Cost-free pharmacotherapy in smokers with TIA or stroke: QUIT-MED randomised controlled trial

Robert Reid, Sophia Papadakis, Sophia Gocan, Aline Bourgoin, Mary Ann Laplante, Ashley Armstrong, Debbie Aitken, Demetrios Sahlas, Grant Stotts, Lisa Cotie, Kerri-Anne Mullen, Andrew Pipe, Hassan Mir, Mukul Sharma

ABSTRACT

Objective To examine whether cost-free (CF) smoking cessation medication was more effective than a prescription for cessation medication in patients after transient ischaemic attack (TIA) or stroke.

Design Two-site randomised trial.

Setting Stroke prevention clinics (SPCs) in Ontario, Canada.

Participants Smokers with TIA or stroke, willing to quit smoking.

Intervention Smoking status was assessed in SPC attendees. Smokers were advised to quit smoking and received recommendations for cessation medication and counselling. Consenting participants were randomly assigned (1:1) to either a CF medication group or a prescription-only (Rx) group. CF participants immediately received a 12-week supply of cessation medication. Rx participants were given a prescription for 12 weeks of cessation medication. Follow-up counselling was provided for 26 weeks.

Main outcome The primary outcome was 40-week continuous abstinence verified using a carbon monoxide breath test at 52-week follow-up. Secondary outcomes included abstinence at intermediate timepoints, medication adherence and serious adverse events.

Results Hundred and ninety-four participants were randomised and 131 (67.5%) completed the trial. The 40-week continuous abstinence rate at 52-week follow-up was 15.5% in the CF group versus 14.0% in the Rx group (OR=1.13; 95% CI 0.51 to 2.53). The 14-week continuous abstinence rate at 26-week follow-up was 18.6% in the CF group versus 16.8% in the Rx group (OR=1.20; 95% CI 0.56 to 2.55). Seven-day point-prevalence abstinence at 12 weeks was 38.1% in the CF group versus 26.9% in the Rx group (OR=1.76; 95% CI 0.94 to 3.28). Medication adherence was higher in the CF group versus the Rx group (47.4%±41.2% vs 25.5±36.8%, p<0.001). Serious adverse events occurred in 11.1% of participants and were unrelated to treatment.

Conclusions Our findings were inconclusive; we failed to meet our recruitment target and the effect size was smaller than anticipated. CF medication improved medication adherence.

Trial registration number NCT00962988; ClinicalTrials.gov Identifier.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is the largest reported randomised controlled trial of a smoking-specific intervention for patients after a transient ischaemic attack or stroke.

⇒ The intervention was codesigned with patients, neurologists and nurses to fit within the context of outpatient stroke prevention clinics.

⇒ The primary outcome was verified, long-term abstinence from smoking measured at 52-week follow-up.

⇒ Our results were inconclusive; we failed to recruit our intended sample size because many smokers-patients were not ready to quit smoking within 30 days of their stroke prevention clinic visit.

INTRODUCTION

Cigarette smoking increases the risk for ischaemic and haemorrhagic stroke and there is a strong dose-dependent relationship between amount smoked and stroke risk. Current smokers have a twofold to fourfold increased risk of stroke compared with lifelong non-smokers or individuals who have been smoke-free for 10 years or more. Risk is increased by 12% for every five cigarettes smoked per day, and stroke patients who smoke experience an initial stroke 11.4 years earlier than non-smokers (at 61.8 vs 73.2 years of age; p<0.001). Mechanisms include effects of cigarette smoke on atherosclerosis, coagulation, endothelial dysfunction and oxidation. Cessation of cigarette smoking after a stroke or transient ischaemic attack (TIA) reduces risk of recurrent stroke by half within 3 months and reduces stroke, MI and death by 30% over 5-year follow-up. Consequently, guidelines recommend interventions to increase smoking cessation after a TIA or stroke.

