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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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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).

Keywords

Smoking cessation; disadvantaged population; vulnerable groups

Highlights

- First smoking cessation trial in a community based social service setting
- Participants were socioeconomically disadvantaged smokers with comorbidity
- Case-worker delivered intervention were not effective at aiding abstinence
- Important gains were made in reductions in cigarettes smoked and quit attempts.

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.[1] Rates of tobacco-related diseases such as cardiovascular disease, cancer and chronic respiratory diseases are subsequently much higher in these groups.[2]

Smokers from these disadvantaged, low socioeconomic groups find it harder to quit than more socioeconomically advantaged smokers.[1,3] 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 multicomponent interventions incorporating behavioural counselling either face-to-face or via telephone, motivational interviewing, and NRT hold the greatest promise of successfully achieving abstinence amongst some disadvantaged groups but not all.[4,5]

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.[4-6] In high-income countries including the UK, US and Australia, community social service organisations (CSSO) provide support to the most socially disadvantaged groups[7] with high smoking rates.[8] Small pilot smoking cessation trials suggest that the CSSO setting might be acceptable and feasible,[8,9] however, the effectiveness of this approach has not been evaluated in an adequately powered trial.

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.

Methods

Study design and setting: Call it Quits was a parallel randomised trial of a case-worker delivered smoking cessation intervention.[10] 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.

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).

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,[11] 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.

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,[12] and the taxonomy of Behaviour Change Techniques (BCTs),[13] used brief advice and motivational interviewing techniques to encourage setting a quit date and maximise use of NRT,[14] and provide social support.[15] 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.[14] 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[6] 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.

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).[16] 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.[17] 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,[10] 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 less than 10 ppm.[18] 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.

Statistical analysis: The statistical analysis plan was approved by all investigators before un-blinding (available upon request). Primary analysis was performed using all the available data from participants under the assumption the data is missing completely at random , followed by a range of sensitivity analyses to investigate the impact of departures from the missing data assumptions.[19] As recommended by the CONSORT statement, statistical analyses were conducted on all primary and secondary outcomes, and not on baseline data.

The primary outcome measure - continuous abstinence from baseline (with a two week grace period) – requires that participants be abstinent at both one month and six month follow-up.[16] Thus participants who are missing outcome data at six months, but are followed up at one month and are not abstainers at this time are by definition not continuous abstainers at six months and were classified as such in the analyses. All other participants with missing outcome data were excluded from the primary analysis.

The primary analysis of CO verified continued abstinence from baseline involved a logistic regression model of all available observations (according to the definition above). SAS 9.4 and Stata 13 were used for all analyses, and statistical significance was defined a priori as $p<0.05$. Due to the very small number of participants with the outcome, we did not adjust for the *a priori* covariates (age, gender, marital status, housing status, income, education, postcode, nicotine dependence, quit attempts, use of cessation aids, partner smoking behaviour depression and financial stress) specified for inclusion in the analyses.[10,20] Part way through the study recruitment we discovered a breach in protocol in that some participants were informed of their allocated intervention group prior to obtaining consent. This problem was rectified after 25 participants had been recruited, and blinding to allocation was maintained prior to seeking consent for the remainder of recruitment. However, due to the potential for this to introduce some participation bias, the regression model for the

primary analysis initially included a variable indicating whether individuals had been informed of their intervention status prior to consent. As this variable had no impact on the intervention effect, to preserve power it was excluded from the final model.

For the secondary outcomes a logistic regression model for abstinence outcomes was used (validated continuous abstinence at 1 month, self-reported continuous abstinence, CO confirmed and self-reported 7-day point prevalence abstinence at one and six months), unadjusted for covariates. Linear regression models were used for the number of cigarettes smoked per day, and a negative binomial model for number of quit attempts adjusted for whether or not participants had been informed of their intervention status prior to consent, Heaviness of Smoking Index, depression and anxiety (PHQ4), and self-efficacy, and for number of cigarettes, quit method at baseline was included as a covariate due to possible imbalance between treatment groups at baseline. Robust standard errors were applied to the linear regression to account for slight deviation in the heteroscedasticity of residuals.

For all outcomes, three types of sensitivity analyses were undertaken to include all participants, consistent with the intention-to-treat (ITT) principle: 1) multiple imputation (MI)[21,22] with chained equations to allow for appropriate estimates of variance; 2) analysis considering individuals with missing outcome as worst case outcomes (not continuous abstainers, no change in number of cigarettes smoked and no quit attempts), consistent with common methods of analysis of smoking cessation trials;[16] and 3) using pattern mixture models (PMM),[23] consistent with a Missing Not at Random mechanism.

