



UNIVERSITY
OF WOLLONGONG
AUSTRALIA

University of Wollongong
Research Online

Faculty of Science, Medicine and Health - Papers

Faculty of Science, Medicine and Health

2015

Quit in general practice: a cluster randomized trial of enhanced in-practice support for smoking cessation

Nicholas Arnold Zwar

University of New South Wales, nzwar@uow.edu.au

Robyn Richmond

University of New South Wales

Elizabeth J. Halcomb

University of Wollongong, ehalcomb@uow.edu.au

John Furler

University of Melbourne

Julie Smith

Australian National University

See next page for additional authors

Publication Details

Zwar, N. A., Richmond, R. L., Halcomb, E. J., Furler, J. S., Smith, J. P., Hermiz, O., Blackberry, I. C., Jayasinghe, U. W. & Borland, R. (2015). Quit in general practice: a cluster randomized trial of enhanced in-practice support for smoking cessation. *Family Practice*, 32 (2), 173-180.

Research Online is the open access institutional repository for the University of Wollongong. For further information contact the UOW Library: research-pubs@uow.edu.au

Quit in general practice: a cluster randomized trial of enhanced in-practice support for smoking cessation

Abstract

Objectives. To evaluate the uptake and effectiveness of tailored smoking cessation support, provided primarily by the practice nurse (PN), and compare this to other forms of cessation support. **Methods.** Three arm cluster randomized controlled trial conducted in 101 general practices in Sydney and Melbourne involving 2390 smokers. The Quit with PN intervention was compared to Quitline referral and a usual care control group. Smoking cessation pharmacotherapy was recommended to all groups. Outcomes were assessed by self-report at 3- and 12-month follow-up. Uptake of the interventions is also reported. **Results.** The three groups were similar at baseline. Follow-up at 12 months was 82%. The sustained and point prevalence abstinence rates, respectively, at 3 months by group were: PN intervention 13.1% and 16.3%; Quitline referral 10.8% and 14.2%; Usual GP care 11.4% and 15.0%. At 12 months, the rates were: PN intervention 5.4% and 17.1%; Quitline referral 4.4% and 18.8%; Usual GP care 2.9% and 16.4%. Only 43% of patients in the PN intervention group attended to see the nurse. Multilevel regression analysis showed no effect of the intervention overall, but patients who received partial or complete PN support were more likely to report sustained abstinence [partial support odds ratio (OR) 2.27; complete support OR 5.34]. **Conclusion.** The results show no difference by group on intention to treat analysis. Those patients who received more intensive PN intervention were more likely to quit. This may have been related to patient motivation or an effect of PN led cessation support.

Disciplines

Medicine and Health Sciences | Social and Behavioral Sciences

Publication Details

Zwar, N. A., Richmond, R. L., Halcomb, E. J., Furler, J. S., Smith, J. P., Hermiz, O., Blackberry, I. C., Jayasinghe, U. W. & Borland, R. (2015). Quit in general practice: a cluster randomized trial of enhanced in-practice support for smoking cessation. *Family Practice*, 32 (2), 173-180.

Authors

Nicholas Arnold Zwar, Robyn Richmond, Elizabeth J. Halcomb, John Furler, Julie Smith, Oshana Hermiz, Irene Blackberry, Upali Jayasinghe, and Ron Borland

Quit in General Practice: a cluster randomised trial of enhanced in-practice support for smoking cessation

Running head: Quit in General Practice study

Article category: Health Service research

Authors

Nicholas A Zwar^a, Robyn L Richmond^a, Elizabeth J Halcomb^b, John S Furler^c, Julie P Smith^d, Oshana Hermiz^e, Irene D Blackberry^c, Upali W Jayasinghe^c, Ron Borland^f.

Affiliations

^aSchool of Public Health and Community Medicine, UNSW Australia

^bSchool of Nursing, Midwifery & Indigenous Health, University of Wollongong, Australia

^cGeneral Practice and Primary Health Care Academic Centre, University of Melbourne, Australia

^dAustralian Centre for Economic Research on Health, Australian National University, Australia

^eOshana Hermiz, Centre for Primary Health Care and Equity, UNSW Australia

^fRon Borland, Cancer Council Victoria, Australia.

Corresponding author: Professor N. A. Zwar: School of Public Health and Community Medicine, UNSW Australia, UNSW Sydney NSW 2052 Australia. n.zwar@unsw.edu.au.

Abstract

Objectives

To evaluate the uptake and effectiveness of tailored smoking cessation support, provided primarily by the practice nurse (PN), and compare this to other forms of cessation support.

Methods

Three arm cluster randomised controlled trial conducted in 101 general practices in Sydney and Melbourne involving 2390 smokers. The Quit with PN intervention was compared to Quitline referral and a usual care control group. Smoking cessation pharmacotherapy was recommended to all groups. Outcomes were assessed by self-report at three month and 12 month follow up. Uptake of the interventions is also reported.

Results

The three groups were similar at baseline. Follow-up at 12 months was 82%. The sustained and point prevalence abstinence rates respectively at three months by group were: PN intervention 13.1% and 16.3%; Quitline referral 10.8% and 14.2%; Usual GP care 11.4% and 15.0%. At 12 months the rates were: PN intervention 5.4% and 17.1%; Quitline referral 4.4% and 18.8%; Usual GP care 2.9% and 16.4%. Only 43% of patients in the PN intervention group attended to see the nurse. Multilevel regression analysis showed no effect of the intervention overall, but patients who received partial or complete PN support were more likely to report sustained abstinence (partial support OR 2.27; complete support OR 5.34) .

Conclusion

The results show no difference by group on intention to treat analysis. Those patients who attended for follow-up and received more intensive PN intervention were more likely to quit. This may have been related to patient motivation or an effect of PN led cessation support.

