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Recruitment Into a Cessation Trial Via the New Zealand Quitline: Many Benefits, Few Limitations

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Objective: To report on the use of the New Zealand Quitline for recruiting participants to a smoking cessation trial. *Methods:* Analysis of data on trial recruitment and randomisation. *Results:* 68% of 26,369 callers to the New Zealand Quitline over 12 months indicated an interest in taking part in research, 28% of whom met eligibility criteria for a cessation intervention trial, assessed on the data routinely collected at Quitline registration. Of these, 1317 (26%) were contacted by call back with 1027 (78%) agreeing to take part in the trial. After further eligibility checking 851 people were randomised. Weighting of calls ensured that 25% of participants were Maori. *Conclusions:* Quitlines have good potential to be an effective means of randomising participants into cessation trials and ensuring adequate representation of underrepresented population groups.

Conducting smoking cessation trials in countries such as New Zealand, with its small, widely distributed population presents several challenges. First, in trials comparing a new intervention versus usual care, a large sample size may be needed. Second, recruiting participants face-to-face is expensive and inconvenient for participants. New Zealand's government-funded smoking cessation Quitline operates a toll-free nationwide telephone counselling service, and counsellors can issue 2 months of heavily-subsidised nicotine replacement therapy (NRT) to callers via mailed-out vouchers redeemable from community pharmacies (Grigg & Glasgow, 2003).

In this article we describe the use of New Zealand's national Quitline as the sole source of participants recruited into a large trial of a new cessation treatment, precessation nicotine replacement therapy (NRT) versus usual care, the PQNIQ (Pre-Quitting NRT to Improve Quitting) Trial (Australasian Clinical Trials Network Number: 012605000373673). As such, it presents an ideal means of recruiting participants into smoking-related studies.

Participants and Method

In 2006 almost 33,000 smokers registered with the Quitline for cessation support, and 27,899 NRT vouchers were issued. Typically, more women than men use the service (55% and 43% respectively in 2006), and almost half (49%) are between 25–44 years of age, with similar numbers under 25 years and over 44 years (22% and 26% respectively). A distinctive characteristic of the New Zealand population is its large indigenous population (Maori comprise 15% of the total population), of whom half are smokers, twice the proportion of non-Maori (Ministry of Health, 2004). This marked ethnic difference accounts for a substantial part of the 10-year life expectancy gap between Maori and non-Maori New Zealanders (Blakely, Tobias, Robson, Ajwani, Bonne, et al., 2005). Despite their relative under-utilisation of primary heath care services, Maori comprised 23% of all Quitline callers in 2006 (J. Li, Researcher, The Quit Group, personal communication). The reasons for such success may be attributed in part to targeted television campaigns (Wilson et al., 2005). All callers to the Quitline are asked at registration to indicate their inter-

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est in participating in research. For the initial 12-month recruitment phase of the PQNIQ Trial, the details of callers who indicated an interest and who also appeared to be eligible for the study (based on the standard Quitline caller registration assessment that is undertaken for all callers) were automatically added to a call-back list on a computer-based registration system. The trial eligibility criteria were:

- aged 18 years or over
- first cigarette within 30 minutes of waking
- interested in quitting within next 2 weeks
- not pregnant or breastfeeding
- not currently using NRT or other noncigarette products
- not having had a stroke or heart condition in the past 3 months.

People with mental health conditions were not excluded. As many potential participants from this list who could feasibly be contacted in the time available by two research assistants (both experienced Quitline counsellors) were telephoned and invited to take part in the trial. We were able to set the proportion of Maori participants in the study by adjusting the sampling ratio of Maori:non-Maori according to self-reported ethnicity information provided at Quitline registration. Those people giving consent at this point were immediately randomly allocated by a web-based computer program to either the intervention or control group. A baseline questionnaire was administered during the phone call. After agreeing on a target Quit Day, the Quitline counsellor posted a voucher for NRT to the participant together with instructions for its use, as is standard practice. Follow-up in both study arms involved a proactive telephone call to all participants on the Quit Day and again at 1, 12 and 24 weeks postQuit Day. We conducted simple analyses of the first 12 months of the trial recruitment data.

Results

In 12 months of recruitment (March 2006 to February 2007), 26,369 smokers called the New Zealand Quitline. Of these, 17936 (68.2%) indicated an interest in participating in research and 5354 (28%) of this group met trial eligibility criteria according to the Quitline registration data (Figure 1). From these apparently eligible participants, 1317 were able to be contacted, in the time available to the research assistants, to invite participation in the trial. The majority of these (1037, 78%) gave consent but 184 (14%) were found on further enquiry to be ineligible. Thus, 851 callers (65% of those on the list of those contactable and invited to participate, 3.2% of all callers) were randomised. Similar proportions of Maori and non-Maori callers were successfully contacted from the call-back list (26% Maori vs. 24% non-Maori, $\chi^2 = 1.0$, $p = .3$) but the proportion of non-Maori declining participation or randomisation was significantly higher than for Maori (29% non-Maori vs. 22% Maori, $\chi^2 = 6.1$, $p = .01$).

