

Recruiting family physicians and patients for a clinical trial: lessons learned

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Background. The randomized controlled trial (RCT) is the most definitive tool for evaluating an intervention. However, methodological deficiencies may limit the internal or external validity of the RCT.

Objective. Our aim was to describe the tactics used and the resources required randomly to select and recruit family physicians (FPs) and their patients aged 65 and older (seniors) for a community-based cluster RCT in primary care.

Methods. We randomly selected 48 FPs in 24 urban and rural sites in Southern Ontario, and 889 of their community-dwelling seniors (~20 per FP) taking five or more medications daily. To accomplish this, the principal investigator (an FP) contacted the eligible FPs. The participating FPs' office staff then generated and contacted the roster of eligible seniors, with support provided by the research staff.

Results. Of the 163 randomly selected FPs telephoned, 94 were ineligible and 48 (69.6%) of the remaining 69 participated. The rosters were generated with the assistance of the research staff (taking 1.5–8.0 hours) in each of the 48 practices, using electronic appointment records ($n = 26$), electronic billing records ($n = 17$), electronic medical records ($n = 2$) or written charts or file cards ($n = 3$). Of the 2078 seniors approached, 799 were ineligible and 889 (69.5%) of the remaining 1279 participated. Seniors' refusal rates among practices ranged from 4.8 to 62.3%.

Conclusions. Recruitment of a representative sample and generalizability of results are possible in RCTs in primary care. Involvement of an FP in physician recruitment and clinical research nurses who provided assistance to office staff were keys to success.

Keywords. Generalizability, primary care research, RCT.

Introduction

Primary care is the setting in which many common chronic medical conditions are diagnosed and managed. The relationship between the primary care physician and his/her patients provides an unparalleled opportunity to translate research findings into clinical care that improves population health. In Canada and the USA, most

people receive primary medical care from a community-based family physician (FP).¹ The 1996 Ontario Health Survey found that ~95% of the Ontario population report having an FP (the use of the term 'family physician' refers to both family physicians and general practitioners) and 80% report at least one visit in the previous 12 months.²

The problems that may arise when applying findings from randomized clinical trials (RCTs) conducted in secondary or tertiary care settings to patients in primary care have been described.^{3,4} Evidence generated from RCTs in secondary or tertiary care may not be generalizable to the patients in primary care settings due to differences in disease prevalence and severity.³ For these reasons, it is important to conduct research in the health care setting in which patients are seen. However, primary care researchers conducting RCTs face many challenges

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including the lack of readily available patient sampling frames,⁵ ensuring that busy FPs and their office staff adhere to the study protocol^{6,7} and low rates of patient referral.^{1,4,8} Low participation rates and highly selective eligibility criteria limit the external validity of a trial, decreasing the ability to apply the research evidence in other settings.⁹

This paper describes a successful method of recruiting FPs and their patients aged 65 and older (seniors) to participate in a large community-based randomized trial in 24 sites in Southern Ontario.

Methods

Study design

The Seniors Medication Assessment Research Trial (SMART) was a cluster RCT of the effectiveness of expanded role pharmacists (ERPs) providing consultations to FPs to optimize the pharmacotherapy of seniors taking multiple medications. The project received ethics approval from the Research Ethics Board of the Hamilton Health Sciences Corporation and was carried out between July 1999 and September 2000.

ERPs are practising pharmacists who have received additional training in patient-centred counselling to detect and resolve drug-related problems. The 24 ERPs were volunteers who had completed this training at the University of Toronto, Faculty of Pharmacy, were located in the 16 towns and cities within a 2-hour drive from Hamilton and responded to a letter of invitation. There were ~100 ERPs practising in the 16 areas. The recruitment of FPs and seniors occurred between August and November 1999.

Physician recruitment

FPs were paired on the basis of postal area, and each FP within a pair was assigned randomly to either the intervention (ERP) or the control group. We assumed that patients seeking care within a given geographic area would have similar socio-economic status and access to health care services. Therefore, the first three characters of the postal code of each ERP were used to define the area from which we randomly selected two FPs in the following manner. The sampling frame for each of the 24 postal areas was constructed using the computerized registry of the provincial licensing body for physicians (College of Physicians and Surgeons of Ontario; www.cpsso.on.ca; November, 1999). Physicians registered as GPs, FPs and those without a specialty designation from the Royal College of Physicians and Surgeons of Canada were listed for each of the 24 postal areas and each list was ordered randomly by a random number generator program (STATS 1.1, Decision Analyst Inc., 1998, Arlington, Texas). Physicians on each list were telephoned in sequence by the principal investigator (JS) until two eligible FPs from each postal area had been

recruited. An FP was eligible if he/she was in active practice and reported having ~100 or more community-dwelling seniors as regular patients (i.e. those that the FP had seen within the past year).