Trial Registration: ACTRN012606000304538

Key words: smoking, smoking cessation, general practice, clinical practice nursing research, randomized controlled trial, preventive medicine

Introduction

Tobacco is the most common preventable cause of death in the world today. The World Health Organization estimates that tobacco killed 5.4 million people globally in 2008 and on current trends this will rise to 8 million deaths per year by 2030. (1) Despite the decrease in prevalence in tobacco use in developed countries it remains a major cause of preventable disease and death. The importance of promoting cessation of tobacco use and provision of treatment as part of a comprehensive approach to tobacco control is described in Article 14 in the Framework Convention for Tobacco Control but progress on providing services is variable across signatory countries. (2)

General practice is well positioned to assist in smoking cessation support given the high degree of contact with the population. There is evidence that brief advice from a physician has a small effect (3) and that this can be increased substantially if combined with other evidence based support such as pharmacotherapy. Clinical practice guidelines suggest general practitioners (GPs) should identify smokers and offer cessation support at every opportunity, however there is a range of barriers to routinely providing smoking cessation advice and several studies have found the number of patients who report receiving advice from GPs is low. (4-6)

An alternative to support in general practice is for GPs to identify smokers and refer to other services such as telephone Quitlines or specialist smoking cessation services. In an Australian study, which compared usual care by the GP to referral by the GP to the Quitline, a higher rate of sustained abstinence at three months follow-up was found in the referral group but there was no significant difference at 12 months. (7) In the United Kingdom, GPs are encouraged to identify smokers and refer to specialised tobacco treatment services. Overall service data has shown good short term quit rates but there is considerable local variation across services in throughput, success rates and impact. (8) In Australia, though there are a small number of smoking cessation

clinics and an increasing number of clinicians with specialised skills, there is no similar organised nationwide service.

A model of enhanced cessation support within the practice is provision of advice by practice nurses (PN). The PN workforce in many countries is increasing and nurses have the potential to overcome barriers to providing smoking cessation support in general practice. (9) Nurse-led smoking cessation advice can be effective (10) but trials in general practice have shown variable results. (11-14) There were a range of limitations in these studies including low uptake of the nursing intervention, research designs that involved a one-off consultation and problems with retention of smokers in the study. (15) We conducted a before-after demonstration study of PN-delivered smoking cessation advice in 19 practices in Sydney involving 398 smokers. The results were promising with continuous abstinence from quit day of 16% at six month follow-up and positive qualitative feedback from PNs and GPs on the value and feasibility of the nurse role. (16)

In the current cluster randomised trial we evaluated the uptake and effectiveness of a flexible package of smoking cessation support provided primarily within the practice by the PN and tailored to meet the needs of patients. The intervention was based on the 5As approach (Ask, Assess, Advise, Assist Arrange follow-up), which provides a structure for comprehensive smoking cessation support in primary care. (17) This intervention was compared to Quitline referral and a usual GP care control group. This paper reports the quantitative outcomes of the study.

Methods

Design

A three arm cluster randomised trial, with randomisation at the level of the practice, was conducted. Details of the study protocol have been published. (18) Recruitment started in August 2010 and follow-up was completed in May 2012.

Recruitment

General Practices located in Sydney and Melbourne employing at least one PN were identified with assistance from local general practice organisations and the Australian Practice Nurses Association and invited to participate. Interested GPs and PNs were visited by study staff to explain the study and obtain informed consent.

Patients were approached in the waiting room of participating practices by trained research assistants over a two-week period and assessed for eligibility. Patients were potentially eligible if they were aged 18 years and over and either daily or weekly smokers. Individuals who were pregnant, unable to give informed consent or had insufficient English to participate were excluded. The study was explained to eligible patients and they were invited to participate. Baseline information on demographics, smoking status, nicotine dependence and co-morbidities was collected and patients were given a card indicating their enrolment and the allocation group of the practice to take into the GP consultation. In the Quit with PN practices, a copy of this card was provided to the PN and GPs encouraged patients to make an initial appointment to see the PN. De-identified data on age, gender and residential postcode were collected from those who declined to participate.

Randomisation

Randomisation of practices was performed after practice recruitment but prior to patient recruitment with allocation concealment by a researcher who took no further part in the study.

Interventions

Quit with Practice Nurse

Details of the interventions have been previously published. In brief, nurses had attended a one-day training program where they were educated in the 5As approach to smoking cessation counselling. (17) This approach forms the basis of clinical practice guidelines in Australia and a number of other countries and its effectiveness is supported by evidence from a randomised trial. (19) It can be provided in primary care and does not depend on referral to specialised services. Checklists for use by the nurses at each patient visit were provided as well as “Quit kits” (a printed resource used by Quitlines nationally) for distribution to patients. Nurses were supported

in providing the intervention by three pro-active mentoring telephone calls from an experienced smoking cessation counsellor.

In the intervention model, GPs from practices randomised to the Quit with PN group encouraged all smokers to see the PN. At an assessment visit patients were assisted by PNs to develop a quit plan based on the 5As approach. (17) Patients were offered a flexible package of ongoing support with a further three face-to-face visits to the PN encouraged but telephone support from the nurse or the Quitline offered for patients unable to attend for face-to-face consultations or who preferred telephone counselling. PNs were asked to follow-up by telephone patients who failed to make an initial assessment visit. The practice received payment for the PN time in delivering the intervention at the rate of \$30 per visit.

Quitline referral

In practices allocated to the Quitline referral group GPs were asked to assess the patients' willingness to quit, and to offer brief advice. Patients with interest in quitting were offered referral to the Quitline and, if patients agreed, GP completed a fax referral form to Quitline. (17) On receiving a GP referral the Quitline telephoned the patient to offer services to meet their needs. Patients expressing interest in quitting and willing to engage with the Quitline counselling service were offered a series of free evidence-based proactive call back counselling/advice sessions. (20) The GP was provided brief feedback from the Quitline on uptake and outcomes of services offered.

