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How evidence based are recruitment strategies to randomized controlled trials in primary care? Experience from seven studies

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Background. Failure to recruit adequate numbers of participants represents a major barrier to the completion of randomized controlled trials in primary care and is associated with substantial opportunity costs. However, uncertainty exists regarding the relative effectiveness of different methods to promote recruitment.

Objectives. The purpose of this study was to estimate the proportion of strategies used to promote patient recruitment to randomized controlled trials in primary care that are evidence based.

Methods. Investigators from seven primary care-based clinical trials of dyspepsia management aiming to recruit a total of 6070 patients participated. Following a survey of trial organization, a Delphi technique was used to reach consensus on levels of evidence on the effectiveness of interventions or organizational characteristics in influencing recruitment. The main outcome measures were the proportions of interventions or organizational characteristics for influencing patient recruitment that are based upon randomized controlled trials, on convincing non-experimental evidence or meeting neither of these criteria.

Results. Out of a total of 56 interventions used across the trials, 35 (63%) were judged as evidence based. Out of a total of 29 organizational characteristics possessed by the trials, five (17%) were judged as evidence based. Across the seven dyspepsia trials, the presence of 'favourable' organizational characteristics appeared to be important contributors towards successful recruitment.

Conclusions. A wide range of interventions and organizational characteristics with the potential to promote recruitment were used or possessed by seven primary care trials. Many were not evidence based. Our experience suggests that organizational characteristics could be more influential in trial recruitment than the use of specific interventions. Given the costs of primary care-based trials, researchers need more rigorous evidence to inform recruitment strategies.

Keywords. Primary care, randomized controlled trials, recruitment.

Introduction

There is a growing recognition of the need for rigorous research in primary care, including randomized controlled trials (RCTs). In 1997, both the Medical Research Council and a Department of Health Working Party highlighted the need to build research and development capability.[1,2] These reports acknowledged the limitations

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of applying the results of trials performed in secondary care to the primary care setting. There may be significant differences between primary and secondary care in case mix, patient concerns and expectations, and availability of skills and resources. For example, patients with depression in primary care differ from those attending psychiatric clinics, in both the clinical characteristics of their presentation and their responsiveness to treatment.[3–5]

Sufficient recruitment rates of both professionals and patients to studies are important for two reasons. First, studies are more likely to be completed. Secondly, the findings of these studies are more likely to be generalizable if a broad range of professionals and patients participate. For example, the skills and resources of primary care teams involved in research may not be representative of those who decline to participate.

However, primary care-based trials represent major investments in time and resources for researchers, health professionals, patients and commissioners.[6] The costs of failed trials are significant and include wasted resources allocated to trials, the opportunity costs of participants' time and discouragement of primary care professionals from co-operating with further research. A predominant factor reported in the failure of primary care-based trials is an inability to attain an adequate sample size.[7–9] Despite this, there is uncertainty regarding the relative effectiveness of different methods to facilitate recruitment of study participants by primary care professionals.

The Dyspepsia Trialists Collaboration was established in 1995 to enable investigators conducting clinical trials of the management of dyspepsia to compare study designs and recruitment strategies and, in time, conduct a prospective meta-analysis of results. Investigators from seven research groups conducting RCTs designed to compare strategies for the initial management of dyspepsia in primary care agreed to take part in this study. Overall, 49% (2975/6070) of targeted participants were recruited, but actual recruitment ranged from 10 to 100% (Table 1). Three trials (West Pennine, North Wales and Torbay) closed prematurely due to poor recruitment. All trials over-ran their intended recruitment periods. Two researchers from a trial that closed prematurely (RF and JP) were curious as to why this happened and wanted to find out whether they should have conducted their trial differently.