Based on previous pilot studies with similar populations,[24] we estimated that the control group quit rate would be 5%. On the basis that an 8% absolute difference in abstinence would be clinically important (i.e., 13% vs 5%), we calculated that a study size of 400 participants

(200 per group), allowing for a 30% loss to follow-up, would have 80% chance of detecting this difference with a 5% (two-sided) significance level.

Results

Figure 1 shows the recruitment and follow-up of participants from 7th February 2012 to 21 July 2014. Of the 301 excluded, 254 (84.4%) were non-smokers, 17 (5.6%) were under the influence of alcohol or other drugs, 8 (2.7%) were too distressed to complete the survey (distress related to factors contributing to accessing emergency relief), and 16 (5.3%) had no reason recorded and 6 (2.0%) experienced technical issues. 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 control group had a higher completed follow-up rate (return for both 1 and 6 month follow-up visits) than the intervention group.

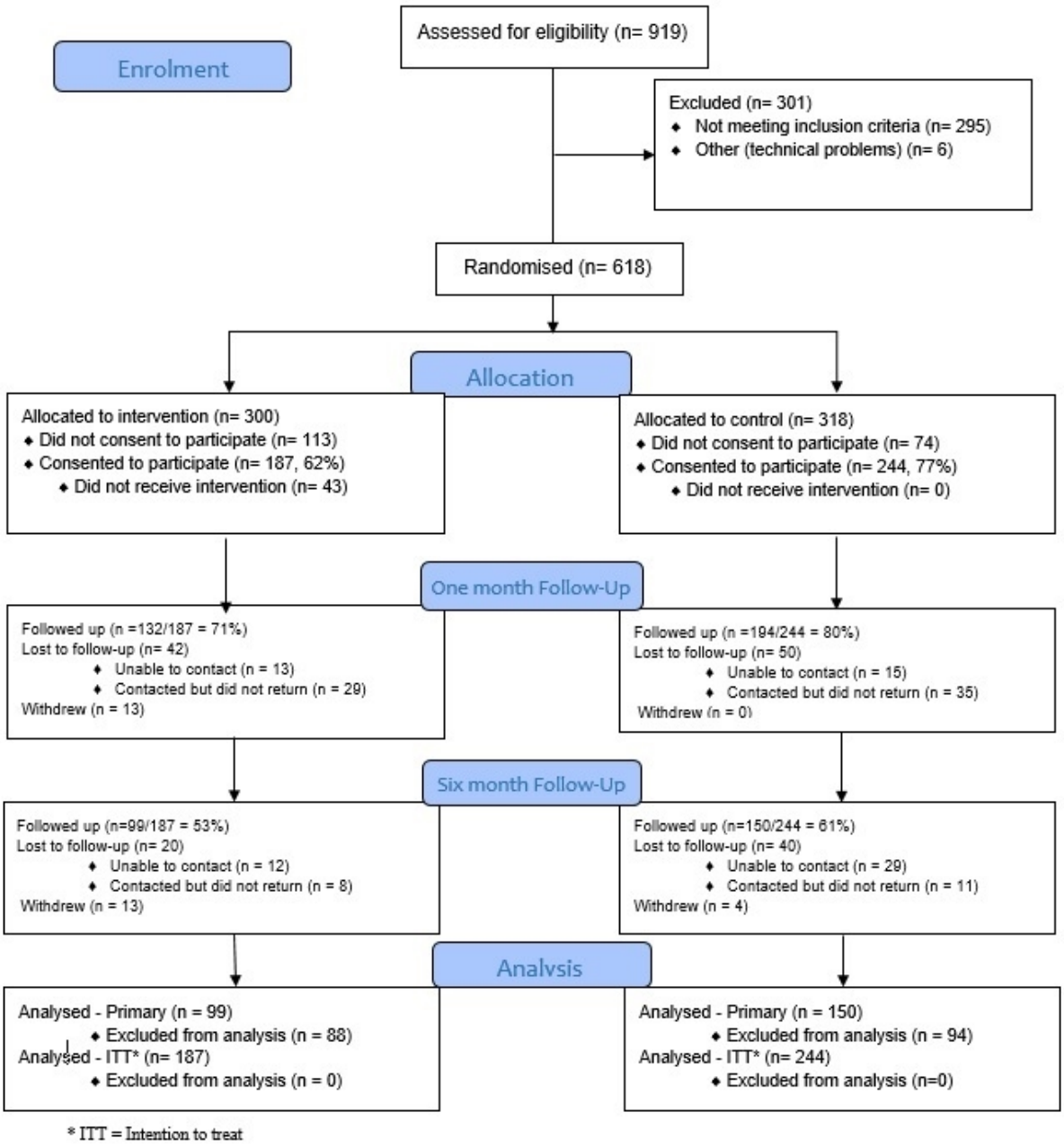

Figure 1. CONSORT Flow diagram

Treatment groups were well balanced with respect to baseline characteristics, with the possible exceptions of fewer participants in the control group who were separated/divorced (Table 1), or last tried to quit smoking by gradually cutting down on cigarettes (Table 2).

Table 1. Participant sociodemographic and psychosocial variables at baseline by treatment group (n=431)

Characteristic	Control (n=244) n (%)	Intervention (n=187) n (%)	Total n (%)
Age in years – Mean (SD)	38 (11)	37 (12)	38 (11)
Gender			
Male	126 (52)	95 (51)	221 (51)
Female	118 (48)	92 (49)	210 (49)
Housing			
Own house	7 (3)	6 (3)	13 (3)
Rental	68 (28)	60 (32)	128 (30)
