Preventive Medicine 112 (2018) 38–44

Contents lists available at ScienceDirect

Preventive Medicine

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

Smoking cessation intervention delivered by social service organisations for a diverse population of Australian disadvantaged smokers: A pragmatic randomised controlled trial

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ARTICLE INFO

Keywords:
Smoking cessation
Disadvantaged population
Vulnerable groups

ABSTRACT

Objectives: There remains a need to identify effective smoking cessation interventions in severely disadvantaged populations. This trial aimed to examine the effectiveness of an intervention (Call it Quits) developed to promote smoking cessation and delivered by community social service case-workers.

Methods: Call it Quits was a pragmatic, parallel randomised trial of a case-worker delivered smoking cessation intervention conducted in a non-government community social service organisation in New South Wales (NSW), Australia. Adult smokers requiring financial assistance were randomly assigned to the five-session Call it Quits intervention or usual care control group. Of the 618 eligible individuals, 300 were randomised to the intervention group, of whom 187 (62%) consented and 318 were randomised to the control group, of whom 244 (77%) consented, resulting in 431 participants.

The primary outcome measure was self-reported continuous abstinence up to 6-month follow-up with biochemical verification. Primary analysis was performed using all the available data from participants under the assumption the data is missing completely at random, followed by sensitivity analyses.

Results: No statistically significant differences in the primary outcome were found (1.4% in the control group versus 1.0% in the intervention group, OR = 0.77, p = 0.828).

Conclusions: A multi-component smoking cessation intervention delivering motivational interviewing-based counselling and free NRT by a trained case-worker within a community social service setting was not effective at achieving abstinence in a highly disadvantaged sample of smokers but increased attempts to stop and led to a reduction in number of cigarettes smoked daily.

Trial registration

This study was registered with Australian New Zealand Clinical Trials Registry (ISRCTN85202510).

1. Introduction

In high-income countries, tobacco smoking rates are highest amongst people with mental illness and substance use disorders, the long term unemployed and homeless populations, and Indigenous peoples (Hiscock et al., 2012). Rates of tobacco-related diseases such as cardiovascular disease, cancer and chronic respiratory diseases are subsequently much higher in these groups (Lawrence et al., 2013).

Smokers from these disadvantaged, low socioeconomic groups find it harder to quit than more socioeconomically advantaged smokers (Hiscock et al., 2012; Kotz and West, 2009). Existing evidence for the effectiveness of smoking cessation interventions for disadvantaged groups is inconsistent and inconclusive. Two systematic reviews of smoking cessation interventions for six disadvantaged groups known to have high smoking rates in high-income countries suggest that multi-component interventions incorporating behavioural counselling either face-to-face or via telephone, motivational interviewing, and NRT hold

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https://doi.org/10.1016/j.ypmed.2018.04.005
Received 8 November 2017; Received in revised form 22 February 2018; Accepted 2 April 2018
Available online 05 April 2018

the greatest promise of successfully achieving abstinence amongst some disadvantaged groups but not all (Bryant et al., 2011; Wilson et al., 2017).

Delivering comprehensive smoking cessation interventions to smokers who experience disadvantage is challenging as these smokers are often hard-to-reach and as a result sample sizes are small (Bryant et al., 2011; Wilson et al., 2017; Bonevski et al., 2014). In high-income countries including the UK, US and Australia, community social service organisations (CSSO) provide support to the most socially disadvantaged groups (Bonevski et al., 2012) with high smoking rates (Christiansen et al., 2010). Small pilot smoking cessation trials suggest that the CSSO setting might be acceptable and feasible, (Christiansen et al., 2010; Bryant et al., 2012) however, the effectiveness of this approach has not been evaluated in an adequately powered trial.

1.1. Objectives

The primary aim of this study was to examine the effectiveness of a CSSO case-worker delivered intervention (Call it Quits) for a diverse population of severely disadvantaged smokers on verified continuous abstinence at six month follow-up.

2. Methods

2.1. Study design and setting

Call it Quits was a parallel randomised trial of a case-worker delivered smoking cessation intervention (Bonevski et al., 2011). The study was conducted in a large Community Care Centre, managed by a national non-government organisation located in New South Wales (NSW) Australia providing counselling, emergency housing and financial aid.

