Addictive Behaviors 64 (2017) 13–20

Contents lists available at ScienceDirect

Addictive Behaviors

journal homepage: www.elsevier.com/locate/addictbeh

Predictors of retention in a randomised trial of smoking cessation in low-socioeconomic status Australian smokers☆,☆☆

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HIGHLIGHTS

- There is a paucity of evidence on the factors associated with low-SES populations retention in smoking cessation studies.
- This study is the first to ascertain which factors were associated with retention of low-SES smokers in a smoking cessation trial and to examine the association between smoking-related, health-related, behavioural, sociodemographic and recruitment source and retention.
- This paper identified a high retention rate of 84%.
- Rigorous reminders and participant reimbursement can prevent high attrition rates in low-SES populations.

ARTICLE INFO

Article history:
Received 25 March 2016
Received in revised form 20 July 2016
Accepted 30 July 2016
Available online 02 August 2016

Keywords:
Smoking cessation
Socioeconomic factors
Method
Retention
Randomized controlled trial

ABSTRACT

Background and aims: Little is known about the factors associated with retention in smoking cessation trials, especially for low-socioeconomic status (low-SES) smokers. This study examined the factors associated with retention of low-SES smokers in the *Australian Financial Interventions for Smoking Cessation Among Low-Income Smokers* (FISCALS) trial.
Design: A two-group parallel block randomised open-label trial with allocation concealment.
Setting: Australia. The study was conducted primarily by telephone-based interviews with nicotine replacement therapy delivered via mail.
Participants: 1047 low-SES smokers interested in quitting smoking were randomised.
Measurements: Participants completed computer assisted telephone interviews (CATIs) at baseline, 2-month and 8-month follow-up. Smoking-related, substance use, mental or physical health, general psychological constructs, sociodemographic and recruitment sources association with retention at 8-month follow-up were examined using binary logistic regression.
Findings: 946 participants (90%) completed the 2-month follow-up interview and 880 participants (84%) completed the 8-month follow-up interview. Retention at 8-months was associated with higher motivation to quit (OR: 1.15; 95% CI: 1.04, 1.27 $p < 0.01$), more recent quit attempts (OR: 1.20; 95% CI: 1.04, 1.40 $p < 0.05$), increasing age (OR: 1.05; 95% CI: 1.03, 1.07 $p < 0.01$), and higher level of education (OR: 2.24; 95% CI: 1.45, 3.46 $p < 0.01$). Lower retention at 8-months occurred for those participants recruited from posters placed in Department of Human Service Centrelink Offices (OR: 0.56; 95% CI: 0.35, 0.89, $p < 0.05$) compared to participants recruited

☆ Clinical trial registration: trial registered with the Australian and New Zealand Clinical Trials Registry (ACTRN) 12612000725864.
☆☆ Declaration of interests: Professor Billie Bonevski has received research funding from a Pfizer Investigator Initiated Grant. Professor Robert West undertakes research and consultancy for companies that develop and manufacture smoking cessation medications. He is unpaid co-director of the National Centre for Smoking Cessation and Training, a not-for-profit organisation involved in training and assessing stop smoking practitioners.

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http://dx.doi.org/10.1016/j.addbeh.2016.07.019

from Quitline services. No significant differences in retention were found for participants recruited via newspaper advertisements or word of mouth compared to Quitline services. No significant associations were found between health-related or behavioural factors and retention.
Conclusions: In the context of high overall retention rates from disadvantaged smokers in a randomised trial, retention was greater in those smokers with higher motivation to quit, more recent quit attempts, increased age, higher level of education and for those recruited through Quitline or newspaper advertisements.

1. Introduction

Participant attrition (Toerin, Brookes, Metcalfe, et al., 2009) is a potential problem in interpreting the findings of clinical trials especially when participants permanently drop out of a study (Lugtig, 2014). There are two principal types of participant attrition: (i) drop out/withdrawal (i.e. participants that no longer wish to participate in any further data collection/study demands); and (ii) loss to follow-up (i.e. participants who are not retained/or lost without reason) (Goldberg, Francois Chastang, Zins, et al., 2006). It is a common problem in clinical trials. For example, a review of health care intervention randomised control trials (RCTs) in six major journals (Toerin et al., 2009), found that 48% of trials that reported a sample size calculation failed to retain adequate numbers at outcome assessment (Toerin et al., 2009; Severi, Free, Knight, et al., 2011).

Excessive loss to follow-up can prolong recruitment, reduce statistical power, threaten the internal validity of study findings, compromise the generalisability of study outcomes, and waste money (Leon, Demirtas, & Hedeker, 2007; Szklo & Nieto, 2012). Study results can be biased when participants retained differ from those who are not (Robinson, Dennison, Wayman, et al., 2007) and bias may be even more pronounced when loss to follow-up differs between intervention and comparison groups (Sprauge, Leece, Bhandri, et al., 2003). Assessment of the characteristics/factors associated with attrition is needed (Goldberg et al., 2006) to assess for selection biases and loss of statistical power (Goldberg et al., 2006; Ellenberg, 1994; Hunt & White, 1998) and these need to be considered in study data analysis and interpretation (Goldberg et al., 2006; Shih, 2002; Twisk & de Vente, 2002). As a rule of thumb, some suggest that loss to follow-up under 5% will result in little bias but over 20% loss can significantly threaten study validity (Severi et al., 2011; Sprauge et al., 2003). Studies indicate that often those participants with incomplete follow-up data, while similar at baseline to those with complete data, may be systematically different at follow-up (Leak, Goggins, Schildcrout, et al., 2015; Woolard, Carty, Wirtz, et al., 2004). Consequently this may limit generalisability of the results and lead to incorrect inferences about treatment effects (Leak et al., 2015). It is imperative that researchers get as close to complete follow-up data as possible (Severi et al., 2011; Sprauge et al., 2003).

