

PROSPeR

Planning Recruitment Options: Strategies for Primary Care Research

**An analytical framework for planning and
sustaining recruitment to research studies in
primary care based on evidence from the
literature**

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What is PROSPeR?

PROSPeR is an analytical framework for planning and sustaining recruitment to primary care studies. It is a practical resource designed for researchers and those who support them with the recruitment component of study design in primary care. It is based on existing evidence from the literature and is comprehensive for all quantitative and qualitative designs.

It is based on evidence from systematic and other high quality reviews; papers published in peer reviewed journals; grey literature – including reports, editorials and published conference proceedings reflecting opinion from experienced researchers.

It is a dynamic resource which will be updated regularly.

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Who is PROSPeR for?

Researchers designing primary care research studies
Research facilitators
Research supervisors
RDS staff

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Simple user guide

1. To find out how PROSPeR has been developed from the evidence base go to [Section 1](#).
2. To read an outline of systematic and other major published reviews on the issue of recruitment to research studies go to [Section 2](#). A reference list for review studies with their associated published papers can be found in [Section 6](#)
3. To help you reflect on the factors that you may need to take into account in your specific study go to [Section 3](#).
4. To identify interventions that have been used by other researchers in primary care or with relevance to a primary care setting go to [Section 4](#).
5. To help identify factors associated with retention of healthcare practitioners and participants and in reducing attrition rates in primary care studies go to [Section 5](#)
6. To go directly to reference lists go to [Section 6](#) for review studies with their associated published papers or [Section 7](#) for a comprehensive annotated bibliography for all literature included in the resource.

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SECTION 1

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INTRODUCTION AND METHODOLOGY

Background

Attaining optimal recruitment rates is important for completion and validity and generalisability of research studies, but delays and problems with recruitment are commonly reported in the literature. Campbell et al (2007) found that only 31% of Medical Research Council (MRC) and Health Technology Assessment (HTA) funded Randomised Controlled Trials (RCTs) achieve their original recruitment target, while a further 53% required grant extensions to complete the original trial. The barriers to participation are also well documented, but although there are studies that have reported successful recruitment strategies, there is little generalisable evidence available to predict the effectiveness of particular interventions.

Recruiting to studies in primary care is particularly complex, requiring the recruitment of organisations (General Practices, Primary Care Trusts), practitioners (General Practitioners and other primary health care professionals) and patients. The UK Clinical Research Network (UKCRN) aims to facilitate the conduct of clinical trials and the main goal of the new Primary Care Research Network (PCRN) is to increase the number of patients recruited or involved in clinical trials and other well designed primary care studies. Existing information on recruitment therefore needs to be utilised in the planning and design of new studies.

This practical resource for planning and sustaining recruitment to research studies in primary care, has been developed from a review of evidence from a wide range of published and publicly available sources. The evidence was assessed to identify:

- What motivates organisations, practitioners and patients to participate in primary care research?
- What interventions and strategies are effective in increasing and sustaining recruitment of research sites, practitioners and patients to studies?

The Development of the PROSPeR Framework

Electronic databases were searched (Medline, Embase, Cochrane, AMED, PsycINFO, BioMed Central) and reference lists of included studies were also checked. Papers were included if they had relevance to the recruitment of organisations, practitioners and patients to UK primary care research studies. Most papers were from UK studies but a number were included from the Netherlands, Australia & New Zealand, Canada and USA where these were considered to have relevance. Four of the included international reviews were published in the USA. A small number of editorials, reports and published conference proceedings were also included reflecting opinion from experienced researchers.

108 papers were included in the review. Of these, 17 were reports from systematic and other reviews. Across the literature there was strong reported evidence of barriers and incentives to participation – particularly those associated with GPs. A range of recruitment strategies was identified, but no robust evidence of generalisable effectiveness. No single recruitment model fits all, but evidence from case studies may be helpful in planning similar studies.

The papers were reviewed using framework analysis to identify evidence of barriers and incentives to participation and recruitment strategies. The identified recruitment strategies were then analysed thematically.

Evidence from the literature confirms the importance of considering recruitment issues from the earliest stages of research design and the need to take account of the incentives and barriers to recruitment of sites and organisations, practitioners and participants. Themes emerging from the analysis include the timeliness and importance of the research; attention to detail at the planning and piloting stages; effective engagement and marketing with stakeholders; understanding and use of appropriate incentives; and routine monitoring and feedback. The results have been used to develop an analytical framework, PROSPeR, to help in the planning and design of primary care research studies. It includes an annotated bibliography of references which may be useful in encouraging reflection on different approaches. PROSPeR is designed to be flexible and can be adapted in the light of new emerging evidence – for instance the increasing use of IT systems as a resource to support recruitment

PROSPeR is being made available to researchers across the Trent RDSU patch through its website. It has also been shared with the UKCRN Primary Care UK Clinical Research Network and the RDSU is involved with a national initiative to develop a recruitment and retention best practice resource for primary care.

Updating

PROSPeR will be regularly updated to reflect new and emerging evidence from published sources.

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SECTION 2

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SYSTEMATIC REVIEWS AND OTHER REVIEW STUDIES

This section provides an outline of systematic and other published review studies on the topic of recruitment to randomised controlled trials and health related research studies in all settings. Those that relate specifically to primary care settings are listed first. A brief study description is provided with the key findings from the review and a link to the relevant reference.

PRIMARY CARE and COMMUNITY STUDIES

REFERENCE	STUDY DESCRIPTION	FINDINGS
Asch, S., Conner, S.E., Hamilton, E.G. & Fox, S.A. (2000) Problems in recruiting community-based physicians for health services research (USA)	A review of the literature to qualitatively determine factors that are associated with higher participation rates in community-based health services research requiring significant physician participation burden. 16 studies identified.	Physician personal contact and friendship networks are powerful tools for recruitment. Minority physicians were more difficult to recruit. Potential participants frequently cited time pressures on staff and themselves as the determining factor in declining to take part in a study. Investigators should transfer as much of the study burden from participating physicians to project staff as possible.
Van der Wouden, J.C., Blankenstein, A.H., Huibers, M.J.H., van der Windt, D.A.W.M., Stalman, W.A.B. & Verhagen, A.P. (2007) Survey among 78 studies showed that Lasagna's law holds in Dutch primary care	Assessment of factors related to success and failure of recruitment in general practice research, by systematically assessing potentially relevant factors in 78 Dutch studies in general practice from 1999-2003	Lasagna's Law (over-optimistic recruitment prediction) also holds in Dutch primary care research: almost 40% of projects had to extend the fieldwork period by at least 50%. Three factors were strongly associated with the proportion of patients recruited vs. planned : <ul style="list-style-type: none">• Studies that focused on prevalent cases were more successful than studies that included only incident cases (prevalent cases can be easily identified by searching computerised patient files for the relevant disease category).

research (Netherlands)		<ul style="list-style-type: none"> Studies that required the GP to be alert during consultations were less successful. When GP or practice assistant was the first to inform the patient about the study, patient recruitment was less successful than when the patient received a letter by mail. <p>These 3 characteristics were also strongly correlated.</p> <p>Other findings:</p> <ul style="list-style-type: none"> Participation was lower where patients had an aversion to the topic or the intervention Significant association between the complexity of inclusion and exclusion criteria and planned number of patients within planned time period GPs already taking part in an existing research network were more willing to participate than others.
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REVIEWS FROM MIXED SETTINGS

Cochrane Database of Systematic Reviews

REFERENCE	STUDY DESCRIPTION	FINDINGS
Mapstone, J. Elbourne, D. & Roberts, I. (2007) Strategies to improve recruitment to research studies	Systematic review to quantify the effects of strategies to improve participation in research studies 15 eligible trials included	Benefits were demonstrated in: <ul style="list-style-type: none"> Trials of monetary incentives Providing an additional questionnaire at invitation Treatment information on the consent form <p>These specific benefits from individual trials are not easily generalisable.</p>

		On this evidence it is not possible to predict the effect that most interventions will have on recruitment.
Rendell, J.M. Merritt, R.K. & Geddes, J.R. (2007) Incentives and disincentives to participation by clinicians in randomised controlled trials	Systematic review to assess the effect of incentives and disincentives on clinician participation in RCTs. No RCTs of interventions found. 11 observational studies included.	Concern that the doctor-patient relationship would be adversely affected by participation was a deterrent. Clinicians who had recruited were more likely to report some difficulties including 'trials involve extra work' and 'inviting patients to participate is embarrassing' The impact of factors varied across studies. Researchers need to be aware that aspects of design and conduct of trials can affect clinicians' willingness to invite patients to participate. Researchers also need to be aware that some clinicians may feel obliged to sign up to a trial – especially if they are known to the researchers – without necessarily being motivated to recruit.

HTA Monographs

REFERENCE	STUDY DESCRIPTION	FINDINGS
Prescott, R.J. Counsell, C.E. Gillespie, W.J. et al (1999) Factors that limit the quality, number and progress of randomised controlled trials	Systematic review of bibliographic databases for 1986-96 identified 78 papers reporting barriers to recruitment of clinicians and patients to RCTs Mixed settings Predominantly hospital based, some community (N American studies) No UK primary care studies included	Barriers to clinician participation were identified as: <ul style="list-style-type: none"> • Time constraints • Lack of staff and training • Concern about the impact on doctor-patient relationships • Concern for patients • Loss of professional autonomy • Difficulty with consent procedures • Lack of reward & recognition Barriers to patient participation were identified as: <ul style="list-style-type: none"> • Additional demands of trial – procedures & appointments, travel problems

		<ul style="list-style-type: none"> • & costs • Patient preferences • Worry caused by uncertainty • Concerns about information and consent <p>The recruitment aspects of an RCT should be carefully planned and piloted.</p>
Hussain-Gambles, M., Leese, B., Atkin, K., Brown, J., Mason S. and Tovey, P. (2004) Involving South Asian patients in clinical trials	<p>Narrative review of the available literature, based mainly on US studies, on why ethnic minority groups are under-represented in clinical trials.</p> <p>Also included 3 qualitative interview studies.</p>	<p>The conduct of clinical trials occurs within a 'charged' historical and socio-political context.</p> <p>Barriers to ethnic minority participation in clinical trials:</p> <ul style="list-style-type: none"> • Fear and mistrust • Inappropriate exclusion criteria • Poorly designed trials • Access • Costs associated with interpretation / translation • Shortage of ethnic minority trial coordinators • Consent issues • Socio-cultural barriers • Stereotypes and cultural myths
King, M., Nazareth, I., Lampe, F., Bower, P., Chandler, M., Morou, M., Sibbald, B. and Lai, R.(2005) Conceptual framework and systematic review of the effects of participants' and professionals' preferences in randomised controlled trials	<p>Systematic review included 34 RCTs (1966-2004) that incorporated participants' and professionals' preferences.</p>	<p>Patient preferences influence whether people participate in randomised trials but there is little evidence that they significantly affect validity.</p> <p>In may trials substantial numbers refused randomisation because of preferences. Some indication that the more 'empowered' (educated, employed) are more likely to refuse randomisation because of preferences. No convincing evidence that external validity was seriously compromised.</p> <p>No evidence that preferences affect attrition rates. Limited support to the hypothesis that preferences significantly compromise internal validity.</p>