Control – usual care

In control group practices the GPs were asked to assess patients' willingness to quit and offer assistance in accordance with their usual practice. This could include advice within the practice, referral to Quitline or both, but no provision was made to facilitate either.

Smoking cessation pharmacotherapy

The need for smoking cessation pharmacotherapy was assessed by the GP or PN and offered in all three groups according to clinical practice guidelines. A copy of these guidelines was provided to participating GPs and PNs. (17) Patients in all groups who held a pharmaceutical

concession card and who were assessed as nicotine dependent and suitable for nicotine patches were eligible for free patches for a period of eight weeks. Other pharmacotherapies were either prescribed by the GP (bupropion or varenicline) or purchased by the patient over the counter (other forms of nicotine replacement therapy).

Outcome measures

Measures were performed at baseline and three and 12 months after recruitment. The three and 12 month outcomes were collected via Computer Assisted Telephone Interviews (CATI) by trained research assistants who were blind to group allocation. The primary outcome measures were sustained abstinence (\geq one month at the three month follow up point and \geq 10 months at the 12 month follow-up) and point prevalence abstinence (\geq seven days sustained abstinence at the three month and 12 month follow-up points). In line with guidance from the Society for Research on Nicotine and Tobacco validation of smoking cessation was not performed.(21) Uptake of the intervention was also measured in each group.

Analysis

We analysed the data by intention to treat. This analysis involved planned imputation where patients with missing outcome data were assumed to be smokers. This conservative imputation is common in smoking cessation studies. (22) We also conducted a planned analysis of outcomes for patients with complete outcome data. Given the incomplete uptake of interventions experienced in the trial we conducted an additional analysis of the outcomes for patients who had received the intervention versus not received. In the univariate analyses differences between groups were compared using the χ^2 test statistic. In the other analyses multilevel logistic regression models were used with two dichotomous dependent variables adjusted for clustering of three occasions at level 1, patients at level 2 and practices at level 3. We conducted multilevel multivariable analysis using MLwiN. (23) Time is defined as the number of months from baseline and treated as a continuous variable. The significance of the parameter estimates was assessed using the Wald joint χ^2 test statistic. The intraclass correlation coefficients (ICC) for the primary outcomes were calculated using the latent variable method. (24)

Sample Size

The study was powered to detect a between group differences at 12 months in sustained abstinence of 5.5% between Quit with PN intervention versus the referral intervention and a 9.4% difference between Quit with PN intervention and the usual care control group with 80% power at the 5% significance level. Adjustment for clustering was made on the basis of the ICC of 0.013 observed by Lennox et al. in a smoking cessation trial in general practice. (25) We planned to recruit 90 clusters with a cluster size of 25. The resulting sample size of 2250 allowed for an 18% loss of patients to follow-up.

Results

In total, 323 GPs and 135 PNs from 101 practices in Sydney and Melbourne participated in the study. Fifteen (14.9%) were solo practices. The mean age of the GPs was 49.5 years (SD 11.3) and 189 (59.4%) were male. The mean age of PNs was 50.0 years (SD 9.9) and 129 (95.6%) were female. The research assistants identified 3676 eligible patients of whom 2390 (65.0%) agreed to participate. Those who declined were more likely to be male (53.2%) ($P < 0.001$) but there were no differences between those who agreed and declined to participate in mean age or in socioeconomic status as determined by socio-economic indexes for areas (26) classification of the residential postcode. As shown in table 1 the groups were very similar on demographics and smoking behavior at baseline. As shown in the CONSORT diagram (figure1), 2282 (95.5%) completed the three month follow up and 1969 (82.4%) provided outcome data at the 12-month follow-up giving an attrition rate at 12 months of 17.6%. Retention was 81.7% in the Quit with PN, 83.1% in the Quitline referral and 82.3% in the GP usual care groups.

Intervention uptake across groups was assessed from patient report of contacts for smoking cessation collected by CATI. Uptake was low across all three groups. In the Quit with PN group, 502 (57.3%) received no support from the PN (no visits), 140 (16%) received partial support (one or two visits), 148 (16.9%) received complete support (three or more visits) and 86 (9.8%) had missing data. In the Quitline referral group 588 (70%) had no support from the Quitline (no calls), 36 (4.3%) had partial support (one to three calls), 25 (3%) had complete support (four or more calls) and 187 (22.4%) had missing data. In the GP usual care group 310 (45.7%) had no support (no follow-up visits where smoking was discussed), 193 (28.5%) had partial support

(one to two visits where smoking was discussed), 95 (14%) had complete support (three or more visits where smoking was discussed) and 80 (11.8%) had missing data.

Smoking cessation pharmacotherapy use was similar across intervention groups with 413 (49.3%) patients in the Quit with PN group, 422 (53.2%) in the Quitline referral group and 282 (43.3%) in the usual GP care group using one or more forms pharmacotherapy in the study period. Nicotine patches were the most commonly used form of pharmacotherapy, used by 284 (33.9%) patients in the Quit with PN group, 299 (37.8%) in the Quitline referral group, 170 (26.0%) in the GP usual care group and 753 (33.0%) in the whole study population. Of these 753 patch users, 534 (70.1%) were pharmaceutical concession card holders and 219 (29.1%) were not. This suggests that some patients who were not concession card holders were supplied with free nicotine patches. Uptake of varenicline was similar across groups with 121 (13.8%) of patients in the Quit with PN group, 123 (14.7%) in the Quitline referral and 89 (13.1%) in the GP usual care group using this medicine in the study period. Only 18 patients in the study used bupropion.

