	15 (44)	47
	No pilot	19 (56)	53
	'Rescue' plan in case of poor recruitment	12 (35)	42
	'No rescue plan'	22 (65)	55
Experience	Principal investigator conducted previous trials in primary care	28 (82)	50
	No previous trials	6 (18)	50
	Principal investigator conducted previous trials in clinical area	18 (53)	50
	No previous trials	16 (47)	50
Methods for identifying patients	Primary care professional	15 (44)	53
	Other	19 (56)	47
	Systematic identification from practice records	14 (41)	50
	Other	20 (59)	50
	Screening in the waiting room	3 (9)	0
	Other	31 (91)	55
	Advertisement in practices	8 (24)	38
	Other	26 (76)	54
Workload of primary care professionals	Patients identified by the primary care professional	15 (44)	53
	Other	19 (56)	47
	Consent taken by the primary care professional	8 (24)	13
	Other	26 (76)	62
	Patients randomized by the primary care professional	9 (27)	33
	Other	25 (73)	56
	Study investigation by the primary care professional	14 (41)	43
	Other	20 (59)	55
Networks	Study used local primary care research networks	10 (29)	40
	Did not use networks	24 (71)	54
Methods of improving recruitment	Academic GPs on the research team	29 (85)	52
	No academic GP	5 (15)	40
	Other primary care academics on the research team	14 (41)	43
	No primary care academic	20 (59)	55
	Patient representative on the research team	3 (9)	67
	No patient representative	31 (91)	48
	'Local opinion leader' on the research team	17 (50)	47
	No local opinion leader	17 (50)	53
	Financial incentive for professionals	11 (32)	46
	No financial incentives	23 (68)	52
	Educational incentives for professionals	8 (24)	38
	No educational incentives	26 (76)	54
	Interventions not accessible outside trial	19 (56)	58
	Not accessible	15 (44)	40
	Financial incentives for patients	0 (0)	NA
	No financial incentives	34 (100)	
	Newsletters and direct mailings about recruitment	17 (50)	41
	None	17 (50)	59
	In-person reminders about recruitment	20 (59)	40
	None	14 (41)	64
	Feedback on actual recruitment rates	20 (59)	40
	None	14 (41)	64

NA, not applicable.

(a) Extent of recruitment difficulties—the mean planned sample size was 1086 patients (SD 1562), and planned recruitment duration was 12 months (SD 8.3, range 1–36). The mean achieved sample size was 1002 (SD 1585). Ten trials (29%) recruited to timetable, 12 (35%) required up to 50% greater time than planned and 12 (35%) required over 50% additional time.

(b) Responses to recruitment problems—these included extending the recruitment period (56%); seeking additional funds (31%); introducing other recruitment methods (18%); increasing the number of sites (44%); recalculating power (21%) and finishing with insufficient patients (18%).

(c) The relationship between trial characteristics and recruitment—17 (50%) trials recruited to time or overran by less than 50%. One variable was statistically associated with recruitment duration. If GPs were responsible for gaining patient consent, only 12.5% of trials recruited within 50% of the planned time, compared with

61.5%, where the GP was not responsible ($\chi^2 = 5.89$, d.f. = 1, $P = 0.04$).

Discussion

Our restriction to published studies means that the results cannot be representative of all trials and are likely to overestimate the effectiveness of recruitment. The response rate was poor, and limiting the inclusion of more prolific and successful trial authors may overestimate recruitment difficulties. Cross-sectional associations cannot determine cause–effect relationships, and the data were restricted to self-report. The analysis of factors associated with recruitment had low power, and some important factors (e.g. the type of disorder or intervention) were not tested. Furthermore, it is difficult to distinguish cause from effect, as trials may adopt methods because of poor recruitment, rather than those methods causing recruitment problems. However, the finding that GPs gaining patient consent is associated with recruitment problems supports the previous findings.[1] Clearly, a larger study using prospective data collection from a trial register is indicated.

Despite these limitations, the results do provide an estimate of the range of delays in primary care trials. Clearly, trials running past their planned recruitment timetable are the norm, and one-third of the published trials were forced to seek additional funds. This has clear implications for both funders and grant applicants.

There is a small but emerging literature on determinants of recruitment.[2,4] If the potential of UK primary care as a platform for high-quality trials is to be realized, there is a need to consider a range of potential interventions and begin a programme of work to test and disseminate different recruitment methods.

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Declaration

Ethical approval: None.
Conflicts of interest: None.

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