<p>Campbell, M.K., Snowdon, C., Francis, D., Elbourne, D., McDonald, A.M., Knight, R., Entwistle, V., Garcia, J., Roberts I. and Grant A. (2007)</p> <p>Recruitment to randomised trials: strategies for trial enrolment and participation study. The STEPS study</p>	<p>Systematic review of 114 trials funded by MRC & HTA recruiting patients from 1994-2003, to explore factors associated with good and poor recruitment.</p>	<p>The study used a number of different perspectives ('multiple lenses'), and three components. Part A: an epidemiological review of a cohort of trials. Part B: case studies of trials that appeared to have particularly interesting lessons for recruitment. Part C: a single, in-depth case study to examine the feasibility of applying a business orientated analytical framework as a reference model in future trials.</p> <p>A variety of strategies are employed to try to increase recruitment but their success could not be assessed.</p> <p>Only 31% of trials achieved original recruitment target within time originally specified. Successful trials appear to be those addressing clinically important questions at a timely point. Such studies were firmly grounded in existing clinical practices and the results were easily applicable to future practice.</p>
<p>Raftery, J., Bryant, J., Powell, J., Kerr, C. & Hawker, S. (2008)</p> <p>Payment to healthcare professionals for patient recruitment to trials: a systematic review</p>	<p>Synthesis of the evidence on effectiveness of monetary incentives in healthcare. 634 studies were identified but only 3 cross-sectional studies were included in the review</p> <p>Study also included primary research to look at attitudes, beliefs and behaviour of healthcare professionals and the public in relation to financial incentives and how such incentives are viewed in relation to other barriers and facilitators.</p>	<p>Evidence from the literature is limited on the subject of payment in terms of both quantity and quality. Findings are therefore inconclusive.</p> <p>Reimbursement of costs associated with recruitment to studies was widely supported, but payments to incentivise were not. Factors such as interest in the topic, scope for patient benefit and good communication were considered more important motivations for research involvement.</p> <p>Ethical stances in Good Clinical Practice were widely endorsed</p>

Other Reviews

REFERENCE	STUDY DESCRIPTION	FINDINGS
Lovato, L.C. Hill, K. Hertel, S. Hunninghake, D.B. & Probstfield, J.L. (1997) Recruitment for controlled clinical trials: literature summary and annotated bibliography (USA)	<p>Literature summary & annotated bibliography of research on recruitment for controlled clinical trials published during 1995.</p> <p>91 articles useful for the formulation of overall recruitment approaches in clinical trials are included in the bibliography.</p>	<p>Stressed the importance of overall recruitment plan and the identification & elimination of barriers to recruitment.</p> <p>Need flexibility within the plan – ability to change or develop recruitment strategy during life of trial.</p> <p>Identification of special recruitment problems associated with prevention trials and trials of certain diseases e.g. HIV, or patient groups e.g. elderly, ethnic minority populations.</p>
Sitzia, J. Wood, N. (1998) Response rate in patient satisfaction research: an analysis of 210 published studies	<p>Review of 210 published patient satisfaction studies published in 1994 to examine the quality of response rate reporting & methodological factors influencing response rates in published patient satisfaction surveys.</p>	<p>Studies generally show poor awareness of the importance of methodological issues relevant to response rate.</p> <p>Poor awareness of non-response bias and the impact on validity.</p>
Haidich, A-B. & Ioannidis, J.P.A. (2001) Determinants of patient recruitment in a multicentre clinical trials group: trends, seasonality and the effect of large studies	<p>Can patient enrolment in large multi-centre trials be modelled in terms of predictors including time parameters (such as long term trends and seasonality), the effect of large trials and the number of new studies launched each quarter?</p> <p>This study used a database of all clinical studies launched by the AIDS Clinical Trials Group between October 1986 and November 1999.</p>	<p>Enrolment differed across different months of the year.</p> <p>Enrolment accelerated over time and was affected by the performance of large studies with target sample size >1000</p> <p>Modelling of enrolment rates may be used to comprehend long-term patterns and to perform future strategic planning</p>

<p>Edwards, P., Roberts, I., Clarke, M., DiGiuseppi, C., Prata, S., Wentz, R. and Kwan, I. (2002)</p> <p>Increasing response rates to postal questionnaires: a systematic review</p>	<p>Systematic review of RCTs of any method to influence response to postal questionnaires.</p> <p>292 eligible trials were included and 75 different strategies for increasing response rates were identified.</p>	<p>The odds of response were more than doubled when a monetary incentive was used.</p> <p>Response was more likely with:</p> <ul style="list-style-type: none"> • Short questionnaires • Personalised questionnaires and letters • Use of coloured ink • Questionnaires were sent by recorded delivery • Included stamped return envelopes • Sent by first class post • Contacting participants before sending • Follow up contact • Providing non-respondents with second copy of the questionnaire • Questionnaires originating from Universities were more likely to be returned than were questionnaires from other sources, such as commercial organisations <p>Questionnaires of a sensitive nature were less likely to be returned.</p>
<p>Badger, F. & Werrett, J. (2005)</p> <p>Room for improvement? Reporting response rates and recruitment in nursing research in the past decade</p>	<p>Analysis of recruitment and response rates in published nursing research in 3 peer review journals in 2002</p>	<p>Lack of consensus on desirable response rates in nursing research.</p> <p>Half of the papers did not report a response rate. Research conducted in hospital and educational setting had higher response rates than those in community settings.</p> <p>Studies with response rates of lower than 60% did not always refer to their rates in the study limitations, and low response rates do not appear to be a barrier to publication.</p>
<p>Watson, J.M. Torgerson, D.J. (2006)</p> <p>Increasing recruitment to randomised trials: a review of randomised controlled trials.</p>	<p>Systematic review of randomised controlled trials on recruitment methods in order to identify strategies that are effective (1996-2004).</p> <p>14 papers included describing 20 different interventions.</p>	<p>Strategies identified demonstrated the potential to have an effect on recruitment but not one that was large enough to warrant a recommendation for their use.</p> <p>Effective interventions include:</p> <ul style="list-style-type: none"> • Telephone reminders. • Questionnaire inclusion. • Monetary incentives.

		<ul style="list-style-type: none"> • Using 'open' rather than placebo design. • Making trial materials culturally sensitive.
McDaid, C. Hodges, Z. Fayter, D. Stirk, D. & Eastwood, A. (2006) Increasing participation of cancer patients in randomised controlled trials: a systematic review	Systematic review to assess effectiveness of interventions to overcome barriers to patient participation in RCTs of cancer treatments. (up to end of 2004). 8 studies were included	There is considerable evidence reported in literature about the barriers to participation. No robust evidence that any of the interventions investigated led to increased participation.
Cohn, E. & Larson, E. (2007) Improving participant comprehension in the informed consent process	Integrative review of literature published 1996 – 2007 about participants' comprehension of informed consent in clinical research and to identify promising intervention strategies. 23 studies met the inclusion criteria	Participant comprehension still remains an issue. There are also differences in the way in which it is defined, assessed and measured. Interventions included simplified written consent information, multimedia approaches and use of a trained person (consent educator) to help with the consent process. No single intervention was identified as consistently successful for improving participant comprehension. Any successful consent process is likely to include various communication modes and is likely to require one-to-one interaction with someone knowledgeable about the study.

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SECTION 3

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FRAMEWORK FOR DEVELOPING RECRUITMENT STRATEGIES FOR ALL TYPES OF STUDY DESIGN IN PRIMARY CARE RESEARCH

FACTORS THAT INFLUENCE RECRUITMENT TO RESEARCH STUDIES IN PRIMARY CARE

This section covers the factors that current literature suggests you need to take into consideration when designing your study. They have been grouped under main headings. Click on the links below or scroll down to the section of interest where you will find an outline of the key factors that can influence recruitment of healthcare professionals, sites, and participants to research studies.

3.1 Factors that influence recruitment of healthcare [professionals and sites](#):

- General views on research
- Project specific factors
- Practical and resource implications
- Health professional / patient relationship

3.2 Factors that influence recruitment of [participants](#):

- General views on research
- Patient preferences
- Practical & personal issues
- Demographic & social factors
- External influences

3.3 [Study design](#) - factors intrinsic to the study design can influence recruitment

- Examples of study designs:
 - Pre-randomisation design
 - Opt-in versus opt-out design
 - Prevalent versus incident cases
 - Comprehensive cohort design
 - Direct versus indirect recruitment design
 - RCT designs in primary care
 - Prospective versus retrospective design

3.1 Factors that influence recruitment of healthcare professionals and sites in primary care research

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This section contains a summary of the factors that influence the recruitment of healthcare professionals (for example GPs, Nursing and Allied Health Professionals) and sites (general practices and primary care organisations) to primary care research studies. The factors are arranged within a number of themes. Each factor has links to the relevant reference from the literature. References with dates in **red** refer to systematic and other review publications.

THEME	FACTOR	REFERENCE
General views on research	Research has low priority over other activities – there is a lack of research culture	Peto (1993), Bell-Syer (2000), Hetherton (2004), Sheard (2006), Delaney (2007), Mason (2007), Salmon (2007)
	Relevance of research to a primary care career	Thomsen (2006), Salmon (2007)
	Relevance & value of research to primary care and clinical practice	Tognoni (1991), Ward (1999), Dean (2005), Salmon (2007), Mason (2007)
	Lack of rewards and recognition	Ross (1999), Mapstone (2007)
Project specific factors	Priority and level of interest in the topic. Relevance of the research question	Ross (1999), Bell-Syer (2000), van der Windt (2000), Pearl (2003), Dean (2005), Csipke (2006), Nelson (2006), Fransen (2007), Hoddinott (2007), Williamson (2007)
	Degree to which healthcare professionals feel they have ownership of the project	Gray (2001), Hetherton (2004), Fransen (2007)
	Disagreements with protocol design	Lovato (1997), Sheard (2006), Hoddinott (2007)
	Issues with the randomisation process – ethical concerns, uncertainty around criteria for inclusion, lack of understanding of the importance of randomisation	Peto (1993), Fairhurst (1996), Bell-Syer (2000), Wilson (2000), Hetherton (2004), Hoddinott (2007)
	Overly strict exclusion criteria - not enough suitable patients	Hunt (2001), Foy (2003), Pearl (2003), Huibers (2004), Csipke (2006), Mosis (2006)
	Level of complexity of the protocol, interventions or data collection	Tognoni (1991), Huibers (2004), Fransen (2007)
Practical & Resource implications	Time constraints	Lovato (1997), Ward (1999), Ross (1999), van der Windt (2000), de Wit (2001), Gray (2001), Ewing (2004), Dean (2005), Csipke (2006), Mosis (2006), Nelson (2006), Sheard (2006), Yallop (2006), Mapstone (2007), Salmon (2007), Williamson (2007)