Supported/government housing	119 (49)	87 (47)	206 (48)
Family/friends/motel/street/other	50 (20)	34 (18)	84 (19)
Aboriginal and/or Torres Strait Islander	48 (20)	26 (14)	74 (17)
Marital status			
Married/living with partner	31 (13)	22 (12)	53 (12)
Divorced or separated	66 (27)	67 (36)	133 (31)
Never married/single	140 (57)	95 (51)	235 (55)
Widowed	7 (3)	3 (2)	10 (2)
Education completed			
Completed up to primary school (grade 6)	43 (18)	39 (21)	82 (19)
Completed secondary school (grade 10-12)	136 (56)	101 (54)	237 (55)
Tertiary qualifications	65 (27)	47 (25)	112 (26)
Income amount*			
Less than $200 per week	68 (30)	47 (27)	115 (28)
$201-$400 per week	130 (57)	104 (59)	234 (58)
More than $400 per week	31 (14)	24 (14)	55 (14)
Income source			
Paid employment (full or part time)	8 (3)	6 (3)	14 (3)
Government benefit	230 (94)	176 (94)	406 (94)
Other	6 (3)	5 (3)	11 (3)
Contact with family			
Never/no family	36 (15)	32 (17)	68 (16)
1-3 days per month/< once a month	72 (30)	46 (25)	118 (27)
1-2 days per week	49 (20)	41 (22)	90 (21)
3-4 days per week or more	87 (36)	68 (36)	155 (36)
Family you can rely on			
No family can rely on	69 (28)	62 (33)	131 (30)
1-2 family members	136 (56)	92 (49)	228 (53)
3 or more	39 (16)	33 (18)	72 (17)
Alcohol use			
Risky consumption	136 (56)	116 (63)	252 (59)
Non-risky/safe consumption	41 (17)	24 (13)	65 (15)
No consumption	64 (27)	44 (24)	108 (25)
Financial stress – mean (SD)	5.7 (1.7)	5.7 (1.8)	5.7 (1.7)
Depression – median (Q1, Q3)	13 (7, 19)	10 (7, 18)	12 (7, 18)
Anxiety – median (Q1, Q3)	4 (2, 6)	2 (2, 5)	3 (2, 5)
Resilience – mean (SD)	2.8 (0.8)	2.8 (0.8)	2.8 (0.8)
Allocation revealed at recruitment	18 (7%)	7 (4%)	25 (6%)

* All currency in AUD

Table 2. Participant smoking-related variables at baseline by treatment group (n=431)