Many smokers who experience a stroke or TIA continue to smoke. Our systematic review of randomised controlled trials (RCTs) of...
smoking cessation interventions in smokers with cerebrovascular disease (four studies, 354 patients) showed that the long-term cessation rate following a smoking cessation intervention was 23.9% (42 of 176) while without one it was 20.8% (37 of 178). A recent review of prospective cohort and clinical trials of smoking cessation after stroke or TIA (25 trials, 1604 to 1920 patients) found self-reported cessation rates of 51%, 44% and 44% at 3-month, 6-month and 12-month follow-up, respectively. Higher levels of disability postevent, lower levels of depression and more intensive support were associated with higher rates of cessation.

Nicotine replacement therapy (NRT), bupropion and varenicline, when combined with counselling, can double or even triple long-term smoking abstinence in smokers trying to quit. Unfortunately, many patients must pay for medication; the cost associated with treatment has been identified as a barrier to use by many smokers, particularly those in the low-income categories. Studies in non-stroke/TIA populations have found that the provision of cost-free (CF) medication increases motivation to quit, the number of quit attempts and long-term smoking abstinence.

We conducted the Cost-free QUITting MEDication for High Risk Smokers with Cerebrovascular Disease (QUIT-MED) study to examine whether the immediate provision of CF smoking cessation medication was more effective than providing a prescription for such medication among patients following TIA or stroke. The main premise of our study was that reducing the time, effort and financial outlay to acquire smoking cessation medications would make it more likely these medications would be used during a quit attempt, and long-term cessation rates would be increased. Interventions were provided by clinic staff to replicate ‘real-world’ conditions.

**METHODS**

**Patient and public involvement**

This project was developed in collaboration with clinicians and patients from the stroke prevention clinic (SPC) at the Ottawa Hospital. Patients were first involved in a survey of smokers who attended the SPC. More than 80% of smoker-patients said they intended to quit smoking within 6 months. They identified the cost of smoking cessation medications as a barrier to making a quit smoking attempt. SPC clinicians helped develop study tools to identify patient smoking status, guide cessation counselling and make decisions about cessation medication. Patients participated in a pilot study of methods used in the current trial.

**Design**

QUIT-MED was a pragmatic, open-label RCT undertaken at two SPCs (Ottawa and Hamilton) in Ontario, Canada from December 2009 to January 2015. SPCs in Ontario offer early assessment, teaching and follow-up to prevent a recurrent event for people with a recent stroke or TIA, generally within 6 weeks of an index event. The trial protocol and statistical analysis plan appear in online supplemental file 1. Consenting smokers with TIA or stroke were randomly assigned (1:1) to either a CF medication treatment group or a prescription only (Rx) usual care group.

**Participants**

Individuals were recruited during their visit to the SPC. Current daily smokers over the age of 18 years with a confirmed diagnosis of TIA or stroke who were willing to quit smoking in the next 30 days using an approved smoking cessation medication were invited to participate in the study. We excluded patients: who were pregnant or lactating; with cognitive impairment that would preclude study participation (in the opinion of the attending neurologist); currently using cessation medication; with contraindications to all smoking cessation medications; unavailable for follow-up or unable to speak English or French.

**Randomisation and blinding**

Participants were stratified by site and time to first cigarette of the day (<30 min or ≥30 min) and randomly allocated to either a CF or Rx group. Participants were allocated to treatment using a computer-generated randomisation scheme that was concealed to participants, investigators and healthcare providers with codes sealed in opaque envelopes. When a patient was enrolled, an envelope was opened in sequence to disclose the result of the randomisation. Block randomisation (block sizes of 4 to 8) and allocation concealment were performed by a statistical consultant not affiliated with the study. Participants were not blinded. Outcome assessments were performed by research staff unaware of treatment allocation.

**Interventions**

Prior to study initiation, the SPCs implemented systematic processes and tools to identify and assist smoker-patients based on the Ottawa Model for Smoking Cessation. SPC neurologists and nurses received training regarding processes for identifying smokers, providing counselling and prescribing smoking cessation medication.