	Demands and expectations of research and research team	Ward (1999), Gray (2001)
	Work-load associated with project	Tognoni (1991), Peto (1993), Foy (2003), Mosis (2006),
	Competing demands of different research studies – ‘trial fatigue’	Peto (1993), Ward (1999), de Wit (2001), Gray (2001),
	Clarity about roles – who is responsible for what within the project	Nelson (2006)
	Length of the study - especially at times of organisational change	Nelson (2006), Hoddinott (2007)
	Financial reimbursement / payment	Lovato (1997), Ward (1999), de Wit (2001) Pearl (2003) Csipke (2006), Yallop (2006), Fransen (2007), Hoddinott (2007), Salmon (2007)
	Lack of necessary skills and training	Lovato (1997), Ross (1999), Hoddinott (2007), Mapstone (2007), Salmon (2007)
	Staffing capacity – organisational changes, staff shortages, illness	Ross (1999), Ward (1999), Nelson (2006), Fransen (2007), Hoddinott (2007), Mapstone (2007)
	Lack of space	Ward (1999)
	Forgetfulness	van der Windt (2000), de Wit (2001)
	Research regulation and gatekeeping	Ewing (2004)
	Whether the research provides a new service or intervention not normally available at the practice	Ward (1999), McKinstry (2007)
Health Professional / Patient relationship	Not enough time during consultation – impact on working practices	Peto (1993), van der Windt (2000), Prout (2003), Hetherton (2004), Csipke (2006), Mosis (2006)
	Perceived appropriateness of raising research during consultation especially if the consultation is of a sensitive nature	Peto (1993), Hetherton (2004), Nelson (2006), Mason (2007),
	Equipoise between treatments - practitioner preference for one treatment over another, feeling of responsibility if study treatments are found to be unequal	Fairhurst (1996), Lovato (1997), Ward (1999), van der Windt (2000), Hetherton (2004), Sheard (2006), Yallop (2006)
	Impact on the health professional - patient relationship. Randomisation procedure compromises traditional role of providing patients with the best possible treatment	Tognoni (1991), Lovato (1997), Ross (1999), van der Windt (2000), Hunt (2001), Hetherton (2004), Mapstone (2007), Mason (2007), Salmon (2007)

	Perceived threat to professional autonomy – degree of interference with patient care and loss of control	Tognoni (1991), Fransen (2007), Mapstone (2007), Salmon (2007)
	Admitting and dealing with uncertainty over which treatment is best – “shifting their image” in the patient’s eyes	Tognoni (1991), Rendall (2007)
	Difficulties with consent procedure	Lovato (1997), van der Windt (2000), Mapstone (2007)
	Concerns for patients - impact on continuing patient care, burden on patient, protecting patients from research rather than involving them in it	Ross (1999), Mapstone (2007), Salmon (2007), Mason (2007)

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3.2 Factors that influence the recruitment of participants in primary care research

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This section contains a summary of the factors that influence the recruitment of participants to primary care research studies. The factors are arranged within a number of themes. Each factor has links to the relevant reference from the literature. References with dates in **red** refer to systematic and other review publications.

THEME	FACTOR	REFERENCE
General views on research	Personal interest in the research topic	Csipke (2006)
	Altruism	Chang (2004), Hussain-Gambles (2004)
	Previous involvement in research – if positive it is likely to encourage future involvement	Ohmann (2004)
	Fear and mistrust; general concerns about research – not wanting to feel like a guinea pig	Boles (2000)
	Understanding of the importance of research	Boles (2000)
Patient preferences	Intervention equipoise - preference for a particular treatment or for no treatment. Aversion to randomisation	Ward (1999) Boles (2000) Mill (2003) Hetherington (2004), King (2005a), Robinson (2005) Fletcher (2007)
	Dealing with uncertainty	Boles (2000), Fletcher (2007) Mapstone (2007)
	Lack of alternative treatment	Hussain-Gambles (2004)
	Gratitude to physician, feeling special	Chang (2004), Bryant (2005)
	Access to treatment, medication or tests not available outside the research	Ward (1999)
	Not wanting to change from current treatment	Boles (2000)
	The appearance, manner & gender of the recruiter	Chang (2004), Hussain-Gambles (2004)
	Level of confidence and trust in the research team – friendliness, perceived expertise	Hussain-Gambles (2004)
	Direct personal approach more likely to result in successful recruitment	Chang (2004)
Practical & personal issues	Quality, quantity and complexity of patient information	Ward (1999) Ross (1999), Boles (2000), Kendrick (2001), Hussain-Gambles (2004), Robinson (2005), Csipke (2006), Sheard (2006) Mapstone (2007)

	Seasonal variation in number of suitable participants	Haidich (2001), Prout (2003), Csipke (2006), McKinstry (2007)
	Conflicts with domestic, lifestyle, or work commitments, too busy	Bell-Syer (2000), Sellors (2002), Lloyd-Williams (2003), Hussain-Gambles (2004), Sheard (2006)
	Conflicts with caring responsibilities	Lloyd-Williams (2003)
	Conflicts with other appointments	Lloyd-Williams (2003)
	Personal health and illness severity	Boles (2000), Lloyd-Williams (2003), Fletcher (2007)
	Costs (travel, childcare) & level of reimbursement	Lloyd-Williams (2003), Chang (2004), Mapstone (2007)
	Time commitment	Boles (2000), Ohmann (2004)
	Travel issues, lack of transport	Boles (2000), Lloyd-Williams (2003), Mapstone (2007)
	Additional procedures and appointments – trial burden	Ross (1999), Hussain-Gambles (2004), Mapstone (2007)
	Convenience of access to trial site	Chang (2004), McKinstry (2007)
	Convenience of the intervention	Sheard (2006)
Demographic & Social Factors	Anxiety	Sellors (2002)
	Educational status	King (2005a)
	Greater age	Sellors (2002), Lloyd-Williams (2003), Fletcher (2007)
	Social class	Hussain-Gambles (2004)
	Ethnicity & socio-cultural barriers	Sellors (2002), Hussain-Gambles (2004)
External influences	Gender	Hussain-Gambles (2004)
	Clinician influencing patient decision whether or not to participate	Ross (1999), Hussain-Gambles (2004)
	Peer or family influence	Sellors (2002), Hussain-Gambles (2004)

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3.3 STUDY DESIGN

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Factors intrinsic to the study design can influence the successful recruitment of organisations, healthcare professionals and participants to research studies. This section provides a brief description of possible study designs that can be used in primary care with relevant published reviews or case studies.

Study Design	Description	References
Pre-randomisation design	This is a controversial research method involving the randomisation of participants before obtaining consent that has been used in research studies primarily to overcome issues of recruitment bias. It has been speculated that its use may increase recruitment rates to trials but its use is by no means justified when the objective is merely to speed up recruitment of patients.	Case study: Huibers, M. J. H., Bleijenberg, G., Beurskens, A. J. H. M., Kant, I. J., Knottnerus, J. A., van der Windt, D. A. W. M., Bazelmans, E. and van Schayck, C. P. (2004). "An alternative trial design to overcome validity and recruitment problems in primary care research." Family Practice 21(2): 213-8. Review: Adamson, J., Cockayne, S., Puffer, S. & Torgerson, D.J. (2006) "Review of randomised trials using the post-randomised consent (Zelen's) design" . Contemporary Clinical Trials 27: 305-319
Opt-in versus opt-out design	<p>'Opt-in approach = potential participants must actively signal their willingness to be involved in the research</p> <p>'Opt-out' = potential participants are assumed to be willing to participate unless they signal otherwise</p> <p>The 'opt-in' approach is more favoured by research ethics committees.</p> <p>There is evidence that recruitment rates may be lower in 'opt-in' studies and result in a biased sample. It has been suggested that the opt-out approach could be argued as the best recruitment strategy for studies with low risk to participants.</p>	Case Study: Junghans, C., Feder, G., Hemingway, H., Timmis, A. & Jones, M. (2005) "Recruiting patients to medical research: double blind randomised trial of 'opt-in' versus 'opt-out' strategies." British Medical Journal. 331: 940

Prevalent vs incident cases	Studies focused on prevalent cases were more successful than studies that included only incident cases (prevalent cases can be easily identified by searching computerised patient files for the relevant disease category).	<p>van der Wouden, J. C., Blankensteijn, A. H., Huibers, M. J., van der Windt, D. A., Stalman, W. A. and Verhagen, A. P. (2007). "Survey among 78 studies showed that Lasagna's holds in Dutch primary care research." Journal of Clinical Epidemiology. 60(8):819-24, 2007 Aug.</p> <p>Also discussed in: Wilson, S. Delaney, B. C., Roalson, A., Roberts, L., Redman, V., Wearn, A. M. and Hobbs, F. D. (2000). "Randomised controlled trials in primary care: case study." BMJ 321(7252): 24-7.</p>
Comprehensive Cohort Design	Patients with strong preferences are offered their treatment of choice, those without strong preferences are randomised in the normal way. All patients are followed up in the same way.	<p>Described in: King, M., Nazareth, I., Lampe, F., Bower, P., Chandler, M., Morou, M., Sibbald, B. and Lai, R. (2005). "Conceptual framework and systematic review of the effects of participants' and professionals' preferences in randomised controlled trials." Health Technology Assessment Vol 9(35)</p>
Direct vs indirect recruitment	<ul style="list-style-type: none"> • Direct patient recruitment – e.g. at surgery visits • Indirect patient recruitment – e.g. mailings, telephoning, databases, media 	<p>Discussed in: Nelson, M. (2004). "Recruitment in primary care research. Primary Care Alliance for Clinical Trials (PACT)." Australian Family Physician 33(12): 1039-40.</p> <p>Cost comparisons of direct and indirect recruitment methods: Davey, R., Matthes Edwards, S. and Cochrane, T. (2003). "Recruitment strategies for a clinical trial of community-based water therapy for osteoarthritis." British Journal of General Practice 53:315-317</p> <p>Case study: Geraets, J. J. X. R. de Groot, I. J. M. Goossens, M. E. J. B. de Bruijn, C. P. C. de Bie, R. A., van den Heuvel, W. J. A. and Dinant, G.-J. (2006). "Comparison of two recruitment strategies for patients with chronic shoulder complaints." British Journal of General Practice 56(523): 127-33.</p>

Cluster randomisation	In cluster randomised trials, groups or clusters of individuals rather than individuals themselves are randomised	Review of internal and external validity of cluster randomised trials in primary care: Eldridge, S., Ashby, D., Bennett, C., Wakelin, M. & Feder, G. (2008) "Internal and external validity of cluster randomised trials: systematic review of recent trials" British Medical Journal 336:876-880
RCT designs in primary care	A summary of the principle trial designs available to primary care researchers, discussing contexts in which a particular design may prove most useful.	Sheikh, A., Smeeth, L. and Ashcroft, R. (2002). "Randomised controlled trials in primary care: scope and application." British Journal of General Practice 52(482): 746-51.