The aim of this study was to explore why seven ostensibly similar studies (all based in primary care and exploring the management of a common frequently encountered condition) experienced varying degrees of success in attaining their required sample sizes. To address this aim, we identified the following objectives:

(i) To identify (a) the organizational characteristics of each of the seven research teams (e.g. specialty interest, previous research experience); and (b) the interventions used to encourage recruitment to the trial;
(ii) To identify rigorous evidence supporting the use of the above identified organizational characteristics and interventions to promote recruitment to primary care trails; and

TABLE 1 *Summary of interventions tested in trials and recruitment outcomes*

Trial	Interventions tested	Patient recruitment target	Actual patients recruited (% of target)	Intended length of recruitment period	Actual length of recruitment period
West Pennine	*H.pylori* testing and eradication versus empirical acid suppression	730	70 (9.6)	24	19 (closed prematurely)
Torbay	Empirical acid suppression versus early endoscopy versus *H.pylori* testing and eradication versus *H.pylori* testing and endoscopy	840	102 (12)	24	32 (closed prematurely)
Utrecht	Empirical acid suppression versus empirical prokinetic agent versus either of these two strategies versus early endoscopy	1200	349 (29)	19	24
North Wales	Early endoscopy versus usual management in patients testing positive for *H.pylori*	800	272 (34)	12	18 (closed prematurely)
Nottingham	Early endoscopy versus *H.pylori* testing and endoscopy versus *H.pylori* testing and eradication versus empirical acid suppression	1000	762 (76.2)	24	36
Birmingham	Under 50s: *H.pylori* testing and endoscopy versus empirical acid suppression. Over 50s: early endoscopy versus empirical acid suppression with selective endoscopy	1000	920 (92)	24	36
Odense	*H.pylori* testing and eradication with endoscopy if not improved versus early endoscopy	500	500 (100)	12	14
Total for all trials		6070	2975 (49)		

(iii) To describe which of the strategies to promote recruitment used by the research groups were evidence based.

Methods

A questionnaire was developed following a consultation between other members of the Collaboration and sent to the lead researcher in each research group. The questionnaire sought information on (i) general aspects of the trial organization; (ii) the characteristics of the research groups; and (iii) the specific methods and interventions used by the research group to promote recruitment.

Having identified the range of specific interventions and organizational characteristics used to promote recruitment, one author (RF) looked for supporting evidence. The outcomes of interest were recruitment of GPs to research projects, recruitment of patients, or both. As with other studies evaluating the evidence base for medical care,[10,11] a limited search was undertaken because of the wide range of interventions and attributes assessed and our limited resources. The main sources used were:

(i) systematic reviews of recruitment methods for clinical trials;
(ii) systematic reviews of interventions to change professional behaviour, including those from the Cochrane Collaboration Group on Effective Practice and Organization of Care;[12]
(iii) *PubMed* searches focusing on recruitment to primary care trials (1966–1999) using keywords: randomized controlled trial; clinical trial; recruitment; participation; accrual; primary health care;
(iv) other relevant articles known or identified by members of the Dyspepsia Trialists Collaboration;
(v) secondary references cited in (i)– (iv).

The results of the review were then used to categorize the methods and interventions used by each dyspepsia research group to promote recruitment to the trials. Views about what constitutes satisfactory evidence of effectiveness vary, and therefore a structured Delphi technique was used as a small group consensus process.[13] One author (RF) summarized the evidence for each intervention and organizational characteristic (categorized according to the criteria in Tables 2 and 3) and circulated the summary to a named researcher in each research team. In the first round, nine researchers from the seven studies (including two each from the Birmingham and West Pennine trials) independently rated the evidence provided according to the criteria devised by Ellis *et al.*[10] as shown below:

(I) value or (non-value) established in one or more RCT or systematic review;
(II) sufficient face validity such that randomized trials would be unnecessary;
(III) in use, but meeting neither of the above criteria.

The results from the initial round were then fed back for a second round of rating. The characteristics of the research groups and the interventions used to promote recruitment were deemed to be 'evidence based' if they met criteria (I) or (II) with agreement by at least seven out of the nine investigators.

Results

Four relevant systematic reviews on recruitment to clinical trials[14–17] and eight reviews of interventions to change professional behaviour[18–25] were identified. These sources were supplemented by 23 relevant papers identified by members of the Collaboration, the *PubMed* searches and secondary references.[6–8,26–45] Tables 2 and 3 show how many out of the nine researchers ranked each intervention or organizational characteristic as category (I) or (II) following the second Delphi round.