Current smokers were identified at clinic check-in using a waiting room screening questionnaire. SPC neurologists advised all smoker-patients to quit smoking, indicated that effective cessation treatments were available, and assessed patient interest in making a quit attempt within 30 days. Patients willing to make a quit attempt met with an SPC nurse to complete a smoking cessation consultation. The nurse helped to select cessation medication (NRT monotherapy, combination NRT, varenicline or bupropion), provided practical counselling about quitting (such as anticipating challenges, preparing to quit) and worked with the patient to set a quit date. At the end of the consultation, a prescription for cessation medication was prepared and signed by the SPC neurologist (Nota Bene: NRT does not require a prescription in Ontario;
however, if a patient presents a prescription for NRT at a pharmacy, the pharmacist will assist the patient to find the specified medication and dosage). At the end of the consultation, the SPC nurse asked eligible patients if they were interested in participating in a study of smoking cessation medication. If interested, informed consent was obtained. Participants were then randomly assigned to treatment groups.

Participants in the CF experimental group were immediately provided with a CF 12-week supply of cessation medication. Participants in the Rx usual-care group were provided with a prescription for a 12-week course of medication to fill at a pharmacy at their own cost.

All participants were registered in a centralised smoker follow-up system, staffed with nurse-cessation specialists. The follow-up system automatically placed follow-up telephone calls to participants 7 days before their target quit date and then 3, 14, 30, 60, 90, 120, 150 and 180 days after. Automated calls typically lasted 1–2 min. During the calls, if participants identified that they were unprepared for quitting, had resumed smoking or expressed low confidence in remaining smoke free (<3 on a 5-point scale); a nurse cessation specialist contacted the participant and provided additional assistance, using standardised counselling scripts. The automated calling system has been evaluated in an RCT and improved long-term verified continuous abstinence rates from 29.5% to 38.0% in smokers with heart disease compared with no follow-up counselling.

Baseline and follow-up assessments
At baseline, information about medical history and comorbidities was abstracted from the patient chart. Questionnaires were used to gather information about current pharmacotherapies, smoking history, level of nicotine dependence, previous attempts to quit and insurance coverage for smoking cessation medication. At 26-week and 52-week follow-up, participants returned to the study site and completed an interview with a research assistant blinded to group assignment. The interviewer asked about smoking status since week 12 and over the previous 7 days. Participants who reported they were smoke free were asked to provide a breath sample for carbon monoxide determination. Information was also gathered concerning medication use and serious adverse events (SAEs) since last contact.

Outcomes
The primary outcome was continuous abstinence from smoking (self-report of not having smoked >5 cigarettes during the 40-week period preceding the 52-week follow-up) that was verified using a carbon monoxide breath test (<10 ppm). Participants lost or unavailable for follow-up or carbon monoxide validation were considered smokers for analysis purposes. Secondary abstinence outcomes included verified continuous abstinence during the 14-week period preceding the 26-week follow-up and 7-day point prevalence abstinence at 12, 26 and 52 weeks. Other secondary outcomes included medication adherence, duration of medication use (weeks), participation in counselling calls and SAEs. These outcomes were obtained from study records, enrolments in the telephone follow-up system, nurse-counsellor records and in person assessments completed at 26 and 52 weeks. Medication adherence was self-reported and calculated as the number of doses taken divided by the number of doses prescribed over the initial 12-week medication treatment period. SAEs were defined as any adverse event that was life-threatening or resulted in hospitalisation, persistent or significant disability, incapacity or death. An independent data-safety and monitoring committee reviewed all SAEs to determine whether there was any relationship to study participation.

Sample size
A total of 562 participants were to be included in the study. The primary end point used in the sample size determination was the 40-week continuous abstinence rate measured at 52 weeks. The sample size calculation assumed that the cessation rate in the Rx control group would be 30% compared with 40% in the CF group, with 80% power and an alpha level of 0.05. This base rate assumption was based on quit rates observed among patients with cerebrovascular disease participating in a pilot study with similar intervention.