Characteristic	Control (n=244) n (%)	Intervention (n=187) n (%)	Total n (%)
Cigarettes smoked per day - median (Q1, Q3)	15 (10, 20)	15 (10, 20)	15 (10, 20)
Heaviness of Smoking Index			
Low	76 (35)	54 (32)	130 (34)
Moderate	103 (48)	91 (54)	194 (51)
High	37 (17)	23 (14)	60 (16)
Enjoyment of smoking			
Very much	29 (12)	29 (16)	58 (13)
Quite a bit	80 (33)	58 (31)	138 (32)
Not particularly	81 (33)	60 (32)	141 (33)
Not at all	30 (12)	24 (13)	54 (13)
Don't know	24 (10)	16 (9)	40 (9)
Smoker identity			
Happy about being a smoker	15 (6)	11 (6)	26 (6)
Unhappy about being a smoker	95 (39)	81 (43)	176 (41)
Hate being a smoker	85 (35)	64 (34)	149 (35)
Don't know	49 (20)	31 (17)	80 (19)
Intention to stop smoking			
Quit in the next 30 days	50 (20)	33 (18)	83 (19)
Quit in the next 6 months	58 (24)	63 (34)	121 (28)
Quit but not in next 6 months	42 (17)	18 (10)	60 (14)
Never quit	11 (5)	3 (2)	14 (3)
Don't know	83 (34)	70 (37)	153 (35)
Motivation to quit			
High	85 (35)	77 (42)	162 (38)
Moderate	101 (42)	80 (43)	181 (42)
Low	57 (23)	28 (15)	85 (20)
Ever made serious quit attempt/ Yes	203 (83)	159 (85)	362 (84)
Number of serious quit attempts in previous 12 months			
0-1			
2 or more	139 (57)	109 (58)	248 (58)
	104 (43)	78 (42)	182 (42)
Method at last quit attempt			
Stopped smoking abruptly	84 (41)	50 (31)	134 (37)
Gradual reduction	100 (49)	97 (61)	197 (54)
Can't remember	19 (9)	12 (8)	31 (9)
Quitting self-efficacy			
Extremely sure	26 (11)	18 (10)	44 (10)
Very sure	26 (11)	26 (14)	52 (12)
Moderately sure	67 (27)	43 (23)	110 (26)
Slightly sure	47 (19)	40 (21)	87 (20)
Not at all	78 (32)	60 (32)	138 (32)
Friends or family who smoke			
Most or all	96 (39)	74 (40)	170 (39)
About half	61 (25)	43 (23)	104 (24)
Less than half/some	69 (28)	53 (28)	122 (28)
None	18 (7)	17 (9)	35 (8)

Figure 2 shows no statistically significant difference between intervention groups in the primary outcome of verified continuous abstinence at six months follow-up (1.4% and 1.0% for intervention and control groups; OR 0.77, 95% CI 0.07-8.53, p=0.828).

There were also no statistically significant differences between groups in the secondary outcomes at six months of self-reported continuous abstinence, verified 7-day point prevalence abstinence, and self-reported 7-day point prevalence abstinence. Participants in

the intervention group reported a significantly lower adjusted mean number of cigarettes smoked per day than those in the control group (7.8, 95% CI 4.7-10.8 versus 12.7, 95% CI 9.8-15.6, p<0.001), and a higher adjusted mean number of quit attempts at six months (3.6, 95%CI 2.2-5.9 versus 1.6, 95% CI 1-2.3, p < 0.001).

There was no statistically significant difference between intervention groups in any of the one month abstinence outcomes. At one month follow-up the intervention group showed significantly fewer adjusted mean number of cigarettes smoked per day than control group (10.36, 95%CI 7.68-12.910.8 versus 14.68, 95%CI 12.37-17, p<0.001).