The unadjusted univariate results of the intention to treat analysis are shown in table 2. Though sustained abstinence was higher in the Quit with PN group at 12 months there were no statistically significant between group differences for the primary outcome measures of sustained and point prevalence abstinence at three months or 12 months. The sustained and point prevalence abstinence rates respectively at three months by group were: PN intervention 13.7% and 17.1%; Quitline referral 11.4% and 15.0%; Usual GP care 11.8% and 15.6%. At 12 months the rates were: PN intervention 6.6% and 20.9%; Quitline referral 5.3% and 22.6%; Usual GP care 3.6% and 19.9%. The differences were not statistically significant. Given that multilevel analysis with adjustment for clustering will decrease the effect size and increase P values our statistician (UJ) did not conduct these analyses.(27, 28) The univariate analysis of results for patients with complete outcome data showed similar results.

As shown in figure 2 there were higher quit rates in patients in the Quit with PN group who had attended for smoking cessation support visits with the PN. A multilevel adherence analysis was conducted which examined outcomes for all patients who had received versus not received

intervention (Table 3). Independent variables were included in the model describing the extent of intervention received in all three groups. The variable of partial PN support (defined as one or two visits) and complete PN support or complete PN intervention received (defined as three or more visits) were significantly associated with higher rates of sustained and point prevalence abstinence. Complete PN support associated with higher odds ratios for both point prevalence and sustained abstinence than partial PN support. The extent of GP support received was also associated with cessation, though a dose response effect was not observed. Given the small numbers of patients had received Quitline assistance the categories were collapsed to one or more call versus no support. Receiving one or more call was not associated with higher likelihood of cessation.

Finally a multilevel regression model included variables related to practice size, patient demographics, smoking history and co-morbidities (Table 4). Patient characteristics of older age, previous quit attempts, low nicotine dependence, use of smoking cessation pharmacotherapy in the study period, absence of a mental health problems and absence of co-morbid conditions were significant predictors of cessation.

Discussion

Despite successful participant recruitment and retention, this large cluster randomised trial found no difference in the primary outcomes between intervention groups. As we exceeded our recruitment target for the study we do not believe this was due to a type 2 error. A reason for the lack of effect shown may have been the low uptake of the PN and Quitline referral interventions. Only 43% of patients in Quit with PN practices saw the nurse one or more times while in the Quitline referral practices only 30% had one or more contact with the Quitline. The low uptake of the Quitline may have been due to referrals not being made by GPs despite being randomised to that intervention group or a lack of acceptance by patients. Further, there appears to have been more than usual support within practices in the GP usual care group. Although the nature of the assistance is difficult to compare, levels of contact were almost as high.

Comparison with other research

Low intervention uptake has been found in other studies of practice nurse cessation support. (11, 29) In our study the low uptake may have been related to the recruitment method in that patients were offered the intervention opportunistically when they attended the practice for any reason. This represents the approach suggested in clinical practice guidelines where smokers are identified and offered cessation support at every opportunity. (30) However it is likely to result in a higher proportion of less motivated patients entering the study compared to more targeted recruitment methods such as a mailed out invitation or the GP selecting interested patients. This may explain the differences in outcomes in the trial compared with our earlier before-after study (16) in which GPs identified interested and motivated patients and referred them to the practice nurse for recruitment and intervention. As was found in the study by Sanders et al (29) and also noted in other cardiovascular risk factor interventions by PNs, those patients who attended to see the PN were more likely to report behaviour change. (15). In our study this was even the case with one PN visit but the cessation rate was greater with increasing intervention intensity, suggesting a dose-response effect. However the effect may be simply due to more motivated patients remaining in treatment. The low rate of completion of the nurse visits may have been related to PNs experiencing difficulty in finding the time and organisational support to deliver the intervention as planned. This will be explored in the qualitative evaluation of the study.

In the multilevel regression analysis a number of other independent variables were found to be significantly positively associated with smoking cessation. The strongest association was with use of pharmacotherapy during the study. This is consistent with the known benefits of treating nicotine dependence. (31) The other positive associations for both point prevalence and sustained abstinence were: age 60 years and over, having tried to quit before and the patient's self-rating that quitting would be fairly difficult or less. There was also a positive association for point prevalence abstinence with not having a mental health problem. These associations are consistent with previous literature (32, 33), including our qualitative study involving people reporting current depression at baseline in the Quit in General Practice Study (34) though there is a lack of research on smoker's ability to predict their own quitting success.

Study limitations

There was a substantial level of participation in the study by eligible smokers (65%) but there was possible bias in recruitment in that more women were willing to participate than men. However this is in keeping with the higher attendance rates of women than men in general practice. We have limited information to report in this paper on the fidelity of the intervention provided in the study. Nurses in the Quit with PN practices were asked to use intervention checklists at each visit and to send these to the study team. The extent to which this was done and the content of these checklists will be reported separately. The information gathered in the process evaluation of the impact of the intervention is also beyond the scope of this paper and will be reported in subsequent publications. Biochemical validation of cessation outcomes was not practically possible in this large community-based study so there is the possibility that cessation rates are lower than those reported. However our approach is supported by a review of the evidence conducted by the Society for Research on Nicotine and Tobacco which concluded that in large trials recruited through health care settings misreporting rates are generally very low, typically near zero, except in high-risk medical settings, such as involving patients with heart disease or pregnant women. (21) We assumed that participants lost to follow-up had relapsed to smoking. This is commonly done in smoking cessation studies but could have led to an overestimation of the difference in quit rates from those who had received versus not received the PN intervention.

Study implications

The study that a PN delivered intervention was not effective when offered opportunistically to all smokers presenting in general practice. There was a suggestion however that PN led support may be effective if patients can be engaged and maintained in treatment. Given these findings, and the pressures on PN time, testing strategies to identify those patients with sufficient motivation to attend to see the nurse and offering them the nurse-led intervention may be both effective and efficient. Methods of doing this could be via an invitation to the practice population of recorded smokers, by the GP and/or PN assessing motivation and offering the service when patients who smoke attend for other reasons or by a combination of these methods. Further research, including cost-effectiveness analysis, is needed to evaluate such a nurse-led model of smoking cessation support and how it compares with referral options such as Quit lines and specialised services.