Statistical methods
The statistical analysis was guided by a prespecified analysis plan. All patients randomised were included in the intent-to-treat analysis, except those who died or moved to an untraceable address. For the primary endpoint analysis, we used logistic regression with verified 40-week continuous abstinence status (smoker or non-smoker) at 52-week follow-up as the dependent variable and treatment group and recruitment site as independent variables. Secondary analyses were conducted using similar techniques with verified 14-week continuous abstinence at week 26 and 7-day point prevalence abstinence at 12, 26 and 52 weeks as dependent variables of interest. The post hoc analysis of self-reported 7-day point prevalence abstinence assessed at 12 weeks was not prespecified. Medication adherence and duration of medication use over the first 12 weeks were compared between group using t tests. The proportions of participants using at least one dose of medication, using all recommended doses and using medication at 26-week and 52-week follow-up were compared between groups using χ² tests. SAE rates were described by group using descriptive statistics. Multiple comparisons increase the potential for type I error. Findings for the analyses of secondary outcomes should be viewed as exploratory.

RESULTS
Figure 1 shows the numbers of patients who were enrolled and the numbers who were excluded. The
The principal reasons for exclusion were that the patient did not have a diagnosis of TIA or stroke or was not willing to quit smoking in the next 30 days. We failed to recruit our intended sample size. After inviting 294 eligible patients, 194 agreed to participate and were randomly assigned to treatment: 99 to the CF group and 95 to the Rx group.
Our study was inconclusive as to whether immediate and CF smoking cessation medication was more effective than providing a prescription for smoking cessation.
medication for patients following TIA or stroke. The absolute improvement in the long-term, verified continuous abstinence was 1.5% with CF medication (15.5% vs 14.0%), but our CI did include larger effect sizes that could be clinically important. We failed to meet our recruitment target and the effect size was smaller than the 10% absolute improvement in continuous abstinence anticipated. Fewer patients with stroke and TIA attending the SPCs were willing to quit smoking within 30 days than we anticipated (43% actual vs 63% expected). Participants in the CF intervention group used significantly more medication during their initial quit attempt primarily because a high proportion or patients in the Rx control group (47.4%) failed to fill their prescription. SAEs occurred in 11% of participants over 52-week follow-up; these events were not related to group assignment or smoking cessation medication.

Although we failed to meet our recruitment target, this is the largest reported RCTs to date of a smoking cessation intervention in the context of secondary stroke prevention. The cessation intervention was delivered with high fidelity by regular SPC staff assisted by nurse cessation specialists, rather than research staff, demonstrating that these interventions can be incorporated into SPC routines. Blinding of participants was not possible; however, outcome assessors were unaware of treatment assignment. Carbon monoxide measured in expired breath was used to validate self-reports of non-smoking.

### Table 2

<table>
<thead>
<tr>
<th>Variable</th>
<th>Cost-free group</th>
<th>Prescription group</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>99</td>
<td>95</td>
<td></td>
</tr>
<tr>
<td>Pharmacotherapy type, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NRT monotherapy</td>
<td>13 (13.1)</td>
<td>16 (16.8)</td>
<td>0.61</td>
</tr>
<tr>
<td>NRT combination</td>
<td>52 (52.5)</td>
<td>52 (54.7)</td>
<td></td>
</tr>
<tr>
<td>Varenicline</td>
<td>27 (27.3)</td>
<td>24 (25.3)</td>
<td></td>
</tr>
<tr>
<td>Bupropion</td>
<td>7 (7.1)</td>
<td>3 (3.2)</td>
<td></td>
</tr>
<tr>
<td>*Prescription filled, n (%)</td>
<td>N/A</td>
<td>50 (52.6)</td>
<td></td>
</tr>
<tr>
<td>Used at least one dose, n (%)</td>
<td>72 (72.7)</td>
<td>45 (47.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Medication adherence, mean±SD</td>
<td>47.4±41.2</td>
<td>25.5±36.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Used all recommended doses, n (%)</td>
<td>23 (23.2)</td>
<td>11 (11.6)</td>
<td>0.03</td>
</tr>
<tr>
<td>†Duration of medication use, mean weeks±SD</td>
<td>7.7±4.2</td>
<td>6.3±4.5</td>
<td>0.09</td>
</tr>
<tr>
<td>Using smoking cessation medication at 26 weeks, n (%)</td>
<td>13 (13.1)</td>
<td>19 (20.0)</td>
<td>0.20</td>
</tr>
<tr>
<td>Using smoking cessation medication at 52 weeks, n (%)</td>
<td>10 (10.1)</td>
<td>15 (15.6)</td>
<td>0.23</td>
</tr>
<tr>
<td>Number of automated calls completed, mean±SD</td>
<td>6.4±2.6</td>
<td>5.9±2.9</td>
<td>0.21</td>
</tr>
<tr>
<td>Number of nursing counselling calls provided, mean±SD</td>
<td>3.5±2.6</td>
<td>3.6±2.5</td>
<td>0.78</td>
</tr>
</tbody>
</table>