Interventions

Eleven different types of interventions to promote recruitment were identified from the survey (Table 2). Five were adopted by all trials: didactic style continuing medical education (CME); educational outreach; reminders; audit and feedback; and use of printed educational materials. Others, such as interactive style CME, were used less frequently. In all, 56 interventions (median 8 per trial, range 6–9) were used across the seven dyspepsia trials. Of the 11 types of intervention, three met criterion (I) and four met criterion (II) in the consensus process, and thus, in all, seven interventions were categorized as evidence based. As such, the proportion of interventions adopted by trialists that were evidence based was 63% (35 of 56). The three interventions that fulfilled criterion (I) were all educational in nature.

Organizational characteristics

Ten organizational characteristics that might influence recruitment were identified, of which only two (patient eligibility criteria and implications for practitioner workload) were judged to be evidence based (both as criteria II, see Table 3). The range of organizational characteristics of each trial was greater than the number of interventions adopted (median 4, range 0–9), with the most common attribute being previous experience of primary care research among the GPs responsible for patient recruitment. The three trials that closed prematurely had zero, three and four attributes, respectively. However, of a total of 29 characteristics possessed by the seven dyspepsia trials, only five (17%) were deemed to be evidence based.

TABLE 2 *Effectiveness and use of interventions to promote patient recruitment*

Intervention	Method of delivery within each study	Evidence category (no. out of nine researchers ranking as I or II)	West Penn	Torbay	Utrecht	North Wales	Nott'm	B'ham	Odense	Comment on evidence
Marketing: adapting protocol to needs of GPs	Involving GPs in steering group	III (4)	x	x	x	x		x		Systematic review suggests may augment the use of other interventions to improve health care;[18] case study;[48] opinion[8,27,28]
	Piloting of trial and simplification of protocol	II (7)	x	x	x	x	x	x		Benefits suggested by reviews of case studies;[14–17] case studies;[7,29] opinion[27]
Continuing medical education	Didactic style lectures	III (2)	x	x	x	x	x	x	x	Systematic review (of RCTs) indicates didactic styles ineffective in changing professional behaviour[19]
	Interactive style: accredited learning linked to trial activities	I (9)	x							Systematic reviews (of RCTs) indicate interactive styles more effective in changing professional behaviour[19]
Educational outreach: to general practices, providing information with the intent of comparison suggested changing performance	Visits to practices by researchers	I (9)	x	x	x	x	x	x	x	Systematic review indicates consistently effective for changing modifying prescribing habits;[20] non-randomized comparison suggested; face-to-face contact more effective than mailings alone at promoting participation;[30] RCT suggests personalized approach improves response rate to surveys[31]
Financial incentives to GPs	Payments per patient recruited; postgraduate accreditation for participating in trial	III (5)	x	x	x	x	x	x		Systematic review of RCTs suggests insufficient evidence to support consistent changes in health professional behaviour;[21] systematic review, mainly of case studies, found no clear benefit from 'modest' incentives;[17] RCTs suggests benefit in postal surveys,[32,33,48] descriptive study[34] and opinion[7,35]

TABLE 2 *Continued*

Intervention	Method of delivery within each study	Evidence category (no. out of nine researchers ranking as I or II)	West Penn	Torbay	Utrecht	North Wales	Nott'm	B'ham	Odense	Comment on evidence
Incentives to patients	Provision of free medication; fast access to endoscopy	III (2)		x		x	x		x	No literature specific to treatment trials located
Reminders: manual or computerized prompts to perform a patient-specific clinical action	Manual reminders, visits or telephone calls	II (9)	x	x	x	x	x	x	x	Systematic review of RCTs indicates consistent effect in changing professional behaviour;[22] case studies;[36,37] none used specifically at time of patient visit
Audit and feedback: summary of clinical performance over a specified period of time	Feedback of recruitment rates via newsletters or on an individual basis	II (9)	x	x	x	x	x	x	x	Systematic review indicates variably effective in changing professional behaviour;[23] opinion[6,28]
Use of local opinion leaders: GPs identified by their colleagues as educationally influential	Employment of GPs to recruit other GPs	II (7)	x[a]							Difficult to define 'opinion leaders'; systematic review indicates variably effective in changing professional behaviour;[24] systematic review, mainly of case studies, suggests effective;[17] quasi-randomized trials supporting use of medical peer;[38,39] case studies[36,48]
Printed educational	Newsletters and direct mailings	I (7)	x	x	x	x	x	x	x	Systematic reviews indicate little or no effect in changing professional materials behaviour (but help raise awareness)[25]
Total interventions		11	9	8	8	9	8	8	6	Total used 56
Total evidence based		7	6	5	5	5	5	5	4	Total used 35

[a] Initiated but abandoned due to closure of the trial.