Low-socioeconomic status (low-SES) populations have lower participation rates and higher loss to follow-up rates (Bonevski, Randell, Paul, et al., 2014). Low-SES populations also have characteristics that make follow-up more difficult, including substance abuse and mental health disorders, housing instability, intermittent telephone access, incarceration, and less understanding of and exposure to research (Blumental, Sung, Coates, et al., 1995; Cunningham, Walton, Tripathi, et al., 2008; Ramos-Gomez, Chung, Gonzalez Beristain, et al., 2008). Lower education, low health literacy, and financial stress are also associated with incomplete research follow-up (Leak et al., 2015).

Systematic review evidence shows that few behavioural interventions for smoking cessation have been undertaken for low low-SES smokers (Bonevski et al., 2014; Bryant, Bonevski, Paul, et al., 2011; Courtney, Naicker, Shakeshaft, et al., 2015). For example, a recent review found only one Australian study that reported abstinence rates for smokers with a psychotic disorder (Bryant et al., 2011); however the factors associated with the high 83% retention obtained at 12-month follow-up was not evaluated (Baker, Richmond, Haile, et al., 2006; Baker, Richmond, Haile, et al., 2007). The most recent review examining attrition rates in smoking cessation studies found only nine studies (Belita & Sidani, 2015), and none had examined a low-SES or low income population. Consequently, this study is the first to describe and evaluate the factors associated with retention for low-SES smokers enrolled in a pragmatic RCT.

An increasing body of evidence indicates the challenge facing disadvantaged populations is staying quit, rather than forming the goal of quitting and trying (Borland, 2013). Low-SES smokers are understudied (Courtney et al., 2015) and they face some unique challenges that *may* reduce the likelihood of study retention. For example, low-SES smokers tend to have higher nicotine dependence (Bobak, Jarvis, Skodova, et al., 2000; Hyland, Borland, Yong, et al., 2006; Siahpush, McNeill, Borland, et al., 2006), in addition to more smokers in their social networks and stress in their day-to-day lives (Paul, Ross, Bryant, et al., 2010), but these factors association with retention are yet to be tested for low-SES smokers. In the general smoking population, smoking-related, socio-demographic, behavioural, and health-related factors have been linked to retention, but little is known about the role of these factors and recruitment source in retention of low-SES smokers. Length of previous quit attempts (Borrelli, Hogan, Bock, et al., 2002; Leeman, Quiles, Molinelli, et al., 2006) and confidence in quitting (Nevid, Javier, & Moulton, 1996) are associated with study retention but evidence is mixed for cigarettes smoked per day (Nevid et al., 1996; Bowen, McTiernan, Powers, et al., 2000; Curtin, Brown, & Sales, 2000). On the whole, the association between study retention and other socio-demographic characteristics (e.g. age, (Leeman et al., 2006; Fortman & Killen, 1994), education level, (Borrelli et al., 2002; Curtin et al., 2000) sex, (Greenberger & Knab, 2000) and number of dependent children) (Leeman et al., 2006), behavioural/psychological factors (e.g. weight concerns (Leeman et al., 2006), feelings of guilt, IQ (Beaver, 2013; Lynham, Moffitt, & Stouthamer-Loeber, 1993)) and health-related factors (e.g. depression (Curtin et al., 2000), body mass index (BMI) and other health risk behaviours) (Goldberg et al., 2006; de Graaf, Bijl, Smit, et al., 2000; Deeg, van Tilburg, Smit, et al., 2002; Morrison, Wahlgreen, Hovell, et al., 1997; Siddiqui, Flay, & Hu, 1996) is conflicting.

Further, there is an absence of data from smoking cessation clinical trials in socially disadvantaged populations (Bonevski et al., 2014). Many studies have failed to analyse the independent contributions of these factors to follow-up (Leak et al., 2015). Little effort has been made to investigate other factors that may be more salient in low-SES population groups, for example mental health disorders and poorer physical health (Leak et al., 2015). If factors associated with drop out in smoking cessation trials in low-SES populations are identifiable at study commencement, measures can be taken to enhance retention (Nowak, Sharif, Eischen, et al., 2014).

1.1. Aims and objectives

Our aims were to: (1) describe the retention rates in the *Financial Interventions for Smoking Cessation Among Low-Income Smokers* (FISCALS) RCT and (2) identify whether smoking-related, health-related, behavioural, socio-demographic characteristics, or recruitment source were associated with retention at 2- or 8-month follow-ups.