Discussion

Findings and Interpretations

Most trials that have recruited participants through a quitline have been trials of some aspect of ??quitline support. For example, Zhu et al. (1996) embedded a randomised trial into the normal operation of the California Smokers helpline to test the effectiveness of its telephone counselling protocol. Gilbert and Sutton (2006) used a similar strategy to recruit callers to the UK Quitline into a randomised trial of repeated contact telephone counselling. Only a few trials have been reported that recruited and randomised through a quitline: Borland et al. (2001) randomised callers to the Australian Quitline into a trial of personally-tailored computer-generated advice letters versus usual treatment. A three-arm trial of different 'doses' of information about cigarettes recruited its participants from callers to the New York State Smoker's Quitline (Bansal et al., 2004). Balanda et al. (1999) randomised callers to the Queensland Quitline to receive either of two self-help cessation booklets. We were unable to identify any other quitline-based trials of interventions that used NRT (Medline search 1985–2007: search terms: cessation and ??smok$ and quit$ and trial$).

Quitlines potentially offer advantages over standard study recruitment methods for recruiting participants into cessation trials. First, being based in the setting of a health service they test the 'real-world' effectiveness of an intervention (Zhu et al., 2002) Second, as we and others have found, they have good potential to attract large numbers of participants in a relatively short time at low cost (Bansal et al., 2004; Gilbert & Sutton, 2006; Zhu et al., 2002). This is an attractive feature for trials with a 'usual care' control arm and where the intervention is likely to have only a modest effect. Having quitline-based research assistants, and using a web-based data management and randomisation system, made study processes (registration, consenting, randomisation, treatment allocation and follow-up calls) a highly efficient and seamless process. Participant data were entered directly into the system during each telephone call. Once verbal consent was obtained at the first call the participant was immediately randomised to intervention or usual care at a single key entry. The principal driver of trial cost is the time taken to recruit the study sample target. In this study we found it possible to keep recruitment well within acceptable time limits and thus within budget. Our capacity to draw on the substantial pool of people who indicated a willingness to participate in research was constrained largely by our budget — with more funding we could have employed additional research assistants and recruited at a faster pace. With more resources available to promote the Quitline the number of callers would

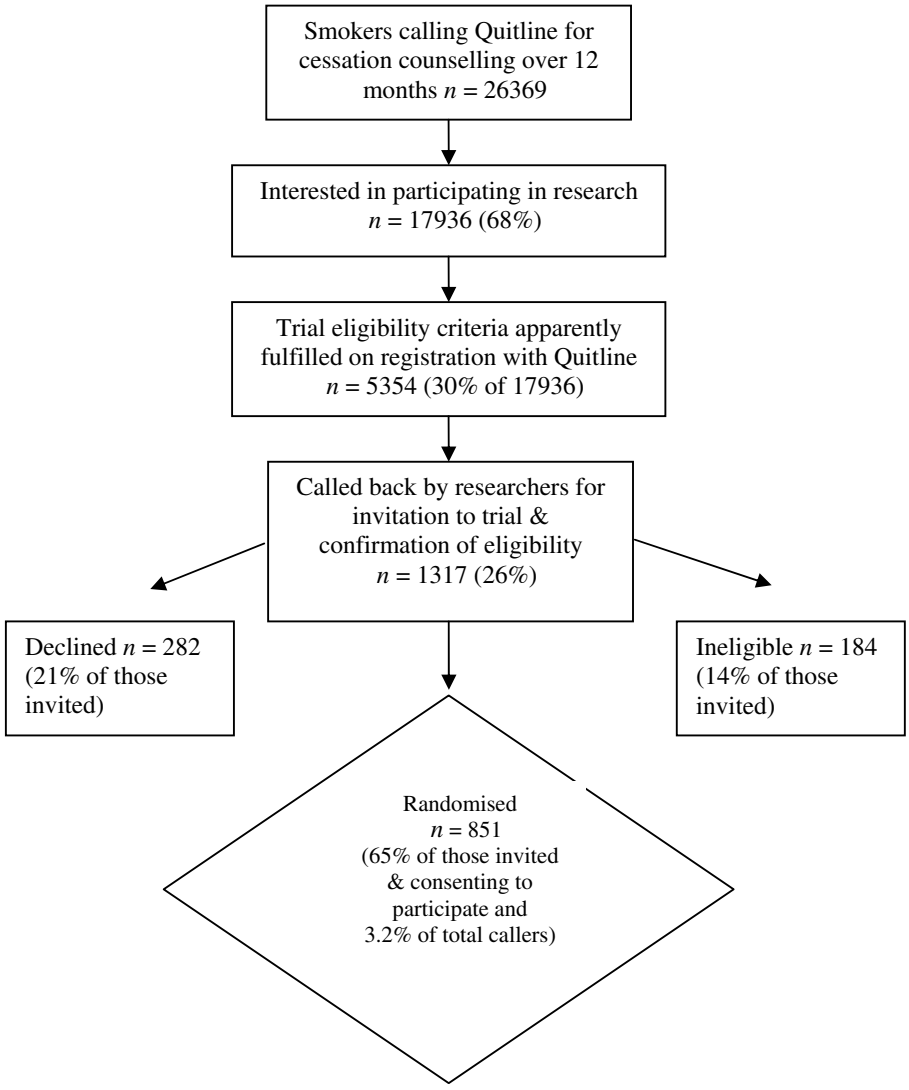

Figure 1
Flow of participants through recruitment and randomisation of trial.

likely have been even higher. Caller numbers are very sensitive to Quitline promotion on television (Wilson et al., 2005) and in the months when there was no television promotion of the Quitline there were periods when the numbers of callers fell markedly.