*Includes only participants in the prescription group.
†Includes only participants who used at least one dose of medication.
NIA, nicotine replacement therapy.

### Table 3

<table>
<thead>
<tr>
<th>Outcome†</th>
<th>Number (%)</th>
<th>Cost-free</th>
<th>Prescription</th>
<th>Adjusted OR&lt;sup&gt;c&lt;/sup&gt;</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of participants</td>
<td>97</td>
<td>93</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Primary outcome</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Verified continuous 40-week abstinence at 52-week follow-up</td>
<td>15 (15.5)</td>
<td>13 (14.0)</td>
<td>1.13 (0.51 to 2.53)</td>
<td>0.77</td>
<td></td>
</tr>
<tr>
<td><strong>Secondary outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-reported 7-day point prevalence abstinence at 12-week follow-up</td>
<td>37 (38.1)</td>
<td>25 (26.9)</td>
<td>1.76 (0.94 to 3.28)</td>
<td>0.08</td>
<td></td>
</tr>
<tr>
<td>Verified 7-day point prevalence abstinence at 26-week follow-up</td>
<td>21 (21.6)</td>
<td>17 (18.3)</td>
<td>1.25 (0.61 to 2.56)</td>
<td>0.54</td>
<td></td>
</tr>
<tr>
<td>Verified continuous 14-week abstinence at 26-week follow-up</td>
<td>18 (18.6)</td>
<td>15 (16.8)</td>
<td>1.20 (0.56 to 2.55)</td>
<td>0.64</td>
<td></td>
</tr>
<tr>
<td>Verified 7-day point prevalence abstinence at 52-week follow-up</td>
<td>22 (22.7)</td>
<td>16 (17.2)</td>
<td>1.41 (0.69 to 2.89)</td>
<td>0.35</td>
<td></td>
</tr>
</tbody>
</table>

<sup>c</sup> = adjusted for recruitment site (Ottawa or Hamilton)
<sup>†</sup>Abstinence was defined as not having smoked more than five cigarettes for the entire 40-week period preceding the 52-week follow-up, which was verified biochemically by an expired carbon monoxide level of less than 10 ppm.
<sup>‡</sup>An assumption was made that all participants with missing data for smoking status were still smoking.
It is surprising that among these smokers wanting to quit, with strong health risks for continued smoking, captured at a teachable moment, that only about half filled their prescription. Cost of medication may have been a factor in the low fill rate in the Rx group. At the time the study was conducted, average medication costs for a 12-week supply were $ CDN294, $588, $286 and $134, for NRT monotherapy, NRT combination, varenicline and bupropion, respectively. Our exploratory analysis of prescription fillers versus non-fillers showed more filling among those with insurance coverage illustrating that having to pay for cessation medication reduces their use. Clinically important improvements in point prevalence abstinence rates in favour of the CF group were noted at 12 weeks (38.1% vs 26.9%).