Our clinical research nurse (CRN) co-ordinator then visited each FP and his/her staff within 2 weeks of telephone recruitment. This visit was to ensure a mutual understanding of how study participation would be accomplished in each office setting. The protocol was reviewed briefly, with emphasis on the approach to patient recruitment, the expected workload for the FP and staff (time spent with patients, ERPs and CRNs), and remuneration for their time. A letter of understanding was signed by the FP to indicate their agreement to participate.

Senior recruitment

With the assistance of a CRN as required, the office staff of each FP produced a sequentially numbered list of their regular senior patients. Our research staff then randomly ordered this list (STATS 1.1). The office staff, with the assistance of a CRN as necessary, further assessed the seniors for eligibility using their medical charts. Eligible seniors were taking five or more medications according to their chart, were not institutionalized and were English speaking or had an interpreter according to the staff. Selection continued until ~30 seniors had been identified as potentially eligible. The office staff contacted the seniors in order, by telephone, and invited seniors to an enrolment interview with a CRN. The office staff were encouraged to refer to a prepared script when making the recruitment calls. Recruitment continued as needed and a CRN conducted the initial interviews in the FP office until ~20 seniors had given written informed consent to participate.

Estimation of cluster size per practice

The sample size of 20 seniors per practice was estimated using an intra-cluster correlation coefficient of 0.08 for the number of daily medication units taken per patient (determined from a pilot study), the desire to detect a 15% reduction in average number of daily units of medications, the probability of a type I error (alpha) of 0.05 (one-sided) and a power of 80%. Given 24 pairs of FPs, it was estimated that 20 seniors per FP should be enrolled to ensure that the necessary 15 would complete the trial.

Statistical methods

To assess the comparability of participants and refusers, year of graduation from medical school and the gender of the FPs were compared. At the time of recruitment, a list of the age and gender of seniors that refused to participate was not kept by the FPs' office staff, therefore a random sample of practices was selected and asked to provide this information for the comparison of the seniors who refused with those who participated. Student's *t*-test for independent samples was used to compare age

and year of graduation from medical school and the chi-square test was used for the gender comparisons. A type I (alpha) error level of 0.05 (two-tailed) was used to indicate a statistically significant difference between participants and non-participants (for FPs and seniors).

Results

Physician recruitment

Using the web-based registry, a total of 677 physicians were identified as potential FPs in the 24 postal areas in which the ERPs practised (Fig. 1). The number of potentially eligible physicians ranged from four to 72 in the different postal areas. Using the randomly ordered

list of 677 potentially eligible FPs, 163 were contacted to reach the required number of participants. Of the 163 FPs telephoned, 69 (21 women and 48 men) were eligible, 48 (69.6%) of whom agreed and participated in the trial. The reasons for ineligibility are shown in Figure 1. Of the FPs who refused, 76.2% (16/21) were male compared with 66.7% (32/48) of those who agreed to participate ($P = 0.43$). The average year of graduation from medical school was similar among FPs who refused and those who participated (1977.3, SD = 12.3 versus 1977.4, SD = 10.5, $P = 0.98$).

Producing senior rosters

There were four categories of office information systems that were encountered and used to generate the sampling