Prospective versus Retrospective trial design	<p>PROSPECTIVE</p> <p>Advantages</p> <ul style="list-style-type: none"> • Screening of patients by practice team likely to be more efficient as referred patients have had initial screening and are more likely to be eligible; mailings more efficient • Well suited for trials of acute conditions • Participant flow likely to be regular • Results more generalisable to consulters <p>Disadvantages</p> <ul style="list-style-type: none"> • High workload for practice staff • Need to keep practice staff highly motivated • Not all patients will consult during the study period • Patient accrual may be slow or insufficient • Results less generalisable to total population with condition 	<p>RETROSPECTIVE</p> <p>Disadvantages</p> <ul style="list-style-type: none"> • High workload for research team in terms of screening and mailing patients • Poorly suited for trials of acute conditions • Participant flow may be irregular • Results less generalisable to consulters <p>Advantages</p> <ul style="list-style-type: none"> • Low workload for practice staff • Less need to retain practice interest throughout the trial • All identified potentially eligible patients sent information on the trial • High yield likely from databases searches • Results more generalisable to total population with condition 	<p>Case Study: McCarney, R., Fisher, P. and van Haselen, R. (2002). "Accruing large numbers of patients in primary care trials by retrospective recruitment methods." Complementary Therapies in Medicine 2002 Jun;10(2):63-8.</p>
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SECTION 4

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FRAMEWORK FOR DEVELOPING RECRUITMENT STRATEGIES FOR ALL TYPES OF STUDY DESIGN IN PRIMARY CARE RESEARCH

INTERVENTIONS FOR DEVELOPING A RECRUITMENT STRATEGY FOR A STUDY IN PRIMARY CARE

This section provides a summary of recruitment interventions and strategies that have been used by other researchers in primary care or with relevance to a primary care setting.

- 4.1 Introduces some of the [challenges](#) for researchers that are reported in the literature.
- 4.2 Provides a range of [general recruitment interventions](#) for use at all stages of the research process including pre-protocol development.
- 4.3 Identifies initiatives relevant to specific aspects of recruitment:
 - [Recruiting sites and organisations](#)
 - [Recruiting healthcare professionals and teams](#)
 - [Recruiting participants](#)

4.1 CHALLENGES FOR RESEARCHERS

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- Development of Research Culture:

Health systems need to prioritise research throughout their contracting, resourcing and training activities.

National Colleges need to incorporate research into their definitions of professional competence and curricula.

Research needs to be core to the main business of health organisations and health services.

- Contributing to a research evidence base is often low priority.
- Gatekeeping by practitioners – difficulty in gaining access to patients to ask them to take part. (Ewing)
- Maintain a salesman's morale: visualise climbing mountains for a view at the top rather than pushing boulders up hill, knock on every door, believe in the end product and have endless enthusiasm, persistence and optimism.

Issues that may prove a challenge for ethical or legal reasons

- Beware of emphasising pilot results prior to recruitment – it can result in unwillingness to be randomised to a control arm.
- Collect recruitment data for each area, identify key themes and tailor your recruitment strategy in an iterative manner.
- Recruitment and consent by research worker
- Compliance with data protection laws and research governance responsibilities

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4.2 GENERAL INTERVENTIONS FOR USE AT ALL STAGES IN THE DESIGN PROCESS, INCLUDING PRE-PROTOCOL

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This section identifies general recruitment interventions from the literature. Each set of interventions is arranged under a main theme and relevant references are provided in the right hand column. References with dates in **red** refer to systematic and other review publications. Links to each theme are provided below:

- [Timeliness and importance](#)
- [Planning](#)
- [Piloting](#)
- [Research team](#)
- [Engagement](#)
- [Education & training](#)
- [Monitoring & feedback](#)
- [Marketing](#)
- [Incentives](#)

Theme	Interventions	References
Timeliness and Importance	Research should address a clinically important area which will appeal to clinicians	Pearl (2003)
	Consideration should be given to intervention equipoise - genuine uncertainty about the effectiveness of an intervention will maximise the acceptance of potential randomisation to a control arm.	Hoddinott (2007) Wilson (2000)
Planning	Use existing information from published literature to inform new studies.	Lovato (1997)
	Adequate and early planning at all stages of the research study is essential.	Lovato (1997) Nelson (2006) Rojavin (2006)
	Planning must take account of methodological issues relating to recruitment and response rates, including potential bias.	Sitzia (1998) Badger (2005) Hoddinott (2007)
	Preliminary exploration of the pragmatic as well as the scientific aspects of a planned research project is essential	Easterbrook (1992)
	Allow sufficient time in for planning and have sufficient resources set aside	Nelson (2004)

	Have sufficient understanding and knowledge of the disease or topic area i.e. specific factors as well as factors related to age, ethnicity and educational status of the target research population. This is crucial for designing the study protocol, developing adequate informed consent and devising a suitable advertising campaign. Involve local clinical experts to inform the study design.	Rojavin (2006)
	Look for any additional influences on availability of patients – seasonality, recruitment trends over time, popularity of the study.	Haidich (2001)
	Obtain reliable data to estimate patient availability and have a realistic recruitment goal.	Nelson (2004) Yallop (2006)
	Consider the use of multi-recruitment strategies	Hussain-Gambles (2004)
	Use broad patient eligibility criteria: allow initial referrals to be made with fairly wide entry criteria and use experienced researchers to apply more detailed entry criteria.	Prescott (1999) Bell-Syer (2000) Foy (2003) Rendell (2007)
	Keep things simple: <ul style="list-style-type: none"> • Keep inclusion and exclusion criteria simple. • Keep the design simple. Simple protocols • Make data collection procedures as straightforward as possible • Simple study documentation and procedures 	Tognoni (1991) Prescott (1999) Foy (2003) Prout (2003) McDonald (2006) Fransen (2007) Van der Wouden (2007) McKinstry (2007)
	Ensure adequate level of funding is sought for the project	McDonald (2006)
	Utilise support from a trials unit	McDonald (2006)
	Budget for marketing costs when planning the trial	Farrell (1998)
Piloting	Undertake a pilot study and include an assessment of the feasibility of the recruitment strategy. Adapt accordingly. Pilot the recruitment methods	Lovato (1997) Prescott (1999) Foy (2003), Hetherington (2004) Nelson (2004) McDonald (2006) Rojavin (2006) van der Wouden (2007)
	Robust contingency plans should be built in to deal with unforeseen recruitment problems	Lovato (1997)
	The recruitment protocol should be flexible: it must be possible to adapt the protocol when GPs cannot use it in practice or when selection criteria are not clear or too strict.	Chang (2004) Fransen (2007)
Research Team	Efficient management of trials is essential. Robust systems and procedures need to be in place that are efficient, effective and flexible.	Farrell (1998)

	There should be clear lines of responsibility and accountability within the team	Lovato (1997) Nelson (2004)
	Good team organisation and communication is important	Prout (2003) Pearl (2003)
	Local recruitment coordinators & dedicated trial manager	Lovato (1997) McDonald (2006)
	The research team should minimise the workload of those involved in recruitment. Recruitment and informed consent undertaken by a researcher	Prout (2003) McKinstry (2007) Foy (2003)
	The research team should work to allay concerns about patient safety.	Ewing (2004)
	Researchers experienced in both primary care and the topic area are associated with better recruitment rates.	Foy (2003) Ewing (2004)
	Keep up the momentum – there should be minimum time lag between study commencement and recruitment.	Haiddich (2003)
	Where there is a small window of opportunity to recruit, having a trial coordinator willing to follow-up patients 7 days a week	McKinstry (2007)
Engagement	Identify all the gatekeepers and stakeholders and their views and motivations	Murphy (1992)
	Engage local opinion leaders and champions from the outset.	Murphy (1992) , Yallop (2006)
	The development of the research question, study design and feasibility should include consultation and collaboration with: <ul style="list-style-type: none"> stakeholders & clinicians <p style="text-align: center;">and</p> <ul style="list-style-type: none"> participants 	Gray (2001) Pearl (2003) Dean (2005) Csipke (2006) Hoddinott (2007) Hetherton (2004) Rojavin (2006)
	Include clinical representatives on the research team. Trials need multi-disciplinary input. Foster greater partnership between research teams and health professionals. Include assistance from other members of the team e.g. practice nurse, in supporting the research Work with professionals experienced in both primary care and the topic area.	McDonald (2006) Foy (2003) Rendell (2007)

	<p>Include patient representatives on the research team</p> <p>Consult representative community members to provide assistance with the study for hard to reach groups</p>	<p>McDonald (2006)</p> <p>Hussain-Gambles (2004)</p>
	It is important to consider what motivates patients to enter clinical trials for any particular population group or study design. (See the PEAK program below)	Rojavin (2006)
	Be aware of hard to reach groups that are difficult to recruit due to ethical or pragmatic reasons. Different recruitment methods may attract different subjects	<p>Nelson (2004)</p> <p>Veenhof (2005)</p>
	<p>The quality of the consent process is vital to maximise successful recruitment.</p> <p>Quality of informed consent</p>	<p>McDaid (2006)</p> <p>Armstrong - Wellcome Trust Report (2007)</p> <p>2 papers by Joffe et al: J of Nat Cancer Inst (Jan 2001) & The Lancet (Nov 2001)</p>
	Use established local research networks. Networks have been found to be important in accessing populations in primary care	<p>Foy (2003)</p> <p>Dean (2005)</p> <p>Sheard (2006)</p> <p>Cooke (2007)</p>
Education & Training	Consider educational opportunities such as educational outreach, printed educational materials or reciprocal training initiatives.	Foy (2003)
Monitoring and Feedback	Provide feedback on recruitment performance and a variety of reminders	Foy (2003)
	Monitor recruitment regularly and address barriers.	<p>Lovato (1997)</p> <p>Nelson (2004)</p> <p>Fransen (2007)</p>
Marketing	Budget for costs of marketing when planning the trial.	Farrell (1998)
	Seek professional advice on how to communicate the trial's unique selling points	Moore (2007)
	Site visits—meet everyone who is involved, directly or indirectly, in the trial. Personal practice visits	Dean (2005)
	Organise Roadshows. Invite a broad audience to listen to a short presentation of the proposed research and allow plenty of time for discussion	Hoddinott (2007)
	Emphasise the benefits to organisations and practices of involvement in the control arm as well as the intervention arm. Present a win-win rather than win-lose scenario.	Hoddinott (2007)