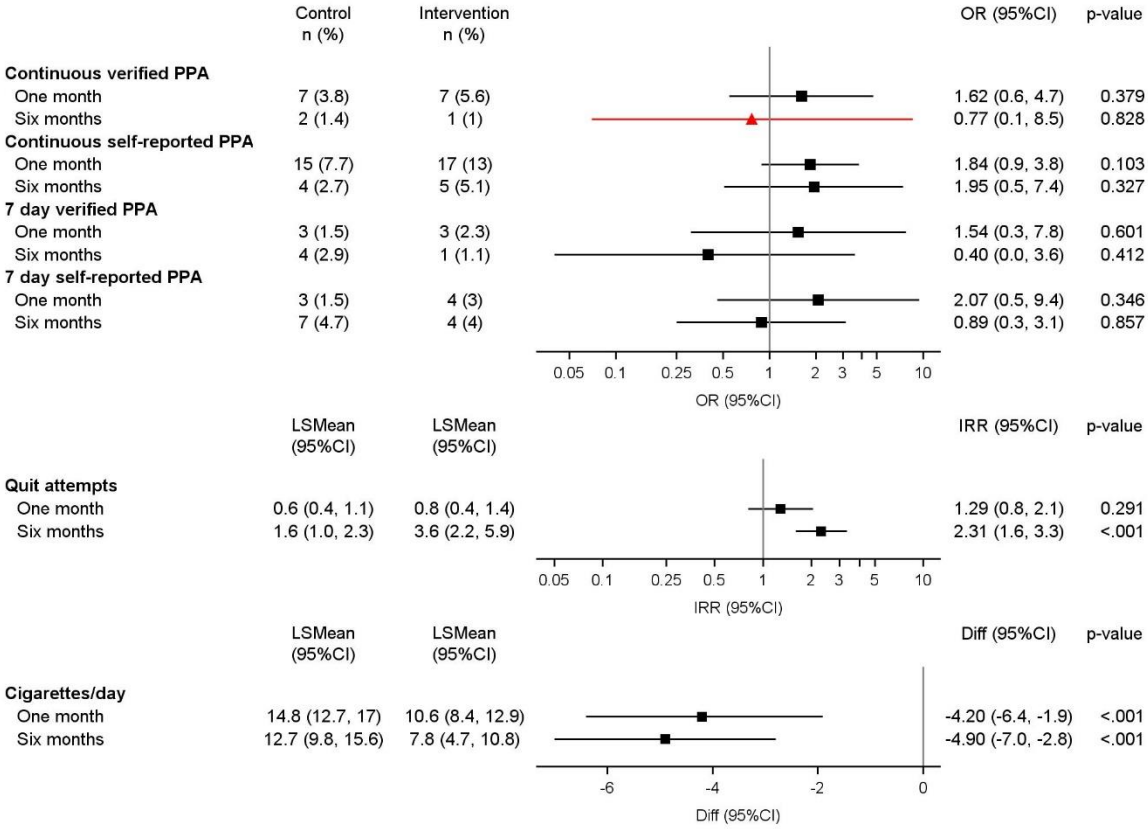

Figure 2. Forest plot of primary and secondary outcomes at 1 month (n=326) and 6 months (249) follow-up. ORs greater than 1 signal that the outcome was favourable for the intervention group.

Overall 326 (76%) participants had a one month follow-up and 249 (58%) had a six month follow-up. Lack of follow-up was predominantly monotone with 5.6% returning for six month follow-up not having attended one month follow-up. Age was associated with being missing only in the intervention group (younger in missing: mean 34 years, SD 10 than present: mean 41 years, SD 12; $p < 0.001$) and income was associated with being missing only in the control group (lower income in missing than present, $p=0.035$).

Sensitivity analyses (MI, worst case and PMM) showed similar results to the available case analysis for the majority of outcomes indicating the results were robust to the treatment of missing data. Estimates of the intervention effect for number of cigarettes smoked per day at 6 months varied between analysis approaches: under worst case the effect had diminished but was still significant (a difference of 2 cigarettes per day, $p=0.02$; and for MI we estimated a non-significant difference of 3 cigarettes per day ($p=0.12$). Pattern mixture modelling estimated a nullified treatment effect occurred if the missing participants were smoking at least 16 cigarettes a day more than those without missing data (an unlikely scenario).

Intervention adherence: Of those randomised to the intervention group (n=187), 43 (23%) did not attend any counselling sessions. Of those who did attend, 22 (15%) attended one session, 30 (21%) attended two sessions, 22 (15%) attended three sessions, 25 (17%) attended four sessions and 45 (31%) attended all five sessions. Based on the audio-recording of 67 counselling sessions, the face-to-face sessions (sessions 1-3) averaged 18.09 minutes in length (range = 7.16 – 46.44 minutes) and the average length of phone sessions (sessions 4-5) was 5.88 minutes (range = 1.53 – 14.53 minutes). In total, 128 intervention group participants accepted an offer of NRT. Analysis of 67 counselling session audio-recordings show that, on average, fidelity to the treatment manual varied from 46% in the initial sessions, 31% in second face to face sessions and 39% in telephone follow ups.

Discussion

Principal findings

A smoking cessation intervention incorporating behavioural counselling with the option of NRT delivered to highly disadvantaged smokers through a community social service by trained case-workers resulted in no higher abstinence rates than no intervention. Abstinence rates at six months follow-up were low for both groups. Participants in the intervention group reported more quit attempts and fewer cigarettes smoked at both one and six month follow-up.