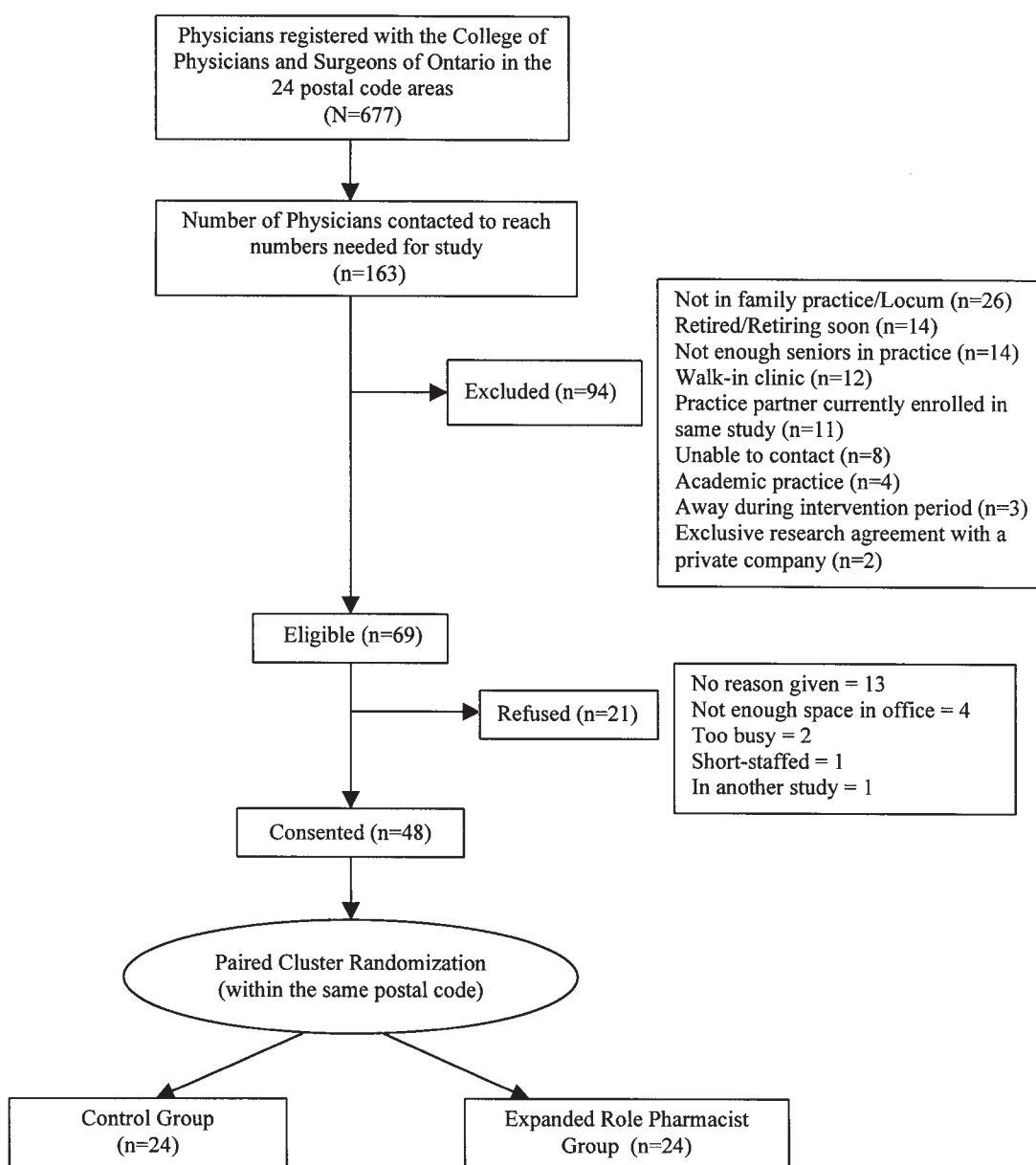


FIGURE 1 Flow diagram showing the recruitment of family physicians into the trial

frames for seniors in each family practice. The easiest available method of generating a sampling frame was used in each case. The use of electronic medical records (EMRs) was the quickest method to generate a sampling frame; however, these were used in only two (4.2%) of the 48 family practices. In these two practices, the process of generating a list of seniors was within the capability of the office staff and no CRN time was expended on this task. In 26 (54.2%) of the remaining practices, computer appointment systems were used, and in 17 (35.4%) computer billing records were used. Among these offices using either computer appointment or billing systems, 20.9% (9/43) required some degree of computer support from our research staff, in the form of a phone call or an office visit. The amount of time spent by research staff assisting these offices was estimated to range from 15 minutes to 2 hours.

In the three (6.3%) practices that did not use a computer for any of these tasks, the roster of seniors was compiled manually by the office staff using the medical charts or an index card file of patients. These practices had the fewest total patients (<1000 patients per practice). The research staff spent between 1.5 and 8 hours in these offices.