	National visibility and repeated publicity at a local level delivered by locally based investigators well known to their primary care community.	McKinstry (2007)
	Consider all potential media channels for publicity: newspapers, journals, notice boards, radio, television, press releases. Editorials or flyers in medical journals Presentations at national/international meetings Use of well-known media personalities to promote	McDonald (2006), Davey (2003) Veenhof (2005) Geraets (2006) McKinstry (2007)
	Support of respected members of the professional community	Fransen (2007)
	Look at the potential for using new technology such as the internet. Set up a project website	McKinstry (2007)
	Waiting room posters informing patients that a study is in progress	Prout (2003) McDonald (2006)
	Targeted poster campaign to encourage recruitment	Farrell (1998) Williamson (2007)
	Publish details of the project in professional newsletters to raise the profile Regular newsletters distributed to collaborators and other interested people.	Hetherton (2004) Williamson (2007)
	Partnership with consumer groups—articles in consumer publications.	Langston (2005)
	Publicising study via Divisions of Primary Care and GP journals.	Farrell (1998) Yallop (2006)
	User friendly, attractive, and stylish trial materials along with tips to ensure their prominence within centres. Create a striking logo and letterhead.	Farrell (1998)
Incentives	Assess which non-financial incentives matter most to the key decision makers.	Hoddinott (2007)
	Payment for patients to take part	Bower (2007) Chang (2004)
	Access to new treatments or interventions not available outside trial	Ward (1999) McDonald (2006) Bower (2007)
	Perception of receiving superior clinical care and more support. More frequent and rigorous monitoring	Lovato (1997) Wilson (1998)
	Contribution to medical knowledge or care of future patients; wanting to give something back. Desire and opportunity to improve primary care	Thomsen (2006)
	Incentives or profile raising products—badges, notepads, pens, certificates of participation, chocolates, prize draw Book voucher as token of appreciation	McDonald (2006) Williamson (2007)

	Payment to professionals to recruit	Bower (2007)
	Reimbursement of costs associated with recruiting patients and taking part in research	Prout (2003) Raftery (2008)
	Access to new treatments or interventions not accessible outside trial – enhanced care for patients.	Csipke (2006) McKinstry (2007)
	Competitions	Prout (2003)
	Educational initiatives for professionals	Bower (2007)
	Acknowledgement of contributing health professionals as co-investigators; recognition as contributing to maintenance of professional development or standards	Pearl (2003)
	Resource manual for site staff.	McDonald (2006)
	A reduced patient load	Ward (1999)
	Improved partnership working between professionals and action within set timescale for some studies	Hoddinott (2007)
	Closer links with a university department for organisations and practices	Ward (1999)
	Acquisition of new knowledge about treatments being tested Interest in or knowledge of research methods	van der Windt (2000)
	An opportunity for staff to be involved in and learn about research – staff development	Ward (1999)
	Incentives or profile raising products—badges, notepads, pens, certificates of participation	Farrell (1998)
	Involvement in research can help to develop research capacity and culture	Sheard (2006)
	Prestige value to organisation or practice of involvement in research	

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4.3 Initiatives relevant to specific aspects of recruitment

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This section contains examples of recruitment interventions that are relevant to specific aspects of recruitment. Each set of interventions is arranged under a main theme and relevant references are provided in the right hand column. References with dates in **red** refer to systematic and other review publications.

4.3a [Recruiting sites and organisations](#)

- Timeliness & Importance
- Infrastructure and Organisational Impact
- Engagement
- Monitoring and Feedback

4.3b [Recruiting healthcare professionals and teams](#)

- Timeliness & Importance
- Workload & impact on working practices
- Engagement
- Practical tools and ideas
- Monitoring and Feedback
- Education & training

4.3c [Recruiting participants](#)

- Interest in research
- Engagement
- Monitoring and Feedback
- Practical tools and ideas

For Incentives and Marketing – see [Section 4.2](#) General incentives

4.3d [Additional practical tools and ideas](#)

4.3a RECRUITING SITES AND ORGANISATIONS

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Theme	Intervention	Reference
Timeliness & Importance	Research that has direct and immediate benefit to the practice or the primary care team	Bell-Syer (2000) McKinstry (2007) Moore (2007)
Infrastructure and Organisational Impact	Using nurse practitioners to tell patients about the study.	Bell-Syer (2000) Richardson (2002)
	GPs who reported that practice nurses were involved in the research project were significantly more likely to recruit patients to trials.	
	Provide support from the research team. Invest researcher time and resources to support the study and minimise the impact on the practice	Moore (2007)
	Reimbursement of excess costs associated with recruiting patients and taking part in research	McKinstry (2007)
	Offering enhanced care for patients	McKinstry (2007)
Engagement	Identify all the stakeholders early in the process and consider their potential response to the study	Murphy (1992)
	Organisations and practices with a research strategy or at least an ethos that understands the importance and benefits of research is more likely to respond positively	Moore (2007)
	Plan strategies for gaining access to sites and organisations carefully. Approaches should be individualised. Consider revised, customised, simplified Trial materials for specific sites. "The quality of access negotiated has a direct effect on the quality of the eventual research data" (Murphy)	Murphy (1992) McDonald (2006) Hoddinott (2007)
	Involve participating organisations in decisions about which population to randomise and how to implement complex interventions	Hoddinott (2007)
	Supply adequate and appropriate information	Murphy (1992)
	Be clear what practice responsibilities are	Nelson (2006)
	Use supportive statements from organisational leaders e.g. chief executives.	McDonald (2006)
	Read relevant local policies, strategies and website information prior to meetings and tailor approach accordingly. Look for opportunities for research to contribute to organisation 'must-do's' strategy, policy etc	Hoddinott (2007)
	Use a bottom-up and top-down approach.	Hoddinott (2007)

	Greater partnership between research teams and health professionals – e.g. reciprocal training	Ewing (2004)
Monitoring and Feedback	Feedback on actual recruitment rates.	Peto (1993), Foy (2003) Bower (2007)
	Site visits, meetings and presentations.	McDonald (2006)

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4.3b RECRUITING HEALTHCARE PROFESSIONALS AND TEAMS

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Theme	Interventions	References
Timeliness & importance	Relevant and interesting research question – emphasise its importance.	van der Windt (2000) Ewing (2004) Dean (2005) Fransen (2007) Moore (2007) Williamson (2007)
	Research that has direct and immediate benefit to the practice or the primary care team	Bell-Syer (2000) McKinstry (2007) Moore (2007)
Workload & impact on working practices	Minimise the burden on the participating practitioner and health care team by providing adequate support from the research team. This may relate to practical issues of time and resources or it may be psychological such a sensitive topic or potential adverse effects. How much involvement is there in other studies? Use computerised lists where possible	Prescott (1999) van der Windt (2000) Asch (2000)
	Recruitment and consent by a research worker	Foy (2003)
	Use nurse practitioners to tell patients about the study and recruit.	Bell-Syer (2000) Richardson (2002)
	Provide adequate financial reimbursement	van der Windt (2000) Pearl (2003) Csipke (2006) Salmon (2007)
	Minimise the disruption to everyday practice	van der Windt (2000)
	Minimise the burden on the patient - no additional costs for the patient	van der Windt (2000)
	No interference with doctor-patient relationship	van der Windt (2000)
	Personal approaches to practitioners are reported as more likely to be successful in recruiting practitioners than indirect approaches. In-person approaches may be more successful than telephone, which may be more successful than written invitations	Peto (1993) Sitzia (1998) Asch (2000) van der Wouden (2007) Hoddinott (2007) Moore (2007)
Engagement	Early consultation and effective communication with GPs and health professionals at the time of study design.	Pearl (2003)

	<p>Use local 'champions' and local opinion leaders to help recruit.</p> <p>RAND method: investigators recruit influential and well respected practitioners, who then invite practitioners within their locality to participate. Be aware of potential for biased sampling within this method</p>	<p>Asch (2000) Foy (2003) Hoddinott (2007) Moore (2007)</p>
	<p>First approaches are vital. Provide well presented information. The amount of information is also important – too much or too little is not likely to capture interest.</p> <p>Description of the research must be clear and concise and convey exactly what is required of the practice or GP</p>	<p>Hoddinott (2007) Moore (2007)</p> <p>McKinstry (2007)</p>
	<p>Include some in-person training within the recruitment process - may help to encourage participation and reinforce the importance of the study</p>	<p>Asch (2000) Ewing (2004) McKinstry (2007)</p>
	<p>Ensure "ownership" – through full engagement of practitioners in design and implementation stages. Invite a practitioner onto the research team or steering group.</p>	<p>Ewing (2004) Fransen (2007)</p>
Practical Tools & Ideas	<p>Selecting patients from computerised lists, allowing informed researchers to apply inclusion criteria can be a successful recruitment strategy.</p> <p>But problems have also been reported with this method</p>	<p>Bell-Syer (2000) Csipke (2006)</p> <p>Davey (2003)</p>
	<p>Regular reminders Clinician desktop reminder cards, for example computer stickers.</p> <p>In-person reminders about recruitment.</p> <p>Telephone reminders</p>	<p>Prout (2003)</p> <p>Bell-Syer (2000) Foy (2003) Bower (2007)</p> <p>Watson (2006)</p>
	<p>Individualised postcards to GPs acknowledging each patient.</p>	<p>Prout (2003)</p>
	<p>Competitions</p>	<p>Prout (2003)</p>
	<p>The CTA (electronic health record-based Clinical Trial Alert) prompted physician consideration of the patients' eligibility and facilitated secure messaging to the trial's coordinator.</p>	<p>Embi (2005)</p>
	<p>Automated patient identification & recruitment and randomisation software – guided GPs through recruitment during consultations (although it was considered too time consuming during consultations)</p>	<p>Mosis (2006)</p>
	<p>RISP (Research Information Sheet for Practices)</p>	<p>See Section 4.3d below</p>

Monitoring and Feedback	Provide feedback on actual recruitment rates and reminders.	Peto (1993) Foy (2003) Bower (2007)
	Regular progress reports and contact with participating practitioners: <ul style="list-style-type: none"> Regular newsletter to participating GPs Update flyers & mailshots Presentations to practitioner groups and recruiters to report on progress of study Site visits, meetings Preferably face-to-face or by telephone To remind and motivate practitioners and pick up and resolve difficulties.	Peto (1993) Farrell (1998) Bell-Syer (2000) Gray (2001) Prout (2003) Hetherton (2004) Nelson (2004) Csipke (2006) McDonald (2006) Yallop (2006) Bower (2007) Fransen (2007)
Education & Training	Training on how to introduce research during consultations	Mason (2007)
	Workshops for recruiters Develop educational and training packages to attract ethnic minority health professionals.	Hussain-Gambles (2004) McDonald (2006)
	Credited postgraduate training opportunities and other educational initiatives for professionals	van der Windt (2000) Bower (2007)
	Resource manual for site staff	McDonald (2006)
	Support the development of interest in a specific area and knowledge of research methods	Sheard (2006)
	Feedback about their own practice	Ward (1999)
	Acquisition of new knowledge about treatments being tested	Fairhurst (1996) Ward (1999)
	Encourage a research 'culture'	Delaney (2007) Mason (2007)

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4.3c RECRUITING PARTICIPANTS