Declarations

Ethical approval: Ethical approval was given by the Human Research Ethics Committee, University of New South Wales (HREC 08362). The study was registered with the University of Melbourne and University of Western Sydney human research ethics committees.

Funding: Project grant from the Australian National Health and Medical Research Council.
Grant Number 568617

Trial registration details: Australian Clinical Trials Registry. Registration number
ACTRN012609001040257

The authors declare they have no conflicts of interest.

Acknowledgments

The authors would like to acknowledge the contribution of the practice nurses, general practitioners and patients who took part in the study, the Divisions of General Practice and Quitline Victoria and New South Wales who supported the study and Ms Fiona Lewi who led the practice nurse training sessions. Funding was from the Australian National Health and Medical Research Council.

References

1. WHO report of the Global Tobacco Epidemic, 2008: the MPOWER Package. Geneva: World Health Organization; 2008.
2. Pine-Abata H, McNeill A, Murray R, Bitton A, Rigotti N, Raw M. A survey of tobacco dependence treatment services in 121 countries. *Addiction*. 2013 Mar 1. PubMed PMID: 23451932. Epub 2013/03/05. Eng.
3. Stead LF, Buitrago D, Preciado N, Sanchez G, Hartmann-Boyce J, Lancaster T. Physician advice for smoking cessation. *Cochrane Database Syst Rev*. 2013;5:CD000165. PubMed PMID: 23728631. Epub 2013/06/04. eng.
4. Pine-Abata H, McNeill A, Raw M, Bitton A, Rigotti N, Murray R. A survey of tobacco dependence treatment guidelines in 121 countries. *Addiction*. 2013 Feb 26. PubMed PMID: 23437892. Epub 2013/02/27. Eng.
5. Zwar NA, Richmond RL. Role of the general practitioner in smoking cessation. *Drug and alcohol review*. 2006 Jan;25(1):21-6. PubMed PMID: 16492574. Epub 2006/02/24. eng.
6. Young JM, Ward JE. Implementing guidelines for smoking cessation advice in Australian general practice: opinions, current practices, readiness to change and perceived barriers. *Family practice*. 2001 Feb;18(1):14-20. PubMed PMID: 11145622. Epub 2001/01/06. eng.
7. Borland R, Balmford J, Bishop N, Segan C, Piterman L, McKay-Brown L, et al. In-practice management versus quitline referral for enhancing smoking cessation in general practice: a cluster randomized trial. *Family practice*. 2008 Oct;25(5):382-9. PubMed PMID: 18689856. Epub 2008/08/12. eng.
8. West R, May S, West M, Croghan E, McEwen A. Performance of English stop smoking services in first 10 years: analysis of service monitoring data. *BMJ*. 2013;347:f4921. PubMed PMID: 23963106. Epub 2013/08/22. eng.
9. Gould DJ, Peach, C., James, T. The role of the practice nurse in smoking cessation. *Clinical effectiveness in nursing*. 2000;4:152-62.
10. Rice VH, Hartmann-Boyce J, Stead LF. Nursing interventions for smoking cessation. *Cochrane Database Syst Rev*. 2013;8:CD001188. PubMed PMID: 23939719. Epub 2013/08/14. eng.
11. Lancaster T, Dobbie W, Vos K, Yudkin P, Murphy M, Fowler G. Randomized trial of nurse-assisted strategies for smoking cessation in primary care. *The British journal of general practice : the journal of the Royal College of General Practitioners*. 1999 Mar;49(440):191-4. PubMed PMID: 10343421. Pubmed Central PMCID: 1313370. Epub 1999/05/27. eng.
12. Murchie P, Campbell NC, Ritchie LD, Simpson JA, Thain J. Secondary prevention clinics for coronary heart disease: four year follow up of a randomised controlled trial in primary care. *BMJ*. 2003 Jan 11;326(7380):84. PubMed PMID: 12521974. Pubmed Central PMCID: 139939. Epub 2003/01/11. eng.
13. Moher M, Yudkin P, Wright L, Turner R, Fuller A, Schofield T, et al. Cluster randomised controlled trial to compare three methods of promoting secondary prevention of coronary heart disease in primary care. *BMJ*. 2001 Jun 2;322(7298):1338. PubMed PMID: 11387182. Pubmed Central PMCID: 32168. Epub 2001/06/02. eng.
14. Steptoe A, Doherty S, Rink E, Kerry S, Kendrick T, Hilton S. Behavioural counselling in general practice for the promotion of healthy behaviour among adults at increased risk of