Discussion

Main findings

Difficulties in attaining sufficient sample sizes in clinical trials have been reported elsewhere.[7–9,29,40] However, these papers have focused largely on the experience of single groups of researchers. This study provides for the first time an analysis based upon a series of similar trials that have contrasting recruitment outcomes. Within our series of seven primary care-based randomized trials, all of which investigated a similar clinical condition, a wide range of measures to promote recruitment was employed. However, only 63% of interventions used and 17% of organizational characteristics were judged as being evidence based. We did not attempt to describe or explore other less tangible factors specific to each research group (e.g. interpersonal relationships or investigator motivation). Although such factors may influence patient recruitment rates, they are invariably treated as 'givens' by researchers, difficult for commissioners to

TABLE 3 *Effectiveness of organizational characteristics on patient recruitment and their presence in the trials*

Characteristic of study	Application to each study design	Evidence category (no. out of nine researchers ranking as I or II)	West Penn	Torbay	Utrecht	North Wales	Nott'm	B'ham	Odense	Comment on evidence
Experience of researchers	Previous research in primary care	III (4)			x	x		x	x	No direct evidence located; RCT suggests affiliations of researchers make no difference to postal survey responses[30]
	Previous research in dyspepsia	III (4)					x	x	x	
Research experience of primary care professionals	Previous research in primary care	III (4)		x	x		x	x	x	No evidence located
	Previous research in dyspepsia	III (2)						x	x	
Method of identifying patients	Systematic identification of patients (e.g. from computer records)	III (4)								Benefit suggested by case study;[40] all trials employed opportunistic identification
Patient eligibility criteria	Fewer restrictions on upper age of recruitment (i.e. >45–50 years eligible)	II (9)			x		x	x	x	Survey of trials to determine scale of pre-randomization losses;[41] case series and studies[40,42,43]
Implications for GP workload	Recruitment and consent by research worker	II (8)							x	No significant impact suggested by small RCT;[44] benefits suggested by systematic review of case studies and surveys;[15] and descriptive study[34]
	Randomization outside primary care	III (4)		x		x			x	
	First line study investigation conducted outside primary care	III (5)		x	x	x			x	
Increasing organizational capability	Use of local research networks	III (3)		x				x	x	Supported by opinion and case studies[45]
Total applicable		10	0	4	4	3	3	6	9	Total used 29
Total evidence based		2	0	0	1	0	1	1	2	Total used 5

measure and may not be modifiable even if resources are directed towards them.

Of the interventions deemed to be evidence based, interactive educational approaches, educational outreach and dissemination of printed educational materials were ranked under category I (value or non-value established in one or more RCT or systematic review). These interventions (along with the use of local opinion leaders under category II) were all educational in nature; specifically, they aimed to change GPs' knowledge and shift their attitudes towards understanding the need for a clinical trial. Notably, rigorous evidence suggests that printed educational materials have little or no effect on professional behaviour but they may still play a role in

raising awareness,[25] potentially enhancing the effect of other interventions.

The four other evidence-based interventions (judged under category II to be of sufficient face validity such that randomized trials would be unnecessary) fulfil other roles. The use of reminders and provision of feedback on practices' recruitment performance largely aim to motivate those already participating in trials. Marketing strategies such as adapting protocols according to perceived needs largely aim to enhance the relevance of the research question to GPs and to simplify the work required from them to recruit patients to the trial. The two evidence-based trial organizational characteristics (broadening patient eligibility criteria and measures to reduce the workload for primary care professionals in recruiting patients—both ranked under category II) also aim to facilitate recruitment. However, the key message from reviewing this evidence concerns how little is known about the most effective characteristics of trial organization. For many factors upon which the success or otherwise of a trial intuitively may appear to depend, e.g. the previous research experience of investigators and the provision of outreach support to GPs, there is no evidence available upon which to base an assessment of their utility. These are factors not only on which applications for funding may be judged, but also on which substantial resources are spent, e.g. in remunerating GPs for participation in research, or in providing clinical or research assistant support to reduce the additional burden of work associated with the trial.