2.2. Participants

Participants were adult clients of the Community Care Centre, who self-reported smoking daily or occasionally, with sufficient English language to give informed consent. Clients who presented to the centre in an inebriated or agitated state or were too distressed (distress related to factors contributing to accessing emergency relief) to participate were excluded.

As clients arrived at the Centre, eligibility was assessed by a research assistant who obtained written consent. First, the research assistant asked participants to complete a general health survey on a touchscreen laptop computer. Second, participants who reported smoking tobacco daily or occasionally were asked by the research assistant to participate in a study where they may or may not receive a smoking cessation program requiring them to return to the Centre. Participant sociodemographic and smoking characteristics were collected during the computer-administered general health survey (Supplementary file 1).

2.3. Randomisation and masking

A computer generated randomisation schedule which was embedded into the computer survey software allocated trial participants in a 1:1 ratio to intervention or control group. The randomisation schedule was developed by an independent computer programmer, incorporated into the Digivey survey software, (Creoso Corporation, 2016) and tested prior to the trial commencing. At enrolment, the sequence was concealed from the research assistant who gained consent into the trial and conducted follow-up assessments. Participants were made aware of their group following allocation with a paper print-out after they completed the computer survey.

2.4. Interventions

All participants received on-screen advice to quit smoking, the state Quitline telephone number, and a “gift bag” with Call it Quits branded gifts. All participants were asked to return to the centre at 1 month and 6 month follow-up for data collection. No further intervention was offered to control group participants.

The smoking cessation intervention which was drawn from existing evidence, the PRIME theory of motivation, (West and Hardy, 2006) and the taxonomy of Behaviour Change Techniques (BCTs), (Michie et al., 2013) used brief advice and motivational interviewing techniques to encourage setting a quit date and maximise use of NRT, (Stead et al., 2016) and provide social support (May et al., 2007). Free NRT was offered to all participants in the intervention group. Combination use of fast acting and sustained release NRT was encouraged based on evidence of increased effectiveness compared with single NRT type use (Stead et al., 2016). The schedule of counselling sessions for intervention delivery included three face-to-face sessions and two telephone sessions. The counselling sessions were delivered by trained volunteer case-workers to mirror usual counselling practice at the Centre and followed a written intervention manual (Supplementary file 2) which incorporated 46 BCTs. The emphasis was on setting a quit date, encouraging use of NRT, managing withdrawal symptoms and urges to smoke, enhancing self-efficacy, social support and prevention of relapse.

Evidence-based strategies were employed to minimise attrition (Bonevski et al., 2014) including collection of comprehensive contact information for the participant and a significant other, flexible scheduling of follow-up assessments with reminder text messages and calls, and project branded gift bags. All participants received up to $120AUD grocery voucher for completion of the surveys.

2.5. Outcomes

The primary outcome was CO verified self-reported continuous abstinence at six months follow-up, with abstinence defined according to the Russell Standard (modified – regarding treatment of missing cases, see below) (West et al., 2005). Prior to un-blinding and data analysis, this was changed from the original protocol outcomes of 24-hour CO verified self-reported abstinence and 7-day point prevalence self-reported abstinence based on recommendations that six months continuous abstinence is the more relevant outcome for evaluating longer-term cessation and health impacts (Hughes et al., 2003). At the same time the 12 month follow-up was abandoned due to concerns regarding attrition and resourcing. To be classified as abstinent, participants had to report that they had smoked fewer than five cigarettes in each of the previous six months, from two weeks after the baseline (grace period) at the six-month follow-up visit and that they had not smoked any cigarettes in the week before the follow-up visit. As explained in the protocol paper, (Bonevski et al., 2011) although cotinine is the recommended gold standard measure for the verification of smoking status, it was impractical and invasive in this study and abstinence was verified by the concentration of exhaled CO of < 10 ppm (Benowitz et al., 2002). All participants were asked to return to the centre to provide a CO reading, regardless of whether they reported abstinence.

Secondary outcomes were self-reported continuous abstinence at 1 month follow-up, and at both 1 month and 6 month follow-up self-reported and verified 7 day point prevalence abstinence, cigarettes smoked per day, and number of serious attempts to quit in the last month.

To assess adherence to the intervention, participation in face-to-face and telephone sessions was recorded by counselling case-workers and participants were asked about use of NRT. Audio-recordings of 67 counselling sessions were coded for manual-specified BCT delivery.