- coronary heart disease: randomised trial. *BMJ*. 1999 Oct 9;319(7215):943-7; discussion 7-8. PubMed PMID: 10514155. Pubmed Central PMCID: 28246. Epub 1999/10/08. eng.
15. Halcomb E, Moujalli S, Griffiths R, Davidson P. Effectiveness of general practice nurse interventions in cardiac risk factor reduction among adults. *International journal of evidence-based healthcare*. 2007 Sep;5(3):269-95. PubMed PMID: 21631792. Epub 2007/09/01. eng.
 16. Zwar NA, Richmond RL, Forlonge G, Hasan I. Feasibility and effectiveness of nurse-delivered smoking cessation counselling combined with nicotine replacement in Australian general practice. *Drug and alcohol review*. 2011 Nov;30(6):583-8. PubMed PMID: 21355911. Epub 2011/03/02. eng.
 17. Zwar N, Richmond R, Borland R, Stillman S, Cunningham M, Litt J. Smoking cessation guidelines for Australian General Practice: Commonwealth of Australia; 2004.
 18. Zwar N, Richmond R, Halcomb E, Furler J, Smith J, Hermiz O, et al. Quit in general practice: a cluster randomised trial of enhanced in-practice support for smoking cessation. *BMC family practice*. 2010;11:59. PubMed PMID: 20701812. Pubmed Central PMCID: 2931485. Epub 2010/08/13. eng.
 19. Katz DA, Muehlenbruch DR, Brown RL, Fiore MC, Baker TB, Group ASCGS. Effectiveness of implementing the agency for healthcare research and quality smoking cessation clinical practice guideline: a randomized, controlled trial. *Journal of the National Cancer Institute*. 2004 Apr 21;96(8):594-603. PubMed PMID: 15100337.
 20. Borland R, Segan CJ, Livingston PM, Owen N. The effectiveness of callback counselling for smoking cessation: a randomized trial. *Addiction*. 2001 Jun;96(6):881-9. PubMed PMID: 11399219. Epub 2001/06/12. eng.
 21. Benowitz N, Jacob, P., Ahijevych, K., Jarvis, M.J., Hall, S., et al. Biochemical verification of tobacco use and cessation. *Nicotine & Tobacco Research*. 2002;4:149-59.
 22. West R, Hajek P, Stead L, Stapleton J. Outcome criteria in smoking cessation trials: proposal for a common standard. *Addiction*. 2005 Mar;100(3):299-303. PubMed PMID: 15733243. Epub 2005/03/01. eng.
 23. Rasbash J BW, Healy M, Cameron B, Charlton C. A user's guide to MLwiN version 2.25: University of Bristol: Centre for Multilevel Modelling; 2012.
 24. Snijders T BR. *Multilevel Analysis: An introduction to basic and advanced multilevel modeling* London: Sage Publications; 1999.
 25. Lennox AS, Bain, N., Taylor, R.J. et al. . Stages of change training for opportunistic smoking intervention by the primary health care team *Health Education Journal* 1998;57:140–9.
 26. Statistics ABo. *Socio-Economic Indexes for Areas: Australian Bureau of Statistics*; 2011 [cited 2013 15/08/2013]. Available from: www.abs.gov.au/websitedbs/censushome.nsf/home/seifa.
 27. Campbell MK, Mollison J, Steen N, Grimshaw JM, Eccles M. Analysis of cluster randomized trials in primary care: a practical approach. *Family practice*. 2000 Apr;17(2):192-6. PubMed PMID: 10758085. Epub 2000/04/12. eng.
 28. Austin PC, Tu JV, Alter DA. Comparing hierarchical modeling with traditional logistic regression analysis among patients hospitalized with acute myocardial infarction: should we be analyzing cardiovascular outcomes data differently? *American heart journal*. 2003 Jan;145(1):27-35. PubMed PMID: 12514651. Epub 2003/01/07. eng.
 29. Sanders D, Fowler, G., Mant, D., Fuller, A., Jones, L., Marzillier, J. Randomized controlled trial of anti-smoking advice by nurses in general practice. *The Journal of the Royal College of General Practitioners*. 1989;39:273-6.

30. Zwar N, Richmond R, Borland R, al e. Smoking cesstion pharmacotherapy: an update for health professionals. Melbourne: Royal Australian College of General Practitioners; 2007.
31. Stead LF, Perera R, Bullen C, Mant D, Hartmann-Boyce J, Cahill K, et al. Nicotine replacement therapy for smoking cessation. *Cochrane Database Syst Rev.* 2012;11:CD000146. PubMed PMID: 23152200. Epub 2012/11/16. eng.
32. Hymowitz N, Cummings KM, Hyland A, Lynn WR, Pechacek TF, Hartwell TD. Predictors of smoking cessation in a cohort of adult smokers followed for five years. *Tobacco control.* 1997;6 Suppl 2:S57-62. PubMed PMID: 9583654. Pubmed Central PMCID: 1766209. Epub 1997/01/01. eng.
33. Hitsman B, Papandonatos GD, McChargue DE, DeMott A, Herrera MJ, Spring B, et al. Past major depression and smoking cessation outcome: a systematic review and meta-analysis update. *Addiction.* 2013 Feb;108(2):294-306. PubMed PMID: 23072580. Pubmed Central PMCID: 3593055. Epub 2012/10/18. eng.
34. Clancy N, Zwar N, Richmond R. Depression, smoking and smoking cessation: a qualitative study. *Family practice.* 2013 Oct;30(5):587-92. PubMed PMID: 23836095.