In all but the two practices using EMRs, once the roster of seniors had been produced the CRNs spent from 4 to 8 hours in each office. This was necessary to determine which seniors were eligible by assisting the office staff to review the medical charts on the recruitment list.

Recruitment of seniors

A total of 10 663 seniors who had been seen in the last year were identified as patients of the 48 FPs (Fig. 2). Of these seniors, a sample of 2078 (19.5%) who appeared to be eligible according to the chart review was selected randomly and approached by the office staff. After initial consideration, 799 were excluded for the variety of reasons described in Figure 2. More than half of the exclusions were due to the inability to communicate in English or the inability to contact the senior at the telephone number available. Of the remaining 1279 eligible seniors, 889 (69.5%) provided written informed consent to participate in the trial at their initial interview with a CRN. The refusal rates for the seniors ranged from 4.8 to 62.3% among the practices. In the 12 practices selected randomly for the comparison of refusers with participants, 110 seniors refused. In contrast to participants, those who refused were statistically significantly older (77.3, SD = 8.7 years versus 74.6, SD = 6.1 years, $P = 0.002$). Participants and refusers were similar with respect to gender; 37.2% (331/889) of the participants were male, compared with 38.2% (42/110) of the refusers. The number of seniors recruited in each practice ranged from seven to 21.

Discussion

The recruitment tactics used in the SMART project were successful for two important reasons. First, it was ascertained carefully, for both FPs and seniors, who should be on the sampling frames. Secondly, the eligible FPs and seniors on the sampling frames were selected randomly and approached carefully by people whom they trusted and who were competent to explain participation in the trial. This strategy minimized the effect of sampling biases that may have threatened the validity of the SMART results, both internally and externally. Internal validity refers to the ability to make inferences about the populations from which samples were drawn, whereas external validity deals with the ability to generalize the findings to other, apparently similar populations.

Lack of staff support in clinical trials has been identified as an important barrier to the recruitment of physicians.⁸ Our acceptance rate among the eligible community-based FPs was high compared with the rates of 8–26% that have been reported previously,^{4,10,11} and all of the practices who agreed to participate were able to recruit patients. Failure to report physician participation rates is not uncommon in published articles, making it difficult for the consumer of primary care research to assess it as evidence.¹²

The availability of the registry of our provincial medical licensing body via the Internet gave us a rapid and efficient way to construct a sampling frame of FPs. The electronic data were easy to manipulate and sort by specific attributes such as postal code and lack of a specialist designation, providing a sampling frame based on the registry, rather than a list of collaborators who had supported the investigators in prior studies. Selection bias has been introduced into previous studies involving FPs when investigators directed their recruitment efforts toward FPs with whom they had a previous positive working relationship.¹²

Both the process and the outcome of the work to produce patient sampling frames from such a broad spectrum of family practices are relevant to primary care researchers. With respect to computer readiness, there was essentially a large group (89.5%) using computers for a few specific tasks, a few FPs (4.2%) who were completely computerized with EMRs and those FPs (6.3%) at the other extreme that did not use a computer. Another lesson learned was that although most of the practices made use of computers for scheduling appointments or for billing purposes, most were not aware that these electronic data could be used to produce a practice roster and many needed assistance to do this relatively simple task. Useful data and the software to manipulate them were there but, generally speaking, the FPs and their staff did not know how to use their systems to obtain the sampling frames. A recent study with community-based FPs also found that only a few family