This trial is similar to previous trials with homogeneous groups of disadvantaged smokers (such as people with a mental illness, Indigenous Australians and prisoners) which have found low cessation rates and null outcomes for the behavioural and pharmacotherapy interventions.[4,5] The body of evidence emerging implies that these smokers find it difficult to quit, even when provided with current best practice smoking cessation aids.[4,5] The current intervention was evidence based with brief advice, behavioural counselling and BCTs, offer of combination NRT, social support and follow-up. One obvious explanation for the lack of effect may be low adherence to the intervention. The process measures collected suggest that only about a third of smokers attended all five counselling sessions and almost a quarter did not attend any at all. Not all participants in the intervention group took up the offer of free NRT (128 of 187), and of those who did take up the offer, many did not persist with the full recommended course. The outcomes suggest that more effort at increasing adherence to treatment is required. Contingency management, with even small financial and non-financial rewards for attendance to counselling sessions and adherence to treatment, is an approach with evidence of effectiveness with samples of people who use substances.[25]

Another explanation for the negative outcome is that, while the intervention may represent best practice for the general population of smokers, it may be insufficient to address the complex needs of smokers from highly disadvantaged groups experiencing comorbidities. There are a number of modifications that could be made to the intervention to strengthen it. Firstly, the provision of brief advice and motivational interviewing across five counselling sessions by minimally trained volunteers appears not to be effective for this group of smokers. Other research since this trial has shown that smokers receiving support in specialist stop smoking centres tend to have a higher short-term quit rate, compared with those receiving support in other settings from professionals for whom smoking cessation is only a part of their work.[26] The current sample reported high scores for anxiety, depression, health-risk alcohol use and financial stress. Referring disadvantaged smokers to more qualified counsellors with experience in managing comorbidities is likely to strengthen the behavioural component of the intervention.

Secondly, it is likely that the intervention would be substantially strengthened through the use of best-practice NRT, with or without other forms of pharmacotherapy for smoking cessation. For example, Cochrane reviews have shown that varenicline and bupropion result in higher cessation rates than NRT alone[27] and are safe for people with mental illness.[28] Furthermore, there are recent suggestions that for smokers who can't quit or who don't want to quit, the harm of tobacco can be substantially reduced by switching to alternative vaporised forms of nicotine delivery.[29] This is an area that deserves more attention for heavy smokers in disadvantaged groups who have tried quitting using other cessation treatments and have failed.

Finally, lack of secure housing, employment, and high prevalence of Indigenous status were also characteristics of the sample. Smoking behaviours are part of the social, cultural and

economic context and environment for smokers from disadvantaged groups.[30] Investment in improving the material and social capital of groups in our society who are disadvantaged is likely to lead to improvement in health behaviours such as smoking. The CSSO setting that this trial used is an ideal vehicle for approaching this issue, however greater investment by government in providing other forms of support to these smokers is likely to improve their chances in quitting smoking and leading healthier lives.

This trial recruited all smokers regardless of motivation level. The study found a significant increase in quit attempts due to the intervention. Furthermore, the intervention resulted in fewer cigarettes smoked over the six-month follow-up period, again implying that the intervention encouraged some action, which was insufficient in itself to achieve longer term cessation. Testing interventions that are applied for longer and with prolonged use of pharmacotherapy support is warranted.

Strengths and weaknesses

The most significant limitations relate to participant consent and attrition. While 49% of participants were randomly allocated to the intervention group (n=300) and 51% to the control group (n=318), a higher proportion consented in the control group (n=244; 77%) than the intervention group (n=187; 62%). The recruitment procedure involved assessing individuals' smoking status during the health survey was completed on a touchscreen laptop computer; all individuals who reported being current smokers were randomised by the software to either intervention group or control group and consent for participation in the study was then sought. The study protocol specified that consent was sought by the research assistant prior to checking the allocation of the individual. However, due to a breach in protocol, the first 25 participants were made aware of their allocation prior to consent-

gaining, resulting in greater consent into the control group. Similarly, knowledge they would be required to return to the centre for three face-to-face counselling sessions if randomised to the intervention group may have been a disincentive for some. For the remainder of the recruitment, the research assistant and participants were blinded to allocation prior to obtaining consent. The impact of the lack of blinding of allocation for the initial participants had some impact on the group numbers, which was exacerbated by more participants in the intervention group withdrawing consent following allocation to group. The possible bias is likely to be small as baseline characteristics were similar between the two intervention groups. The attrition rates were high but not unusual for studies of this type[11] and were reasonably similar for the two intervention groups, 47% in the intervention group and 41% in the control group at 6 month follow-up. The imbalance in numbers highlights the difficulties in recruiting smokers in disadvantaged groups into smoking cessation trials. Evidence-based strategies were employed to boost retention, and attrition may have been greater had these strategies not been used. The consistency in the results from primary and sensitivity analysis to account for missing data points provide confidence that the impact of attrition is minimal. Also, the generalisability of the study is limited to similar CSSOs within high-income countries and their clients.