Importantly from an equity perspective, we found that the Quitline was an excellent source of Maori participants. Maori underuse primary care and other services compared to non-Maori New Zealanders, have a high smoking prevalence and a heavy burden of smoking-related illness (Holt et al., 2005), so it is especially important that cessation interventions that might work for them are trialled. Without sufficient numbers, analysis of consistency of effect with a larger population group, or assessment of an independent effect of the intervention, is not possible (Bramley et al., 2005). In our study, disproportionate 'over'-sampling of Maori callers was achieved by simply adjusting the call-up ratio to ensure that Maori formed 25% of all participants. This approach makes it feasible to include sufficient numbers of participants with particular sociodemographic characteristics of interest, or for whom underrepresentation is likely, so that at a minimum consistency of effect of an intervention may be assessed. Our finding that Maori participants were more likely to participate in our study than non-Maori was contrary to expectation and may reflect a greater desire among Maori smokers to try new ways of supporting a quit attempt when previous attempts have failed.

Despite several limitations and challenges presented by using this approach, none proved irresolvable. Slow internet connections between the Quitline and the study centre server (located in different cities) intermittently disabled the web-based data entry and randomisation process but were largely rectified with technology improvements over the course of the study. The time taken to obtain informed consent and elicit moderately

detailed information for the baseline and subsequent assessments (around 30–40 minutes) proved too much for some respondents, who withdrew. Without face-to-face contact between participant and researchers it is particularly challenging to sustain participant interest (Gilbert & Sutton, 2006). We found that the research assistants' skill in establishing and maintaining rapport was a critical success factor in limiting the numbers of early withdrawals. In anticipation of this we invested significant time and effort in selecting, training and supporting highly competent research assistants with extensive experience as Quitline advisors.

Because study participants were recruited from throughout New Zealand, it was not feasible to undertake face-to-face validation testing of the participants who reported quitting at 6 months after Quit Day. Instead, we collected saliva samples for cotinine testing only from the self-reported quitters residing in one large nearby city (with a quarter of the nation's population), representing around a quarter of those participants reporting at 6 months to have stayed 'quit'.

A potential limitation of recruiting study participants through quitlines is that individuals who use them may differ from other smokers, such as being more ready to quit than smokers recruited from other sources (Borland et al., 2001) or being heavier smokers than the general smoking population (Balanda et al., 1999). Thus an intervention that works for quitline callers might not be generalisable to all smokers. A recent analysis by the Quit Group suggests that callers to the New Zealand Quitline are similar in ethnicity to all smokers, although with slight underrepresentation of Asian and Pacific people (The Quit Group, 2007). Similarly males and older smokers are slightly underrepresented in callers to Quitline. With regard to dependence, there is evidence of a trend away from more dependent smokers among callers to Quitline, although they still comprise a substantial proportion of all callers (Li & Grigg, 2007). However, a far greater threat to external validity is a lack of internal validity, and this risk can only be mitigated by ensuring that a particular study is conducted to high standards of rigour.

Implications

We conclude that the benefits of using the New Zealand Quitline to recruit participants to cessation trials far outweighed any limitations, and indeed have conferred a distinct advantage over standard recruitment methods in enabling recruitment to a prespecified target of a particular population group of interest. Accordingly, our research group is using this same approach to recruit to a further two large cessation trials (each needing around 1400 participants) of interventions involving novel ways of using NRT. Other smoking cessation researchers elsewhere may find these principles and experiences useful in conducting their research, in particular where there is a need to recruit from underserved population groups.

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Competing Interests

This study was designed, conducted, analysed and interpreted independently of all sponsors.

Ethical Statement

On behalf of, and having obtained permission from all the authors, I declare that:

- the material has not been published in whole or in part elsewhere
- the article is not currently being considered for publication elsewhere
- all authors have been personally and actively involved in substantive work leading to the report, and will hold themselves jointly and individually responsible for its content
- all relevant ethical safeguards have been met in relation to patient or subject protection, or animal experimentation.

Connection With Tobacco, Alcohol, Pharmaceutical or Gaming Industry

The authors of this paper have no connection with the tobacco, alcohol, or gaming industry. Hayden McRobbie and Robyn Whittaker have received benefits in kind (hospitality, and so on) and travel support from, and have provided consultancy to the manufacturers of smoking cessation medications.

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