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Theme	Intervention	Reference
Interest in research	Altruism - contribution to medical knowledge or care of future patients; wanting to give something back	Lovato (1997) Chang (2004)
	Enthusiasm for research in a particular topic area e.g. over 65s Participation may be encouraged if the research focuses on an important community issue	Hellard (2001) Csipke (2006)
	Benefits to self - learning more about their condition, helping them cope with changes of lifestyle	Chang (2004)
Engagement	Direct and personal approach to patients.	Fransen (2007)
	The personal qualities of the recruiter are important – personality, gender, confidence, competence and friendliness	Chang (2004) Hussain-Gambles (2004)
	Patient representatives on the research team or in research user groups	McDonald (2006) Bower (2007) Lindenmeyer (2007)
	Partnership with consumer groups to reach and help recruit potential participants.	Farrell (1998) Langston (2005)
	Consult representative community members to provide assistance with the study.	Hussain-Gambles (2004)
	Use focus groups to identify any potential barriers	Hussain-Gambles (2004)
	Provision of extra information about the study: benefits to participants or risks of the disease being researched to the person being consented to participate.	Kendrick (2001) Mapstone (2007)
	Screening patients for suitability for research trials through a secure Internet portal – PatientSite (USA)	Leveille (2007)
Monitoring & Feedback	Regular newsletters to participating participants	McDonald (2006)
	Participants should be kept well informed about the progress of the study and should be constantly encouraged to continue to participate.	Hellard (2001)
Practical Tools and Ideas	Simple, understandable information leaflets. Use large fonts for leaflets	Boles (2000) Sheard (2006) Csipke (2006)
	Making trial materials culturally sensitive	Hussain-Gambles (2004)

	Referral staff should be suitably familiar with project	Csipke (2006)
	Successful consent processes include the use of a variety of communication methods – written, verbal, asking the participant to repeat back what they have understood. Consent should be sought in a one-to-one situation by someone knowledgeable about the study	Cohn (2007)
	Ensure interventions are suitable for participant lifestyle and circumstances, take account of age and severity of symptoms, domestic or work commitments	Fletcher (2007)
	Reimbursement of costs associated with participation	Chang (2004)
	PEAK (Patients' Expectations, Attitudes and Knowledge) Program	See Section 4.3d below

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4.3d Additional practical tools and ideas

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This section provides a range of additional material including practical tools to aid recruitment

<p>PEAK (Patients' Expectations, Attitudes and Knowledge) Program</p> <p>A set of questionnaires designed to identify the factors that motivate patients to take part in a clinical trial and capture the experiences of patients completing a trial.</p>	<p>Rojavin, M. A., Downs, P., Shetzline, M. A., Chilingirian, R. and Cohard-Radice, M. (2006). Factors motivating dyspepsia patients to enter clinical research</p>
<p>3 useful questions for planning recruitment:</p> <ul style="list-style-type: none"> • The exact purpose for recruiting participants, that is, what question are you trying to answer? • What characteristics are desirable or undesirable in the study population, that is, ensuring that your population is representative of the general population • How large a sample will you need to be able to generalise your findings. 	<p>Wilson & Rose (1998) Patient recruitment and retention strategies in randomised controlled trials</p>
<p>Assessing recruitment strategy at grant application stage</p> <p>The authors have identified a series of 'prompts' that could be addressed at grant application stage, in part or in whole, to provide evidence that the recruitment methodology has been properly planned using real, rather than theoretical or aspirational patient data. The prompts would assist the applicant in the planning stages and the reviewers at assessment stage of projects.</p> <p>Prompts cover: evidence of rigor in recruitment strategies, assessing likely compliance and attrition, confirmation of site agreement and support and additional funding requirements if recruitment falls behind planned schedule.</p> <p>The authors suggest that these prompts could be used in a pilot study to test recruitment strategies.</p>	<p>Bowman & MacFarlane (2007) on behalf of the Arthritis Research Campaign Data Monitoring Committee. Successful patient recruitment in investigator-led clinical trials</p>
<p>RISP (Research Information Sheet for Practices)</p> <p>A template developed to provide a brief overview of important information about proposed research and its practical implications for GP practices and patients. It is designed to help practices make informed decisions about participation in research.</p>	<p>Bateman (2002) A Research Information Sheet for Practices (RISP): a tool to facilitate research participation</p>
<p>Framework for ethical decision-making in recruitment of marginalised groups into research</p> <p>The author discusses the need for specific design methodologies considered within an ethical framework for research studies that seek to recruit vulnerable and marginalised people. The Framework for ethical decision-making uses the concept of 'responsible advocacy' to help healthcare professionals move away from the paternalistic 'gatekeeper' role which tends to exclude such groups.</p>	<p>Smith (2008) How ethical is ethical research? Recruiting marginalised, vulnerable groups into health services research</p>

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SECTION 5

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REDUCING ATTRITION RATES IN RESEARCH STUDIES

Many of the initiatives described in Section 4 may be useful in planning for retention of organisations, healthcare professionals and research participants throughout the life of a study. There is some literature specific to the issue of retention to studies covering both the factors that may influence participants and healthcare professionals and incentives to reduce attrition rates. This section will be developed in future versions of this resource.

5.1 Factors that affect attrition

Participants:

Useful reference source - [Wilson](#) (1998)

- Perceived lack of efficacy
- Adverse events / side effects
- Impact of study – too much time, too frequent visits etc
- Study is too intrusive
- Unhappy with randomisation to a particular group
- Bad publicity about trials
- Social factors
- Participants feeling better or worse
- Length of wait between consent and intervention
- Loss of interest in the study
- Psychological factors – anxiety, depression
- Long follow-up periods – moving house

Healthcare Professionals

Useful reference source - [Williamson](#) (2007)

- Too busy, not enough time
- Not enough patients
- Problems with creating a patient list for mailing out questionnaire
- Patients didn't like the questionnaire / didn't want to participate
- No staff or colleague support
- Project time-line changes
- Inability to follow study protocol

5.2 Incentives to reduce attrition

- Incentives at certain points in the trial – agreed with ethics committees – gifts, increased financial reimbursement
- Better targeting of messages and information
- Appointment reminders, emails and regular newsletters

- Keeping the participants well informed of the study progress can help to prevent attrition (Hellard 2001, Partridge 2002)
- If participants view the trial as well run they are more likely to continue to participate (Hellard 2001)

Retention of GPs

Reference source - [Williamson](#) (2007)

- Establishing relationship with GP and clinic staff and providing regular contact
- Minimising tasks for participants and providing support
- Providing clear instructions for participation

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SECTION 6

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REFERENCES FOR SYSTEMATIC REVIEWS AND OTHER REVIEW STUDIES

PRIMARY CARE

1. Asch, S. Conner, S.E. Hamilton, E.G. & Fox, S.A. (2000). **"Problems in recruiting community-based physicians for health services research"** Journal of General Internal Medicine 15:591-599

Literature review to determine factors that are associated with higher participation rates in community-based health services research requiring significant physician participation burden.

2. van der Wouden, J. C. Blankenstein, A. H. Huibers, M. J. van der Windt, D. A. Stalman, W. A. and Verhagen, A. P. (2007). **"Survey among 78 studies showed that Lasagna's law holds in Dutch primary care research."** Journal of Clinical Epidemiology. 60(8):819-24, 2007 Aug.

Assessment of factors related to success and failure of recruitment in general practice research, by systematically assessing potentially relevant factors in 78 Dutch studies in general practice – 1999-2003

MIXED SETTINGS

Cochrane Database of Systematic Reviews

3. Mapstone, J. Elbourne, D. and Roberts, I. (2007). **"Strategies to improve recruitment to research studies."** Cochrane Database of Systematic Reviews 2007;(3): (MR000013).

The Cochrane Collaboration — Systematic review of strategies to improve recruitment of participants to research studies.

4. Rendell, J. M. Merritt, R. D. and Geddes, J. R. (2007). **"Incentives and disincentives to participation by clinicians in randomised controlled trials."** Cochrane Database of Systematic Reviews(2): MR000021.

The Cochrane Collaboration – systematic review of incentives and disincentives to participation by clinicians in randomised controlled trials

HTA Programme Monographs

5. Campbell, M.K. Snowdon, C. Francis, D. Elbourne, D. McDonald, A.M. Knight, R. Entwistle, V. Garcia, J. Roberts I. and Grant A. (2007) **"Recruitment to randomised trials: strategies for trial enrolment and participation study. The STEPS study"** Vol 11(48)

HTA Monograph series to identify factors associated with good and poor recruitment to multicentre trials.

Associated publications:

- Walker, A; Campbell, M; Grimshaw, J. "A recruitment strategy for cluster randomized trials in secondary care settings". J Eval Clin Pract. 2000 May;6(2):185-92.
- Langston, A; McCallum, M; Campbell, M; Robertson, C; Ralston, S. "An integrated approach to consumer representation and involvement in a multicentre randomized controlled trial". Clinical Trials. 2005;2(1):80-7.
- McDonald, A; Knight, RC; Campbell, MK; Entwistle, VA; Grant, AM; Cook, JA; Elbourne, DR; Francis, D; Garcia, J; Roberts, I; Snowdon, C. (2006) "What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies". Trials. 2006 Apr 7;7:9..

6. Hussain-Gambles, M., Leese, B., Atkin, K., Brown, J., Mason, S. and Tovey, P. (2004a) **"Involving South Asian patients in clinical trials"** Health Technology Assessment, Vol. 8 (42)

A review of the literature on minority ethnic participation in clinical trials, plus outputs from three qualitative interview studies.

Associated publications:

- Hussain-Gambles, M. "Ethnic minority under-representation in clinical trials: whose responsibility is it anyway?" Journal of Health, Organisation & Management, 17, (2) 138-143.
- Mason, S; Hussain-Gambles, M; Leese, B; Atkin, K; Brown, J,. "Representation of South Asian people in randomised clinical trials: analysis of trials' data" (2003) BMJ Volume 326 7 June, Pages 1244-1245.
- Hussain-Gambles, M; Atkin, K; Leese, B,. "Why ethnic minority groups are under-represented in clinical trials: a review of the literature" (2004b) Health and Social Care in the Community volume 12 part 5 pages 382-388.
- Hussain-Gambles, M,. "South Asian patients' views and experiences of clinical trial participation" (2004c) Family Practice Volume 21 Number 6 pages 1-7
- Hussain-Gambles, M; Atkin, K; Leese B. "South Asian participation in clinical trials: the views of lay people and health professionals". (2006) Health Policy; Jul;77(2);149-65 Epub 2005 Oct 10.

7. King, M., Nazareth, I., Lampe, F., Bower, P., Chandler, M., Morou, M., Sibbald, B. and Lai, R. (2005a). **"Conceptual framework and systematic review of the effects of participants' and professionals' preferences in randomised controlled trials."** Health Technology Assessment Vol 9(35)

HTA Monograph - systematic review of RCTs that incorporated participants' preferences to test whether:

- preferences influence recruitment to trials & thus reduce external validity
- preferences influence outcomes in trials and thereby reduce internal validity.