Figure 1: CONSORT flowchart

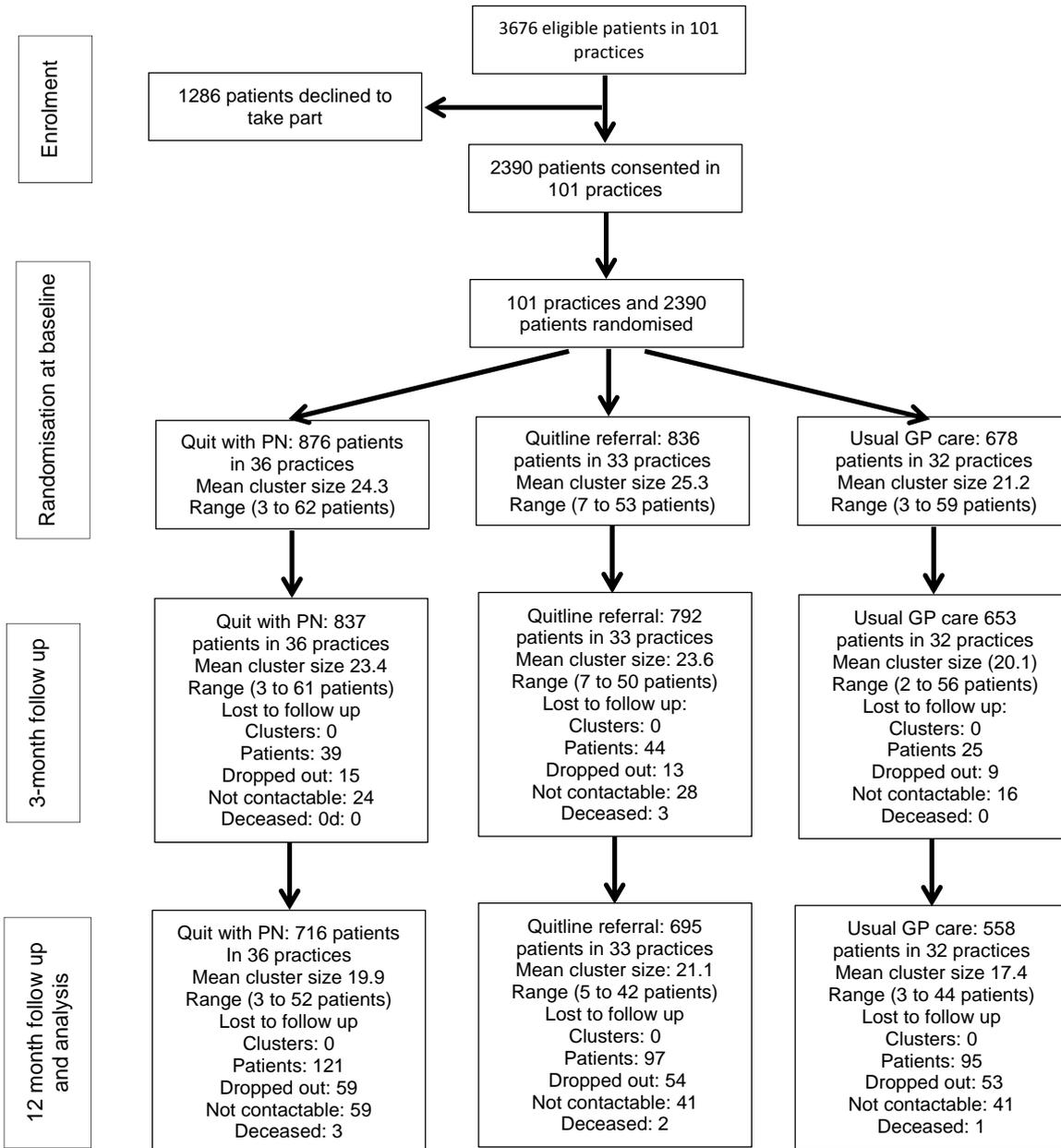


Figure 2: Abstinence rates by number of practice nurse visits in Quit with PN group

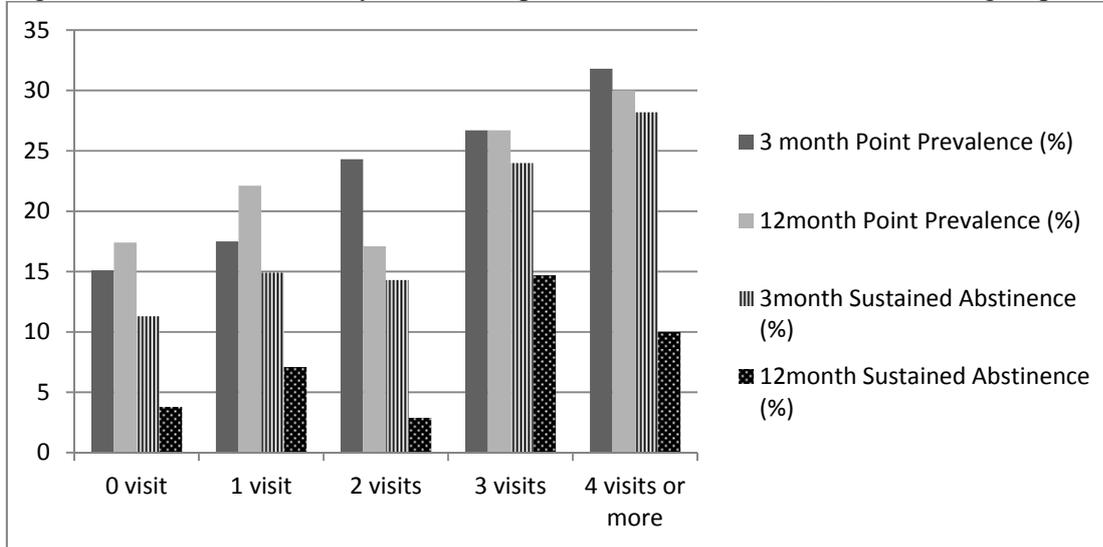


Table 1 | Baseline characteristics of groups. N=2390. Data collected from August 2010 to XXXX**Figures are means (SDs) unless otherwise stated**

	Quit with PN (n = 876)	Quitline (n = 836)	Usual GP care (n = 678)
Mean age in years (SD)	42.6 (14.4)	43.5 (14.3)	42.1 (15.2)
Number (%) of men	398 (45.4)	378 (45.2)	320 (47.2)
Number (%) born in Australia	458 (67.6)	587 (70.2)	603 (68.8)
Number (%) English spoken at home	778 (88.8%)	773 (92.5%)	606 (89.4%)
Number (%) reported Aboriginal or Torres Strait Islander heritage	33 (3.8)	28 (3.3)	15 (2.2)
Number (%) completed High School	599 (68.4)	565 (67.6)	482 (67.6)
Number (%) holding pharmaceutical concession card	492 (56.2)	448 (53.6)	324 (47.8)
Number (%) employed part or full time	402 (45.9)	385 (46.1)	355 (52.4)
Number (%) reporting mental health problem	333 (38.0)	309 (37.0)	221 (32.6)
Mean number (SD) of co-morbidities	1.3 (1.5)	1.2 (1.3)	1.0 (1.3)
Mean number (SD) of cigarettes per day	18.0 (11.0)	17.4 (10.7)	15.9 (9.7)
Mean heaviness of smoking index (SD)	2.6 (1.3)	2.4 (1.3)	2.4 (1.4)
Number (%) reporting previous quit attempt	732 (83.6)	701 (83.9)	531(78.3)
Number (%) rated quitting as fairly difficult or less	249 (28.4)	250 (29.9)	212 (31.3)
Number (%) responded “no” to higher quit success with assistance	50 (5.7)	76 (9.1)	89 (13.1)
Number (%) responded “not sure” to higher quit success with assistance	270 (30.8)	251 (30.0)	191 (28.2)
Number (%) previously used smoking cessation pharmacotherapy	413 (47.1)	422 (50.5)	282 (41.6)