Strengths and weaknesses of this study

In this study, we assessed the evidence base underpinning the different recruitment strategies used by the seven trials in the Dyspepsia Trialists' Collaboration. Given the diversity of researchers' professional experiences and the nature of dyspepsia (it is a prime example of a common clinical problem encountered in primary care), it is likely that we have captured information on all but the most infrequently used strategies employed by researchers to promote recruitment to primary care trials. As such, our findings are likely to be relevant to other research groups working in primary care.

The search for evidence on the influence of interventions and organizational characteristics was not systematic and is unlikely to be complete. We did, however, draw upon recent systematic reviews addressing recruitment to controlled trials. Evidence drawn from the Cochrane Collaboration on Effective Practice and Organization of Care (EPOC) module was applied to strategies to promote clinician participation in clinical trials. Although health professionals might place a higher priority on patient care than helping with research, we assumed that interventions to change professional behaviour would still be effective in enhancing trial recruitment. This assumption is debatable. If the EPOC findings are excluded from this analysis, only poor quality evidence remains to support the use of piloting and simplification of trial protocols, educational outreach, reminders and local opinion leaders.

The literature search revealed only limited evidence on the impact of interventions and organizational characteristics on recruitment. However, the absence of evidence does not necessarily imply absence of effect. Hence, the use of the consensus process allowed some flexibility for grading of interventions or organizational characteristics lacking robust evidence but of high face validity.

We standardized the consensus process by using more formal techniques than used in previous analogous studies.[10,11] In these studies, interventions that had not been validated in randomized trials were classified as 'convincing non-experimental evidence' (category II) only when the authors were unanimous.[10,11] If one or more researcher disagreed, the intervention or characteristic was relegated to category III. Such 'strict' approaches reduce the likelihood of consensus being attained,[13] although the use of more 'relaxed' criteria may mask significant underlying disagreement. Our requirement for agreement among seven out of the nine investigators may have resulted in more organizational characteristics and interventions being classified as evidence based than with previous methods. This approach, combined with the inclusion of category II evidence and material from the EPOC module, are highly likely to have resulted in an overestimation of the number of interventions for which there is evidence available to support their use as mechanisms to enhance patient recruitment.

Selection of interventions to promote recruitment by the dyspepsia trials

Just as strategies to change professional behaviour are more likely to be effective if tailored according to local circumstances and needs,[19] researchers running clinical trials must address anticipated barriers to recruitment. Among the seven trials in this study, a wide range of strategies were used. It is unclear, however, whether this reflected targeted responses to specific local barriers, or simply the use of as many interventions as possible to try and enhance slower than expected recruitment rates. Given the paucity of evidence we unearthed to support different interventions, the latter explanation may be more plausible and reflect genuine uncertainty about which recruitment strategies do and do not work in primary care. Even if evidence-based interventions can be identified, their effectiveness in practice may depend on the accurate identification of the barriers to recruitment they are designed to overcome.

The rate of recruitment was lower than anticipated, even among trials that achieved their recruitment targets. This may reflect optimistic expectations about the number of eligible patients, and of GPs' time and ability to recruit patients. The introduction of payments

represented a response to this and some GPs' demands for reimbursement. There is debate as to the relative effectiveness and ethics of payments to enhance patient recruitment.[46] Experience from one of our seven trials, published elsewhere, suggested that reimbursement improved recruitment rates.[47]

Potential impact of organizational characteristics in the dyspepsia trials

The literature review suggests that the evidence base for organizational characteristics is substantially weaker than that for recruitment interventions. Further work is thus required in this area. Whilst accepting that the primary purpose of this study was to describe the use of recruitment strategies and characteristics of research groups and not to evaluate *per se* the effectiveness of these factors, some observations on the potential impact of organizational characteristics merit further, if tentative, consideration.

Three trials that failed to recruit received feedback from GPs about the entry criteria being too restrictive, a problem encountered elsewhere in a trial addressing dyspepsia management.[43] The use of such criteria presents a difficult balance between the need to exclude patients for whom the intervention or lack of one may be deemed too 'risky' by investigators or local research ethics committees, and the need to maximize the generalizability of trial results.