Associated publications:

- King, MD; Nazareth, I; Lampe, F; Bower, P; Chandler, M; Morou, M; Sibbald, B; Lai, Mlib R. (2005b) "The impact of participant and professional choice on randomised trials: a systematic review" JAMA The Journal of the American Medical Association 2005 Mar 2;293(9):1089-99.

Systematic review of RCTs that incorporated participants' preferences

8. Prescott, R. J., Counsell, C. E., Gillespie, W. J., Grant, A. M., Russell, I. T., Kiauka, S., Colthart, I. R., Ross, S., Shepherd, S. M. and Russell, D. (1999). **"Factors that limit the quality, number and progress of randomised controlled trials."** Health Technology Assessment Vol 3(20)

Systematic review of factors that limit the quality, number and progress of randomised controlled trials. Literature covering the period 1986-96

Associated publications:

- Ross, S., Grant, A., Counsell, C., Gillespie, W., Russell, I. and Prescott, R. (1999). "Barriers to Participation in Randomised Controlled Trials: A Systematic Review." J Clin Epidemiol 52(12): 1143-1156.

9. Raftery, J, Bryant, J., Powell, J., Kerr, C. & Hawker, S. (2008) **"Payment to healthcare professionals for patient recruitment to trials: a systematic review"** Health Technology Assessment Programme Vol.12 (10)

Associated publications:

- Bryant, J. and Powell, J. (2005). "Payment to healthcare professionals for patient recruitment to trials: a systematic review." BMJ 331(7529): 1377-8.

Systematic review of effectiveness of payment to healthcare professional for patient recruitment to trials. HTA Programme Study

Other Reviews

10. Badger, F. and Werrett, J. (2005). **"Room for improvement? Reporting response rates and recruitment in nursing research in the past decade."** Journal of Advanced Nursing 51(5): 502-10.

Analysis of recruitment and response rates in published nursing research in 3 peer review journals in 2002

11. Cohn, E. & Larson, E. (2007) **"Improving participant comprehension in the informed consent process."** Journal of Nursing Scholarship. Third Quarter 2007

Integrative review of literature published 1996 – 2007 about participants' comprehension of informed consent in clinical research and to identify promising interventions strategies.

12. Edwards, P., Roberts, I., Clarke, M., DiGuseppi, C., Pratap, S., Wentz, R. and Kwan, I. (2002) **"Increasing response rates to postal questionnaires: a systematic review."** BMJ 324 18 May 2002 1183

Systematic review of RCTs of any method to influence response to postal questionnaires

13. Haidich, A. B. and Ioannidis, J. P. (2001). **"Determinants of patient recruitment in a multicentre clinical trials group: trends, seasonality and the effect of large studies."** BMC Medical Research Methodology 1: 4.

Can patient enrolment in large multi-centre trials be modelled in terms of predictors including time parameters (such as long term trends and seasonality), the effect of large trials and the number of new studies launched each quarter.

Database of all clinical studies launched by the AIDS Clinical Trials Group between October 1986 and November 1999.

14. Lovato, L. C., Hill, K., Hertert, S., Hunninghake, D. B. and Probstfield, J. L. (1997). **"Recruitment for controlled clinical trials: literature summary and annotated bibliography."** Controlled Clinical Trials 18(4): 328-52.

Literature summary & annotated bibliography of research on recruitment for controlled clinical trials published in 1995 USA

15. Mc Daid, C., Hodges, Z., Fayter, D., Stirk, L. and Eastwood, A. (2006). **"Increasing participation of cancer patients in randomised controlled trials: a systematic review."** Trials [Electronic Resource]. 7:16, 2006.

Systematic review to assess effectiveness of interventions to overcome barriers to patient participation in RCTs of cancer treatments. (up to end of 2004).

16. Sitzia, J. and Wood, N. (1998). **"Response rate in patient satisfaction research: an analysis of 210 published studies."** International Journal for Quality in Health Care 10(4): 311-7.

Review of 210 patient satisfaction studies published in 1994 to examine the quality of response rate reporting & methodological factors influencing response rates in published patient satisfaction surveys.

17. Watson, J. M. and Torgerson, D. J. (2006). **"Increasing recruitment to randomised trials: a review of randomised controlled trials."** BMC Medical Research Methodology 6: 34.

Systematic review of controlled trials on recruitment methods in order to identify strategies that are effective (1996-2004).

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SECTION 7

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COMPREHENSIVE ANNOTATED BIBLIOGRAPHY

1. Adamson, J., Cockayne, S., Puffer, S. & Torgerson, D.J. (2006) "Review of randomised trials using the post-randomised consent (Zelen's) design". Contemporary Clinical Trials 27: 305-319

Literature review of citations to the relevant papers published by Zelen since 1990, plus trials from personal knowledge of the authors. 58 relevant trials were identified. The most common justification for the use of the Zelen method of pre-randomisation was to avoid the introduction of bias (e.g. Hawthorne effect). Few trialists had explicitly used the design to enhance patient recruitment.

2. Armstrong, V., Barnett, J., Cooper, H., Monkman, M., Moran-Ellis, J. and Shepherd, R. (2007) "Public Perspectives on the Governance of Biomedical Research: a qualitative study in a deliberative context" The Wellcome Trust, London

Report commissioned by the Wellcome Trust to explore public attitudes towards the governance of biomedical research.

3. Asch, S., Conner, S.E., Hamilton, E.G. & Fox, S.A. (2000). "Problems in recruiting community-based physicians for health services research" Journal of General Internal Medicine 15:591-599

Literature review to determine factors that are associated with higher participation rates in community-based health services research requiring significant physician participation burden.

4. Badger, F. and Werrett, J. (2005). "Room for improvement? Reporting response rates and recruitment in nursing research in the past decade." Journal of Advanced Nursing 51(5): 502-10.

Analysis of recruitment and response rates in published nursing research in 3 peer review journals in 2002

5. Bateman, H. (2002). "A Research Information Sheet for Practices (RISP): a tool to facilitate research participation." Family Practice 19(6): 691-7.

To develop and pilot a research Information Sheet for Practices (RISP) as a tool to facilitate research participation in general practice.

6. Bell-Syer, S. E. and Moffett, J.A. (2000). "Recruiting patients to randomized trials in primary care: principles and case study." Family Practice 17(2): 187-91.

Maximising recruitment of patients to a RCT of exercise classes for back pain patients using 2 distinct methods of recruitment. Recruitment rates depended on the method and rate of GP referrals, the proportion of referrals meeting the entry criteria and the proportion of patients available to attend the exercise classes.

7. Boles, M., Getchell, W.S., Feldman, G., McBride, R. and Hart, R.G. (2000). "Primary prevention studies and the healthy elderly: evaluating barriers to recruitment." Journal of Community Health 25(4): 279-92.

Evaluation of a comprehensive recruitment strategy for a primary prevention study testing aspirin in a healthy elderly population. Focus groups were used to evaluate 225 randomly selected 'eligible refusers'. Issues of equipoise, unwillingness to travel and risk to good health were highlighted.

8. Bower, P., Wilson, S. and Mathers, N. (2007). "How often do UK primary care trials face recruitment delays?" Family Practice Advance Access.

Survey of authors of published primary care trials to assess the extent of recruitment problems; responses to recruitment problems; and the relationship between trial

characteristics and recruitment. Recruitment requiring GPs to gain patient consent was significantly associated with recruitment problems.

9. Bowman, S. J., MacFarlane, G. J. on behalf of the Arthritis Research Campaign Data Monitoring Committee (2007). "Successful patient recruitment in investigator-led clinical trials." *Rheumatology* 46(7): 1207-8.

Letter offering suggested 'prompts' to include in a clinical trial application form to assist the applicant and reviewers in the assessment of likely patient recruitment

10. Brealey, S. D., Atwell, C., Bryan, S., Coulton, S., Cox, H., Cross, B., Fylan, F., Garratt, A., Gilbert, F. J., Gillan, M. G., Hendry, M., Hood, K., Houston, H., King, D., Morton, V., Orchard, J., Robling, M., Russell, I. T., Torgerson, D., Wadsworth V. and Wilkinson, C. (2007). "Using postal randomization to replace telephone randomization had no significant effect on recruitment of patients." *Journal of Clinical Epidemiology*. 60(10):1046-51, 2007 Oct.

To test the effect of postal randomisation on recruitment of patients into a multi-centre pragmatic orthopaedic RCT in primary care. Postal randomisation had no significant effect on recruitment in this trial.

11. Bryant, J. and Powell, J. (2005). "Payment to healthcare professionals for patient recruitment to trials: a systematic review." *BMJ* 331(7529): 1377-8.

Systematic review of effectiveness of payment to healthcare professional for patient recruitment to trials. HTA Programme Study

12. Campbell, M.K., Snowdon, C., Francis, D., Elbourne, D., McDonald, A.M., Knight, R., Entwistle, V., Garcia, J., Roberts I. and Grant A. (2007) "Recruitment to randomised trials: strategies for trial enrolment and participation study. The STEPS study" Vol 11(48)

HTA Monograph series to identify factors associated with good and poor recruitment to multicentre trials.

13. Chang, B.-H., Hendricks, A. M., Slawsky M. T. & Locastro, J. S. (2004). "Patient recruitment to a randomized clinical trial of behavioural therapy for chronic heart failure." *BMC Medical Research Methodology* 4: 8.

Experiences of patient recruitment for a behavioural intervention randomised trial of elderly patients with chronic heart failure. Enrolment rate was low primarily due to travel considerations, but valuable information was identified for planning recruitment for future studies

14. Cohn, E. & Larson, E. (2007) "Improving participant comprehension in the informed consent process." *Journal of Nursing Scholarship*. Third Quarter 2007

Integrative review of literature published 1996 – 2007 about participants' comprehension of informed consent in clinical research and to identify promising interventions strategies.

15. Cooke, J., Mathers, N. & Mitchell, C. (2007) "Reciprocity and paying attention to process: an important issue for the UK Clinical Research Network in primary care" *Primary Health Care Research & Development*. 8:292-296

This paper highlights the experience and learning of networks in primary care and evidence about what supports recruitment to clinical trials.

16. Crombie, I. K., McMurdo, M. E. T., Irvine, L. and Williams, B. (2006). "Overcoming barriers to recruitment in health research: concerns of potential participants need to be dealt with... Hewison J, Haines A. Overcoming barriers to recruitment in health research. *BMJ* 2006;333:300-2. (5 August)." *BMJ* 2006 Aug 19; 333(7564): 398 (2 ref).

Response to Hewson & Haines (ref below)

17. Cross, P. L., Parsons, S. and Letley, L. (2003). Recruitment strategies for research, *British Journal of General Practice*. 53(492)(pp 568), 2003. Date of Publication: 01 Jul 2003.