The study has a number of strengths. This trial is one of the first to include a large and diverse sample of highly disadvantaged smokers, recruiting 431 participants, regardless of motivation to quit. Abstinence was verified using carbon monoxide readings. Self-reported abstinence rates were higher than confirmed abstinence, particularly in the intervention group highlighting the importance of objective verification of abstinence self-report. Our sensitivity analysis used multiple imputation as described in the methods in addition to traditional approaches to missing data in smoking cessation studies because evidence shows that the assumptions underpinning multiple imputation are more defensible than are those assumed

when using other approaches to missing data. The results of the sensitivity analyses were consistent with the primary analyses indicating robustness of these analyses.

Implications from this research

New smoking cessation interventions for smokers from socially disadvantaged groups need to be developed and tested. The current study was conducted in the context of a high-income country with strong tobacco control measures and low general population smoking prevalence rate. Smokers who are highly socially disadvantaged appear to require more intensive smoking cessation interventions and possibly longer term, than smokers from the general population or more affluent groups. This has implications for resourcing and timeframes. Referral to specialist services or additional training for counsellors and care providers may be appropriate. Furthermore, new stop smoking medicines have become more readily available since this trial, including varenicline which has strong evidence of effectiveness and should be offered to smokers from disadvantaged groups.

Conclusions

In this study, evidence that a case-worker delivered smoking cessation intervention was effective at aiding abstinence was lacking. The secondary outcomes suggest that the intervention influenced processes towards abstinence such as increasing the number of attempts to quit and reducing the number of cigarettes smoked daily. For this population of highly disadvantaged smokers, with comorbidities, high proportion of Indigenous Australians and financial concerns, these are important outcomes. Because of the exceptionally high smoking rates amongst socially disadvantaged groups worldwide it is imperative that research continues to examine strategies for promoting smoking cessation.

Contributors

BB, CP, CD'E, RW, MS conceived and designed the study. LT implemented the study and collected the data. CD'E, CO, KP conducted data analysis. BB wrote the first draft of the article and affirms that the manuscript is an honest, accurate, and transparent account of the study reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained. All authors met the criteria for authorship, had full access to all of the data (including statistical reports and tables) in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Ethics approval

Human research ethics approval was gained from the University of Newcastle Human Research Ethics Committee (HREC-2010-1002).

Data statement

De-identified data can be obtained from the corresponding author upon request.

Conflict of interests

BB has received Investigator Initiated Research grants from Pfizer and Boehringer Ingelheim. CP and CDE have received Investigator Initiated Research grants from Boehringer Ingelheim. RW undertakes research and consultancy for companies that develop and manufacture smoking cessation medications. He is an unpaid advisor to the UK's National Centre for Smoking Cessation and Training. His salary is funded by Cancer Research UK.

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References

1. Hiscock R, Bauld L, Amos A, Fidler JA, Munafò M. Socioeconomic status and smoking: a review. *Ann N Y Acad Sci.* 2012;1248(1):107–123.
2. Lawrence D, Hancock KJ, Kisely S. The gap in life expectancy from preventable physical illness in psychiatric patients in Western Australia: retrospective analysis of population based registers. *BMJ.* 2013;346:f2539.
3. Kotz D, West R. Explaining the social gradient in smoking cessation: it's not in the trying, but in the succeeding. *Tob Control.* 2009;18(1):43–46.
4. Bryant J, Bonevski B, Paul C, McElduff P, Attia J. A systematic review and meta-analysis of the effectiveness of behavioural smoking cessation interventions in selected disadvantaged groups. *Addiction.* 2011;106(9):1568–1585.
5. Wilson A, Guillaumier A, George J, Denham A, Bonevski B. A systematic narrative review of the effectiveness of behavioural smoking cessation interventions in selected disadvantaged groups (2010-2017). *Expert Rev Respir Med.* 2017(In press).
6. Bonevski B, Randell M, Paul C, et al. Reaching the hard-to-reach: a systematic review of strategies for improving health and medical research with socially disadvantaged groups. *BMC Med Res Methodol.* 2014;14(1):42.
7. Bonevski B, O'Brien J, Frost S, et al. Novel setting for addressing tobacco-related disparities: a survey of community welfare organization smoking policies, practices and attitudes. *Health Educ Res.* 2012;28(1):46–57.
8. Christiansen BA, Brooks M, Keller PA, Theobald WE, Fiore MC. Closing tobacco-related disparities: using community organizations to increase consumer demand. *Am J Prev Med.* 2010;38(3):S397–S402.
9. Bryant J, Bonevski B, Paul C, Hull P, O'Brien J. Implementing a smoking cessation program in social and community service organisations: a feasibility and acceptability trial. *Drug Alcohol Rev.* 2012;31(5):678–684.

