

INFLUENCE OF CLINICIAN CHARACTERISTICS AND OPERATIONAL FACTORS ON RECRUITMENT OF PARTICIPANTS WITH LOW BACK PAIN: AN OBSERVATIONAL STUDY



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ABSTRACT

Objective: The purpose of this study was to identify factors that influence recruitment of patients to an observational study of low back pain (LBP).

Methods: From 1147 primary care (first health contact) clinicians initially contacted, 138 (physiotherapists and chiropractors) agreed to participate in a large observational study of LBP and were the focus of the current study. Data were collected pertaining to clinicians' characteristics, operational factors, and the number of patients recruited. The association of a variety of clinician characteristics and operational factors with recruitment rate was determined using a multivariate negative binomial regression analysis.

Results: From October 2011 to November 2012, 1585 patients were screened by 138 study clinicians with 951 eligible patients entering the observational study. Clinicians who were members of their professional association had a recruitment rate less than half that of those who were nonmembers ($P < .0001$). Clinicians who were trained by telephone had a recruitment rate 4.01 times higher than those trained face to face ($P < .0001$). Similarly, clinicians who referred a larger number of ineligible participants had a slightly higher recruitment rate with an incident rate ratio of 1.04 per ineligible patient ($P < .0001$). Other clinicians' characteristics and operational factors were not associated with recruitment.

Conclusion: This study provides evidence that it is feasible to recruit participants from primary care practices to a simple observational study of LBP. Factors identified as influencing recruitment were professional association (negative association), training by telephone, and referring a higher number of ineligible participants. (*J Manipulative Physiol Ther* 2015;38:151-158)

Key Indexing Terms: *Patient Selection; Back Pain; Primary Health Care; Physical Therapy; Chiropractic*

Participant recruitment is one of the most challenging phases of the research process and may cause studies to become unfeasible.^{1,2} It is estimated that 85% of

studies do not conclude on schedule due to low participation, 60% to 80% of studies do not meet their chronological endpoint because of challenges in recruitment, and 30% of

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study sites fail to recruit even a single participant.^{1,3,4} Unsatisfactory and/or untimely participant recruitment has serious consequences, leading to an underpowered study, increased resource use and higher costs.⁵⁻⁷ Importantly, the integrity and validity of the study also rely on obtaining an adequate sample size, and failure to achieve this may cause a study with inconclusive findings.⁸

Most previous studies have focused on investigating factors that increase recruitment to randomized controlled trials (RCTs).^{3-5,7,9-12} Although RCTs are considered the “gold standard” of study design,¹³ not all scientific questions can be answered with this design. Researchers are often interested in questions regarding etiology and prognosis, which may be better answered using an observational study design. Many of the barriers encountered when recruiting participants to RCTs may be similar to those encountered when conducting observational studies; however, factors affecting recruitment to observational studies have not been carefully evaluated.¹⁴

Previous studies have identified reasons clinicians do not enroll eligible patients into clinical trials.^{15,16} Although these reasons have been identified predominantly from studies evaluating general practitioners, it is likely that many also apply to allied health practitioners (physiotherapists and chiropractors) who are operating as first contact practitioner for patients presenting with back pain. These reasons include difficulty for practitioners in following the study protocol and completing the recruitment process and patient preference for a certain therapy and difficulties obtaining informed consent from patients. In primary care, these recruitment barriers are often heightened by the clinician’s lack of time, which significantly affects their ability to recruit participants.¹⁷ Other factors reported to influence recruitment of patients include the importance of the research question, the simplicity of the research design, and ease of access to treatment. Financial reimbursement has been suggested as a possible factor^{10,18,19}; however, a recent systematic review found that, in randomized controlled trials, reimbursement for time spent on recruitment is not associated with better recruitment.²⁰ In addition, it is possible that recruiting from health professionals other than general practitioners such as physiotherapists and chiropractors may produce a different outcome. Regardless, recruitment of patients in primary care remains a significant issue.^{5,7} Therefore, studies that use simple recruitment strategies, minimal clinical involvement, and health professionals other than general practitioners may have an advantage in recruiting patients in primary care settings.

The reasons certain studies recruit successfully while others do not remain unclear.²¹ A better understanding of clinicians’ characteristics and the study operational characteristics (eg, method of training and type and number of contacts) may lead researchers to identify study strategies associated with recruitment of a larger number of participants. Therefore, the aim of this study was to identify factors that influence recruitment to an observational study of triggers for low back pain (LBP).

METHODS

Design

This observational study investigated primary care clinicians enrolling patients with acute LBP to a case-crossover study (TRIGGERS). Participants were recruited from October 2011 to November 2012. The methods and procedures for recruitment of patients to the TRIGGERS study have been published elsewhere.²² Participants in the TRIGGERS study (n = 999) were also eligible to enroll in the PACE clinical trial.²³ The PACE clinical trial is a double-blind placebo-controlled trial assessing the effect that paracetamol has on recovery from acute nonspecific LBP. The inclusion criteria for the TRIGGERS and PACE studies were similar; therefore, patients recruited for the PACE clinical trial could also be enrolled in the TRIGGERS study. However, data collected from recruiting clinicians (eg, personal information) and the study operational procedures were different for both studies. Therefore, we reported the data collected from participants who enrolled in the TRIGGERS study only (n = 951). Ethical approval for the study was granted by the University of Sydney Human Research Ethics Committee (protocol no. 05-2011/13742).

Participants

TRIGGERS recruited patients seeking care for LBP in primary care clinics across Sydney, Australia. Eligible participants met the following inclusion criteria: (1) comprehends spoken English, (2) main complaint of LBP with or without leg pain (pain between 12th rib and buttock crease), (3) current episode of back pain less than or equal to 7 days duration, (4) new episode (preceded by at least 1 month without LBP), (5) pain of at least moderate intensity during the first 24 hours of this episode (scored on a 6-point scale from none to very severe). The exclusion criterion was confirmed or suspected serious spinal pathology (ie, cancer, fracture, and infection).

Clinician Recruitment

Primary care clinicians were recruited for this study. In Australia, primary care clinicians are those registered to provide the first health contact for patients presenting from the community and include general practitioners, practice nurses, psychologists, physiotherapists, chiropractors, and pharmacists.²⁴ According to the original protocol, general practitioners and pharmacists would be contacted to aid recruitment. However, no attempts were made to recruit general practitioners or pharmacists as adequate numbers of patients were recruited through physiotherapists and chiropractors. In this study, the recruiting primary care clinicians were physiotherapists and chiropractors.

Lists of physiotherapists working in Sydney were acquired from their association’s Web site. All physiotherapists drawn from the Australian Physiotherapy Association database were

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