We observed a non-significant increase in 1.5% in the long-term continuous abstinence rate in our CF intervention group compared with the Rx control group (15.5% vs 14.0%). We expected to see an absolute increase in 10% with the CF intervention, based on our pilot study.21 Both groups received active cessation treatment that included both counselling and a prescription for a first-line quit-smoking medication, based on best practice guidelines, making it difficult to demonstrate incremental benefit. Government policy regarding coverage for smoking cessation medication changed mid-way through the study. Starting in 2011, the Ontario government provided payment coverage for varenicline and bupropion for patients over the age of 65 or those with disability coverage. Our data suggest that insurance coverage for smoking cessation prescriptions made it more likely that prescriptions would be filled by people in the Rx group. This would have reduced differences between groups.

The timing of our intervention may have been suboptimal. We identified and recruited smokers during visits to outpatient SPCs; these visits are typically scheduled to occur in the immediate days to weeks after initial hospital presentation for TIA or stroke. Evidence from studies of hospitalised smokers suggests that interventions should be commenced in the hospital (or in the emergency room), as motivation to quit smoking may be highest at these ‘teachable moments’.32 In addition, patients seen in SPCs typically have cerebrovascular events that resolve fully or result in non-disabling symptoms. Higher levels of disability are associated with higher cessation rates.10

Our results point to a new direction for research. If the true difference in long-term abstinence with CF medication compared with prescription is only 1.5%, a sample size of several thousand per group (>8000) would be required to definitively test a between-group difference of this magnitude. Also, changes in government policy have resulted in expanded access to CF medication, making our original question less relevant, at least in Canada. Since most of the 45 SPCs in Ontario have still not introduced systematic processes to identify smokers and deliver smoking cessation interventions, a better next step might be to evaluate a practice-level intervention like the Ottawa Model for Smoking Cessation enhanced

### Table 4 Serious adverse events

<table>
<thead>
<tr>
<th>Event</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cost-free</td>
</tr>
<tr>
<td>Number of participants</td>
<td>99</td>
</tr>
<tr>
<td>Participants with a serious adverse event</td>
<td>10</td>
</tr>
<tr>
<td>Total number of serious adverse event</td>
<td>16</td>
</tr>
<tr>
<td>Died</td>
<td>1</td>
</tr>
<tr>
<td>Stroke</td>
<td>1</td>
</tr>
<tr>
<td>Worsening stroke symptoms</td>
<td>0</td>
</tr>
<tr>
<td>TIA</td>
<td>1</td>
</tr>
<tr>
<td>Carotid endarterectomy</td>
<td>1</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>1</td>
</tr>
<tr>
<td>Unstable/stable angina</td>
<td>0</td>
</tr>
<tr>
<td>Cardiac revascularisation</td>
<td>3</td>
</tr>
<tr>
<td>ICD insertion</td>
<td>1</td>
</tr>
<tr>
<td>Deep vein thrombosis</td>
<td>1</td>
</tr>
<tr>
<td>Other, requiring hospitalisation</td>
<td>6</td>
</tr>
</tbody>
</table>

*ICD = implantable cardioverter defibrillator*
to include strategies for both patients interested and not interested in quitting (ie, a quit date would not be required). Such an intervention could include strategies such as motivational enhancement and ‘reducing-to-quit’ approaches for those not ready to quit at the time of presentation to the SPC. Cluster randomised trials are well suited to the evaluation of health system interventions. They are ideal for testing interventions when the decision about whether to implement the intervention will be taken on behalf of a group.

CONCLUSIONS

Most smokers with TIA and stroke are still smoking 1 year later. The present study of CF medication was inconclusive because we failed to meet our recruitment target; the effect size was smaller than anticipated. Additional work will be required because we failed to meet our recruitment target; the effect size was smaller than anticipated. Additional work is needed to better understand how to implement these lifesaving interventions in patients after TIA and stroke. A cluster randomised trial should be conducted to evaluate the effectiveness of practice-level interventions for smoking cessation in SPC in Ontario.

Supplemental material

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ORCID iDs

Robert Reid http://orcid.org/0000-0001-8688-9128
Hassan Mir http://orcid.org/0000-0002-7486-8123

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