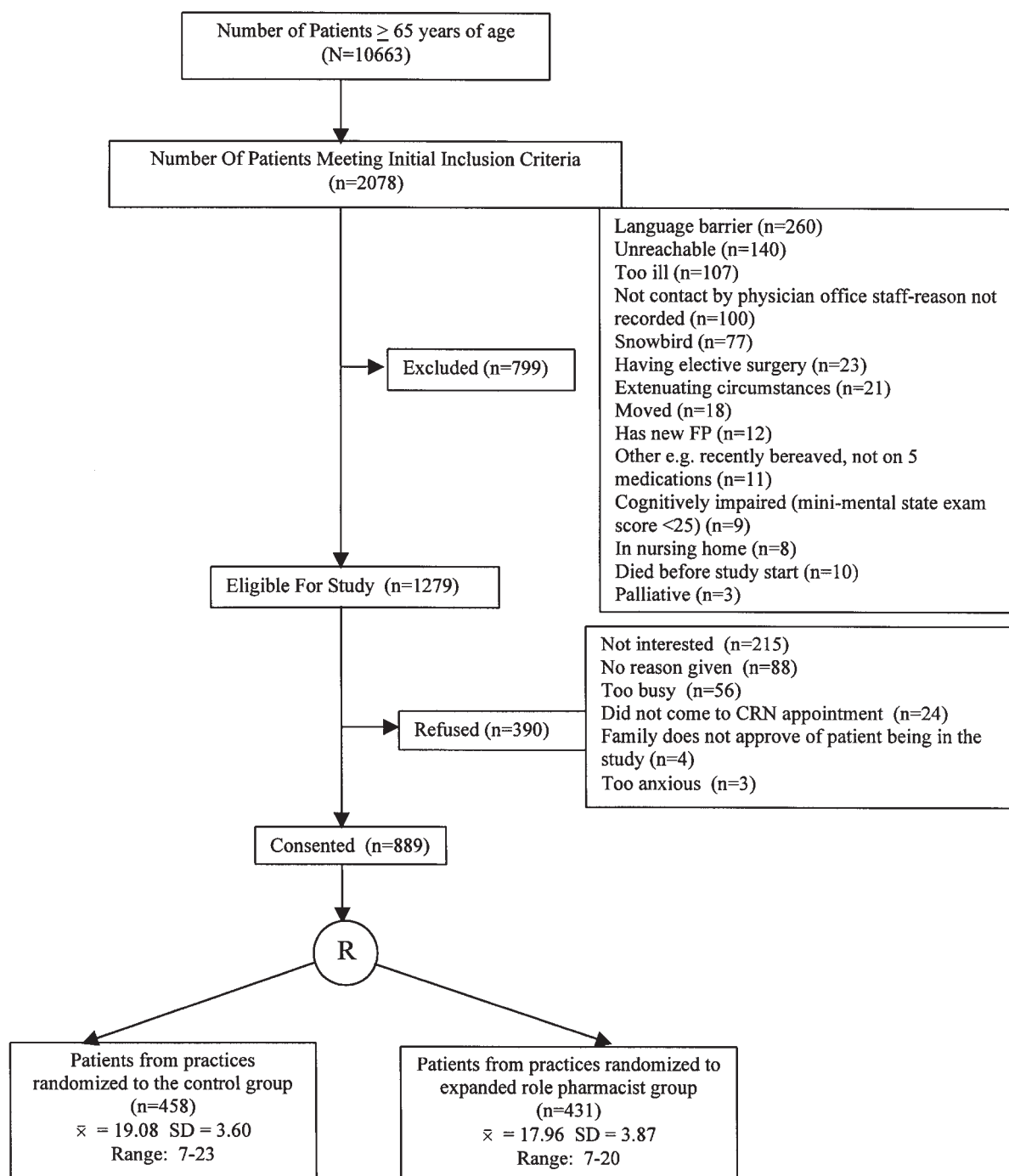


FIGURE 2 Flow diagram showing the recruitment of patients into the trial

practices could use their computer system to identify potential participants for a study.¹

A common ethical problem in primary care research is the potential loss of confidentiality for patients in a family practice that is involved in a research project. Researchers face the dilemma of needing to select patients in a methodologically rigorous fashion, yet unless there is informed consent from patients, the FP must protect his/her patients' identity and information. Our use of CRNs on-site was a compromise that permitted the

study methodology to be applied with fidelity but also protected patient confidentiality until patients had been informed initially about the study by the office staff. In addition, we felt that it was preferable for our CRNs to train the office staff in making the initial telephone contact since it seemed likely that patients would be more receptive to contact by their own FP's office staff with whom they were familiar.

The challenges produced by the lack of readily available sampling frames,⁵ non-adherence to study protocol

by physicians and office staff⁶⁻⁸ and low rates of patient referral^{1,8} were minimized in this trial by using carefully planned and executed recruitment tactics. These tactics included the use of an electronic registry of physicians and the involvement of an FP in the telephone recruitment of other FPs. It was illuminating that with some technical support, the majority of FPs and their office staff could generate lists of their patients based on their available resources. CRNs and office staff worked effectively together to recruit eligible patients while safeguarding patient confidentiality. We hope that sharing our lessons from the early stages of this trial will encourage other primary care researchers to strive for methodological rigour.

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