Does sending a home safety questionnaire increase recruitment to an injury prevention trial? A randomised controlled trial

D Kendrick, M Watson, M Dewey, A J Woods

Few publications have examined maximising recruitment to randomised controlled trials in primary care. Mass mailings have been used as a recruitment strategy,[1–3] but have had low response rates. Short messages in mass mailings have acheived better recruitment rates than longer messages.[4] Within a primary care injury prevention trial we assessed response and recruitment rates to the trial using mass mailing, comparing an invitation to participate with and without a home safety questionnaire. We considered that sending a questionnaire may reduce the recruitment rate because of the time and effort needed for completion[4] or because questions on safety behaviours and previous injury may be perceived as intrusive; alternatively we considered that the questionnaire may raise awareness of risk of injury and through this might increase the recruitment rate.[5]

Methods

The study population comprised the first 2397 families eligible for a randomised controlled trial of the effectiveness of health visitor advice and low cost safety equipment. Families with children under 5 years on the caseloads of participating health visitors working in general practices in deprived areas (Townsend score >0) were eligible to take part. Families living in areas where safety equipment was already provided as part of a local programme, those with children on the child protection register and those whom the health visitor felt may be distressed by an invitation to take part in the study (for example, recent child death) were excluded. Families were randomised to receive an invitation to participate, the questionnaire including the consent form, the study information leaflet and a freepost envelope or to receive an invitation to take part, the information leaflet, a consent form and a freepost envelope without the questionnaire. The 16 page questionnaire contained questions on safety behaviours, sociodemographic details and previous injuries. Closed questions were used, the majority of which had ordered responses with an option for parents to specify other answers. Piloting the questionnaire ascertained the average completion time to be 11 minutes. Within each health visitor caseload, families identified only by a unique identifying number, were randomly allocated to each group using ACCESS by a researcher not involved with the project. The invitations were sent by post in January 2000. The outcome measures of interest were the response and recruitment rates to the first mailing measured three weeks after sending the invitations. The sample size calculation based on an estimated 24% response rate to the first mailing, 90% power and a 5% significance level, indicated 1149 families in each group would allow a difference in response rate of 25% (from 24% to 30%) to be detected. Data were entered onto an ACCESS database, verified by double entry and analysed using EPI-INFO version 6.

Results

A total of 2397 families were randomised, 1203 to receive the questionnaire with the invitation to take part and 1194 to receive the invitation without the questionnaire. Four invitations were returned as not known at that address and were excluded from the analysis. In total 425 (17.8%) invitations were returned after the first mailing and 374 (15.6%) families agreed to participate in the study. The response and recruitment rates for the two methods are shown in table 1.

Discussion

Including a safety questionnaire increased the response and recruitment rates for an injury prevention trial. Previous work suggests that people choose to participate in trials for a variety of reasons including the extent to which they feel physically threatened by their illness.[5] It is possible that completion of the safety questionnaire raised awareness of the risk of injury and increased recruitment through doing this. Even if the data collected on the questionnaire are not required for each participant, for example for assessing baseline characteristics, researchers may wish to include a questionnaire to increase recruitment rates. This has to be weighed against the increased costs of questionnaire production and postage. A further advantage of including a questionnaire is that some families will complete it but

Division of General Practice, Floor 13, Tower Building, University Park, Nottingham NG7 2RD, UK
D Kendrick
M Watson

Trent Institute for Health Services Research
M Dewey

Postgraduate Division of Nursing, University of Nottingham, Queens Medical Centre
A J Woods

Correspondence to:
Dr Kendrick
(denise.kendrick@nottingham.ac.uk)

Accepted for publication
25 May 2001

Table 1 Response and recruitment rates for the invitations with and without the safety questionnaire

Method	*Responded to invitation (%)*	*RR (95% CI)*	*Recruited to trial (%)*	*RR (95% CI)*
Invite with questionnaire (n=1203)	259 (21.5)	1.54 (1.29, 1.84)	217 (18.0)	1.37 (1.13, 1.65)
Invite without questionnaire (n=1190)	166 (13.9)	χ^2=23.53, 1 df, p<0.001	157 (13.2)	χ^2=10.65, 1 df, p=0.001

choose not to participate, so differences between participants and non-participants can be examined, which is useful when considering the generalisability of the results of the study.

Funding: NHS Executive Trent
Conflicts of interest: none.

1 Cosgrove N, Borhani NO, Bailey G, *et al*. Mass mailing and staff experience in a total recruitment program for a clinical trial: the SHEP experience. *Control Clin Trials* 1999; **20**:133–48.
2 Kiernan M, Phillips K, Fair JM, *et al*. Using direct mail to recruit Hispanic adults into a dietary intervention: an experimental study. *Ann Behav Med* 2000;**22**:89–93.
3 Lovato LC, Hill K, Hertert S, *et al*. Recruitment for controlled clinical trials: literature summary and annotated bilbiography. *Control Clin Trials* 1997;**18**:328–52.
4 Gerace TA, George VA, Arango IG. Response rates to six recruitment mailing formats and two messages about a nutrition program for women 50–79 years old. *Control Clin Trials* 1995;**16**:422–31.
5 Verheggaen FW, Nieman F, Jonkers R. Determinants of patient participation in clinical studies requiring informed consent: why patients enter a clinical trial. *Patient Educ Couns* 1998;**35**:111–25.