Trials with less experienced personnel appeared to take longer to initiate recruitment following funding. This may reflect additional time required in establishing the trial infrastructure (including the trial office and all that this encompasses), promoting local interest in the projects, establishing trust and training practitioners in the use of protocols. An established research group with access to a network of clinicians from a prior collaboration appears advantageous. The impact of primary care research networks is unclear, and the quality and cohesion of these networks may differ considerably amongst geographical areas.

It is also notable that researchers from one study that closed prematurely (West Pennine) drew upon more interventions than any other study to promote recruitment. The interpretation of such a finding within the context of this study is problematic; trials suffering from poor recruitment will obviously use more and more interventions to try and increase recruitment rates than will trials where recruitment is progressing well. More importantly, the West Pennine study lacked any of the 'favourable' organizational characteristics. In contrast, two of the more successful trials (Odense and Birmingham) had the highest number of favourable characteristics.

Experience from this group of trials suggests that factors that are associated with an appropriate recruitment rate include previous experience of research, simplified recruitment criteria and methods, and administrative and clinical support for GPs. As recommended elsewhere,[16] researchers need to make realistic estimates of the time it takes to recruit practices and the targeted numbers of patients. As all trials surveyed used four interventions judged to be effective (educational outreach, reminders, feedback on recruitment performance and distribution of printed educational materials), it was not possible to explore any potential relative impacts on recruitment rates. However, favourable organizational characteristics (i.e. a strong trial infrastructure) could be decisive contributory factors to the successful completion of clinical trials.

The need for evidence-based guidance

The recognized need for better quality research in primary care, following the MRC Topic Review and Mant Report, has been accompanied by increased funding in the UK.[1,2] Failure to recruit adequate numbers of participants represents a major problem. It is associated with substantial opportunity costs for trials that fail to complete, and a loss of power for completed trials.[14] There are a growing number of reports of successful and unsuccessful trials in the literature—but much advice to current and aspiring investigators remains based upon case studies and opinion rather than on sound evidence. For example, it would be relatively non-contentious to argue that research networks can promote greater participation in primary care research. It is less certain whether they actually improve trial recruitment rates and represent a worthwhile use of resources compared, for example, with the use of financial incentives.

Current or aspiring investigators need practical guidance when embarking on a clinical trial. Following our review of the evidence and experience of recruiting patients to a series of seven similar studies, we would suggest that factors outlined in Box 1 should be considered by researchers planning randomized trials in primary care. However, the validity of these and other recommendations needs to be tested. We believe it is imperative to generate more rigorous evidence of the relative effectiveness of recruitment strategies if we are to ensure that limited resources are not wasted on ineffective recruitment strategies.

Given the limitations of our literature search, a systematic review would represent an appropriate first step. More reliable approaches to identifying potential barriers to and facilitators of recruitment should be developed. Information is also needed on the context of the research (e.g. setting) and the precise nature of any interventions used (e.g. quality and intensity).[17] The ideal design would involve randomizing a sufficient number of clinical trials to compare the effectiveness and resource implications of different interventions to improve recruitment. A prospective study following up the recruitment outcomes of a cohort of trials would identify promising recruitment strategies and provide better evidence than is available presently.

Box 1 *Recommended recruitment strategies for clinical trials in primary care based upon literature review and experience from seven trials*

Recommendations based upon evidence from literature review (evidence category)	Recommendations based upon experience of seven trials
Interventions	Interventions
Piloting of recruitment methods and simplification of protocol (II)	Incentives for patients[a]
Educational outreach (I)	Organizational characteristics
Reminders (II)	Experienced researchers (in both primary care and topic area)
Feedback on recruitment performance (II)	Experienced primary care professionals (in both primary care and topic area)
Use of local opinion leaders (II)	Broad patient eligibility criteria
Printed educational materials (I)	Recruitment and consent by research worker
Organizational characteristics	Use of local research networks
Broad patient eligibility criteria (II)	
Recruitment and consent by research worker (II)	

[a] Others not possible to judge because of widespread use of most interventions.

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