Table 2 | Univariate analysis of primary outcomes at three months and 12 months

Variable	Quit with PN (n = 876)	Quitline referral (n = 836)	Usual GP care (n = 678)	Chi squared 2 degrees of freedom	P
Sustained abstinence					
3 months	115 (13.1%)	90 (10.8%)	77 (11.4%)	2.47	0.29
12 months	47 (5.4)	37 (4.4)	20 (2.9)	5.37	0.068
Point prevalence					
3 months	143 (16.3)	119 (14.2)	102 (15.0)	1.47	0.48
12 months	150 (17.1)	157 (18.8)	111 (16.4)	1.63	0.44

Table 3 | Multilevel logistic regression analysis and adherence analysis. Effect of independent variables on primary outcome measures. (N=6366* of 7170)

Variables (reference variable or group)	Point prevalence abstinence OR (95% CI)	Sustained abstinence OR (95% CI)
<i>Groups and time effect</i>		
Quit with PN group (usual GP care group)	0.86 (0.65 to 1.13)	0.99 (0.70 to 1.39)
Quitline referral group (usual GP care group)	0.94 (0.71 to 1.24)	0.92 (0.65 to 1.31)
Time	1.11 (1.09 to 1.13) [‡]	0.98 (0.95 to 1.00)
<i>PN, GP and Quitline support effect</i>		
Partial nurse support (no nurse support)	1.79 (1.3 to 2.47) [‡]	2.27 (1.49 to 3.45) [‡]
Complete nurse support (no nurse support)	3.39 (2.41 to 4.78) [‡]	5.34 (3.51 to 8.14) [‡]
Partial GP support (no GP support)	1.61 (1.29 to 2.00) [‡]	2.45 (1.81 to 3.32) [‡]
Complete GP support (no GP support)	1.32 (0.98 to 1.79)	1.79 (1.19 to 2.70) [‡]
Quitline support one call or more (no Quitline support)	1.41 (0.85 to 2.32)	1.32 (0.67 to 2.62)
ICC (intracluster or intrapractice correlation)	0.012	0.00

Note: [‡]P < 0.001

* number of practices = 101

Table 4: Multilevel logistic regression analysis for effect of patient and practice characteristics on primary outcomes (N=6714 of 7170)**

Variables (reference variable)	Point prevalence abstinence OR (95% CI)	Sustained abstinence OR (95% CI)
<i>Patient demographics effect</i>		
Age in years		
40-59 (19-39)	0.96 (0.77 to 1.20)	1.13 (0.84 to 1.53)
60 or more (19-39)	1.57 (1.12 to 2.21) [†]	1.90 (1.20 to 3.03) [†]
Female sex (male sex)	0.85 (0.70 to 1.03)	0.74 (0.56 to 0.96)
Home language other than English (English)	0.88 (0.61 to 1.25)	0.95 (0.59 to 1.53)
Aboriginal or Torres Strait Islander (Other than aboriginal)	1.00 (0.56 to 1.76)	0.93 (0.41 to 2.09)
Employment status*		
Employed (other employment)	1.06 (0.82 to 1.36)	1.07 (0.76 to 1.52)
Retired/pensioner (other employment)	0.71 (0.51 to 0.98)	0.67 (0.43 to 1.04)
At least high school completed (high school not completed)	1.20 (0.96 to 1.50)	1.12 (0.82 to 1.51)
Pharmaceutical concession card holder (not pharmaceutical concession card holder)	0.95 (0.75 to 1.20)	1.28 (0.93 to 1.77)
<i>Smoking history effect</i>		
Tried to quit before (did not try to quit before)	1.50 (1.12 to 2.02) [†]	1.65 (1.07 to 2.53)*
Rated quit difficulty fairly difficult or less (difficult or very difficult)	1.56 (1.27 to 1.92) [‡]	1.45 (1.09 to 1.94)*
Higher quit success with assistance		
Reported no (reported yes)	1.18 (0.84 to 1.67)	0.89 (0.54 to 1.48)
Reported not sure (reported yes)	1.14 (0.92 to 1.41)	1.10 (0.82 to 1.48)
Heaviness of smoking index		
Low dependence (high dependence)	3.10 (1.54 to 6.22) [†]	2.61 (1.05 to 6.47)*
Medium dependence (high dependence)	1.71 (0.87 to 3.37)	1.41 (0.59 to 3.38)
Used pharmacotherapy during study (did not use pharmacotherapy)	5.85 (4.83 to 7.09) [‡]	5.78 (4.43 to 7.54) [‡]
<i>Comorbidities effect</i>		
No mental health problem reported (reported mental health problem)	1.34 (1.00 to 1.79)*	0.92 (0.61 to 1.38)
Number of comorbid conditions		

Zero (2 or more comorbidities)	1.25 (0.91 to 1.74)	1.88 (1.19 to 2.97) [†]
One (2 or more comorbidities)	1.13 (0.85 to 1.49)	1.14 (0.77 to 1.68)
<i>Effect of practice size</i>		
Solo practice (group practice)	1.04 (0.74 to 1.47)	1.30 (0.85 to 1.99)
ICC (intracluster or intrapractice correlation)	0.020	0.019

Note: * P < 0.05, [†] P < 0.01; [‡] P < 0.001

** number of practices = 101