10. Bonevski B, Paul C, D'Este C, et al. RCT of a client-centred, caseworker-delivered smoking cessation intervention for a socially disadvantaged population. *BMC Public Health.* 2011;11(1):70.

11. Creoso Corporation. *Digivey Survey Suite 3.1.36.0* [computer program]. Arizona, USA2016.

12. West R, Hardy A. A Theory of Addiction. Malden, MA. In: Blackwell Publishing; 2006.

13. Michie S, Richardson M, Johnston M, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. *Ann Behav Med.* 2013;46(1):81–95.

14. Stead LF, Koilpillai P, Fanshawe TR, Lancaster T. Combined pharmacotherapy and behavioural interventions for smoking cessation. *The Cochrane Library.* 2016.

15. May S, West R, Hajek P, McEwen A, McRobbie H. Social support and success at stopping smoking. *J Smok Cessat.*. 2007;2(2):47–53.

16. West R, Hajek P, Stead L, Stapleton J. Outcome criteria in smoking cessation trials: proposal for a common standard. *Addiction.* 2005;100(3):299–303.

17. Hughes JR, Keely JP, Niaura RS, et al. Measures of abstinence in clinical trials: issues and recommendations. *Nicotine Tob Res.* 2003;5(1):13-25.

18. Benowitz NL, Jacob III P, Ahijevych K, et al. Biochemical verification of tobacco use and cessation. *Nicotine Tob Res.* 2002;4(2).

19. Hajek P, West R. Commentary on Smolkowski et al.(2010): Why is it important to assume that non-responders in tobacco cessation trials have relapsed? *Addiction.* 2010;105(6):1016–1017.

20. Barnes SA, Larsen MD, Schroeder D, Hanson A, Decker PA. Missing data assumptions and methods in a smoking cessation study. *Addiction.* 2010;105(3):431–437.

21. Sterne JA, White IR, Carlin JB, et al. Multiple imputation for missing data in epidemiological and clinical research: potential and pitfalls. *BMJ.* 2009;338:b2393.

22. Carpenter JR, Kenward MG. Multiple Imputation of Unordered Categorical Data. *Multiple Imputation and its Application.* 2013:112–126.

23. Little RJ. Selection and pattern mixture models. In: Fitzmaurice G, Davidian M, Verbeke G, Molenberghs G, eds. *Longitudinal data analysis.* CRC Press; 2008.

24. Mikhailovich K, Morrison P. An evaluation of a smoking cessation program for special populations in Australia. *J Smok Cessat.* 2008;3(1):50–56.

25. Kropp F, Lewis D, Winhusen T. The effectiveness of ultra-low magnitude reinforcers: Findings from a "real-world" application of contingency management. *J Subst Abuse Treat.* 2017;72:111-116.

26. Song F, Maskrey V, Blyth A, et al. Differences in longer-term smoking abstinence after treatment by specialist or nonspecialist advisors: secondary analysis of data from a relapse prevention trial. *Nicotine Tob Res.* 2015;18(5):1061-1066.

27. Cahill K, Stead LF, Lancaster T. Nicotine receptor partial agonists for smoking cessation. *Cochrane Database Syst Rev.* 2010;12.

28. Roberts E, Eden Evins A, McNeill A, Robson D. Efficacy and tolerability of pharmacotherapy for smoking cessation in adults with serious mental illness: a systematic review and network meta-analysis. *Addiction.* 2016;111(4):599-612.

29. Gartner C. The potential impact of vaporized nicotine products on vulnerable subpopulations. *Addiction.* 2017;112(1):18-19.

30. Hiscock R, Dobbie F, Bauld L. Smoking cessation and socioeconomic status: an update of existing evidence from a national evaluation of english stop smoking services. *BioMed Res International.* 2015.