Letter concerning recruitment via local newspaper advertisements

18. Csipke, E., Serfaty, M. and Buszewicz, M. (2006). "Optimising recruitment from primary care: methods of recruiting older people with depression." *Primary Health Care Research and Development* 7: 116-123.

To determine how recruitment to RCTs in primary care may be optimised. A wide range of recruitment methods was used. Recruiting from primary care can be successful if primary health care teams are willing to work in partnership with researchers, and if researchers are willing to be flexible in their recruitment approaches.

19. Davey, R., Matthes Edwards, S. and Cochrane, T. (2003). "Recruitment strategies for a clinical trial of community-based water therapy for osteoarthritis." *British Journal of General Practice* 53:315-317

This paper describes the efficiency and costs of recruitment of elderly patients using two methods: the GP database and a local newspaper.

20. de Wit, N. J., Quartero, A. O., Zuithoff, A. P. and Numans, M. E. (2001). "Participation and successful patient recruitment in primary care.[see comment]." *Journal of Family Practice* 50(11): 976.

Practice and physician characteristics associated with successful patient recruitment. 165 family practitioners participated in a combined RCT/cohort study on treatment of dyspepsia in the Netherlands.

21. Dean, S. C., Harper, C. E., Cappuccio, P., Rink, E., Dirckx, C., Arnout, J., Zito, F. and Iacoviello, L. (2005). "The challenges of cross-national research in primary health care across Europe." *Family Practice* 22: 341-346.

Challenges of recruiting to a cross-national European study and suggestions for those undertaking future international collaborations. Outcomes based on a study to evaluate dietary habits and myocardial infarction risk

22. Delaney, B. (2007). "Engaging practitioners in research; time to change the values of practice rather than the way research is carried out?" *Family Practice* 24: 207-208.

Response to Salmon (ref below)

23. Easterbrook, P. J. and Matthews, D. R. (1992). "Fate of research studies." *Journal of the Royal Society of Medicine* 85(2): 71-6.

Retrospective survey of 720 research protocols approved by an NHS ethics committee to determine the fate of research studies from inception. Main reason for abandoning studies was difficulty in recruiting participants (28%)

26. Edwards, P., Roberts, I., Clarke, M., DiGiuseppi, C., Pratap, S., Wentz, R. and Kwan, I. (2002) "Increasing response rates to postal questionnaires: a systematic review." *BMJ* 324 18 May 2002 1183

Systematic review of RCTs of any method to influence response to postal questionnaires

24. Eldridge, S., Ashby, D., Bennett, C., Wakelin, M. & Feder, G. (2008) "Internal and external validity of cluster randomised trials: systematic review of recent trials" *British Medical Journal* 336:876-880

Review of 34 cluster randomised trials in primary care published in 2004 and 2005 in 7 journals to assess aspects of internal validity. Issues affecting internal validity have been widely disseminated and are better addressed by researchers. External validity seems poorly addressed in many trials.

25. Eley, D., Hegney, D. and Patterson, E. (2005). "Patient recruitment for a practice nurse study." *Australian Family Physician* 34(11): 991-2.

Trialling a patient recruitment procedure to assess whether the design would recruit sufficient numbers of patients for a study investigating a practice nurse led collaborative care model of chronic disease management with general practice.

26. Embi, P. J., Jain, A. Clark, J., Bizjack, S., Hornung, R. and Harris, C. M. (2005). "Effect of a clinical trial alert system on physician participation in trial recruitment." *Archives of Internal Medicine* 2005 Oct 24; 165(19): 2272-7 (42 ref).
Use of electronic health record (HER) – based clinical trial alert (CTA) system to improve recruitment rates to a multi-centre trial of patients with type 2 diabetes mellitus. Use of the CTA led to significant increases in physicians' participation and recruitment rates to an ongoing trial.
25. Ewing, G., Rogers, M., Barclay, S., McCabe, J., Martin, A. and Todd, C. (2004). "Recruiting patients into a primary care based study of palliative care: Why is it so difficult?" *Palliative Medicine* 18: 452-459.
Experiences of gaining access to patients for a palliative care study in primary care. Smaller than anticipated study sample recruited. Gatekeeping by ethics committees and practitioner control over sample selection proved to be significant hurdles in accessing patients for the study.
26. Fairhurst, K. and Dowrick, C. (1996). "Problems with recruitment in a randomized controlled trial of counselling in general practice: causes and implications." *Journal of Health Services & Research Policy* 1(2): 77-80.
Semi-structured telephone interviews with GPs participating in a RCT of counselling, to explore reasons for poor recruitment.
27. Farrell, B. (1998) "Efficient management of randomised controlled trials: nature or nurture" *British Medical Journal*. 317:1236-1237
Paper proposing strategies for managing RCTs including efficient marketing to ensure sufficient numbers of participating centres and patients are recruited.
28. Farrin, A., Russell, I., Torgerson, D., Underwood, M. and U. B. T. Team (2005). "Differential recruitment in a cluster randomized trial in primary care: the experience of the UK back pain, exercise, active management and manipulation (UK BEAM) feasibility study." *Clinical Trials* 2(2): 119-24.
Report on the dangers of randomising entire primary care practices when participants cannot be identified before randomisation, as shown by a UK national trial. Impact on patient representativeness
29. Fletcher, K., Mant, J., Holder, R., Fitzmaurice, D., Lip, G. Y. H. and Hobbs, F. D. R. (2007). "An analysis of factors that predict patient consent to take part in a randomized controlled trial." *Family Practice* 24: 388-394.
To assess whether patient, practice or practitioner characteristics are associated with a patient's likelihood of giving consent to participation in a large primary care based RCT of aspirin versus warfarin for stroke prevention.
30. Foy, R., Parry, J., Duggan, A., Delaney, B., Wilson, S., Lewin-Van Den Broek, N. T., Lassen, A., Vickers, L. and Myres, P. (2003). "How evidence based are recruitment strategies to randomized controlled trials in primary care? Experience from seven studies." *Family Practice* 20(1): 83-92.
Study to estimate the proportion of patient recruitment strategies used in RCTs in primary care that are evidence based. Participants = investigators from 7 primary care-based clinical trials of dyspepsia management. Methods = Survey of trial organisation, followed by Delphi to establish consensus on levels of evidence on the effectiveness of interventions or organisational characteristics in influencing recruitment.
31. Fransen, G. A. J., van Marrewijk, C. J., Mujakovic, S., Muris, J. W. M., Laheij, R. J. F., Numans, M. E., de Wit, N. J., Samsom, M., Jansen, J. B. M. J. and Knottnerus, J. A. (2007). "Pragmatic trials in primary care. Methodological challenges and solutions demonstrated by the DIAMOND-study." *BMC Medical Research Methodology* 7: 16.
Methodological challenges and solutions demonstrated by the DIAMOND-study – a pragmatic dyspepsia RCT in primary care

32. Geraets, J. J. X. R., de Groot, I. J. M., Goossens, M. E. J. B., de Bruijn, C. P. C., de Bie, R. A., van den Heuvel, W. J. A. and Dinant, G.-J. (2006). "Comparison of two recruitment strategies for patients with chronic shoulder complaints." *British Journal of General Practice* 56(523): 127-33.

To evaluate the application of two recruitment strategies – via GP and through local newspaper advertisement - in one RCT trial investigating the effectiveness of a behavioural treatment for patients with chronic shoulder complaints. No difference in numbers recruited but slight differences in terms of demographic characteristics and treatment preferences.

33. Gray, R. W., Woodward, N. J. and Carter, Y. H. (2001). "Barriers to the development of collaborative research in general practice: a qualitative study." *British Journal of General Practice* 51(464): 221-2.

Report on difficulties of general practices participating in external collaborative projects. Semi-structured interviews with 19 practice team members.

34. Haidich, A. B. and Ioannidis, J. P. (2001). "Determinants of patient recruitment in a multicentre clinical trials group: trends, seasonality and the effect of large studies." *BMC Medical Research Methodology* 1: 4.

Can patient enrolment in large multi-centre trials be modelled in terms of predictors including time parameters (such as long term trends and seasonality), the effect of large trials and the number of new studies launched each quarter.

Database of all clinical studies launched by the AIDS Clinical Trials Group between October 1986 and November 1999.

35. Hellard, M.E., Sinclair, M.I., Forbes, A.B. & Fairley, C.K. (2001) "Methods used to maintain a high level of participant involvement in a clinical trial" *Journal of Epidemiological Community Health* 55:348-351.

Observational study to describe the strategies adopted to maintain high level participation throughout a community based clinical trial and the reasons given by participants for why they participated in the study.

36. Hetherington, J., Matheson, A. and Robson, M. (2004). "Recruitment by GPs during consultations in a primary care randomized controlled trial comparing computerized psychological therapy with clinical psychology and routine GP care: problems and possible solutions." *Primary Health Care Research and Development* 5: 5-10.

Description of recruitment difficulties experienced during a RCT for depression and anxiety and possible solutions.

37. Hewison, J. and Haines, A. (2006). "Overcoming barriers to recruitment in health research." *BMJ* 2006 Aug 5; 333(7562): 300-2 (16 ref).

Analysis & comment on opt-in vs opt-out recruitment methods.

38. Hoddinott, P., Britten, J. Harrild, K. and Godden, D. J. (2007). "Recruitment issues when primary care population clusters are used in randomised controlled clinical trials: climbing mountains or pushing boulders uphill?" *Contemporary Clinical Trials* 28(3): 232-41.

Description of strategies developed through the authors experiences of recruiting primary care organisations to participate in a national RCT of a policy to provide breast feeding groups for pregnant and breastfeeding mothers.

39. Huibers, M. J. H., Bleijenberg, G., Beurskens, A. J. H. M., Kant, I. J., Knottnerus, J. A., van der Windt, D. A. W. M., Bazelmans, E. and van Schayck, C. P. (2004). "An alternative trial design to overcome validity and recruitment problems in primary care research." *Family Practice* 21(2): 213-8.

Case study of an alternative trial design – pre-randomisation — to overcome validity and recruitment problems in primary care research.

40. Hunt, C. J., Shepherd, L. M. and Andrews, G. (2001). "Do doctors know best? Comments on a failed trial." *Medical Journal of Australia* 174: 144-149.

Exploration of a mental health trial which failed to recruit any patients

41. Hussain-Gambles, M., Leese, B., Atkin, K., Brown, J., Mason, S. and Tovey, P. (2004) "Involving South Asian patients in clinical trials" Health Technology Assessment, Vol. 8 (42)
A review of the literature on minority ethnic participation in clinical trials, plus outputs from three qualitative interview studies.
42. Hussain-Gambles, M. Atkin, K. Leese, B. (2004) "Why ethnic minority groups are under-represented in clinical trials: a review of the literature". Health and Social Care in the Community volume 12 part 5 pages 382-388 2004.
Narrative review of available literature to explore potential barriers to ethnic minority participation in clinical trials. A number of strategies for improving ethnic minority accrual rates in clinical trials are offered
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