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# The effect of COVID-19 on smoking cessation outcomes in a large primary care treatment program



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| Complete List of Authors: | Veldhuizen, Scott; Centre for Addiction and Mental Health, Nicotine Dependence Service<br>Selby, Peter; Centre for Addiction and Mental Health, Addiction; University of Toronto Temerty Faculty of Medicine, Family and Community Medicine<br>Wong, Benjamin; Centre for Addiction and Mental Health, Nicotine Dependence Service<br>Zawertailo, Laurie; Centre for Addiction and Mental Health, ; University of Toronto Faculty of Medicine, Department of Pharmacology and Toxicology |
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Title: The effect of COVID-19 on smoking cessation outcomes in a large primary care treatment program

Scott Veldhuizen[1], Ph.D. (email: scott.veldhuizen@camh.ca; ORCID: 0000-0003-3969-2756)
Peter Selby[1,2,3,4,5], MBBS, CCFP(AM), FCFP, dip ABAM, MHSc (email: peter.selby@camh.ca; ORCID 0000-0001-5401-2996)
Benjamin Wong[1], MPH (email: benjamin.wong@camh.ca; ORCID: 0000-0002-7745-6271)
Laurie Zawertailo[1,2,6], Ph.D. (email: laurie.zawertailo@camh.ca; ORCID: 0000-0002-4547-1565)

1 Nicotine Dependence Service, Centre for Addiction and Mental Health, 175 College St, Toronto, ON M5T 1P7, Canada
2 Department of Family and Community Medicine, University of Toronto, 500 University Ave, Toronto, ON M5G 1V7, Canada
3 Campbell Family Mental Health Research Institute, Centre for Addiction and Mental Health, 60 White Squirrel Way, Toronto, ON M6J 1H4, Canada
4 Dalla Lana School of Public Health, University of Toronto, 155 College, Toronto, ON M5T 3M7, Canada
5 Department of Psychiatry, University of Toronto, 250 College Street, Toronto, ON M5T 1R8, Canada
6 Department of Pharmacology and Toxicology, University of Toronto, 1 King's College Cir, Toronto, ON M5S 1A8, Canada

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Correspondence: scott.r.veldhuizen@gmail.com

## Background

The COVID-19 pandemic has changed smoking patterns and other behaviours, and has led to a virtualization of non-urgent medical care. The net effects of these changes on the effectiveness of formal smoking cessation treatment is unclear.

## Methods

We conducted a cohort study including 43,509 primary care patients enrolled in a large, multi-site smoking cessation program in Ontario, Canada. We fit piecewise mixed-effects logistic models to explore changes by date of enrolment in quit success at 6-month follow-up. We used the local state of emergency declaration on March 17, 2020 as our break-point, and estimated separate time effects for people followed up 1) before this time; 2) in the following 6 months; and 3) thereafter. We controlled for participant characteristics, and tested seasonality and total treatment use as potential explanations for change.

## Results

For people followed up in the 6M after the pandemic began, quit probability declined with date of enrolment. Predicted probabilities were 31.2% (95% CI=30.0%, 32.5%) for people followed up immediately after the state of emergency and 24.1% (95% CI=22.1%, 26.2%) for those followed up 6M later (difference = -6.5%, 95% CI=-9.0%, -3.9%). Seasonality and total treatment use did not explain this decline.

**Conclusion**

The probability of successful smoking cessation following treatment fell during the pandemic, with the decline consistent with an effect of "exposure" to the pandemic-era environment. As many changes happened simultaneously, specific causes cannot be identified; however, the possibility that virtual care has been less effective than in-person treatment should be explored.

## Article summary

### Strengths and limitations of this study

- This is the first large study to evaluate changes in outcomes of smoking cessation treatment during the COVID-19 pandemic.
- The large sample size and the treatment of time effects made it possible to measure changes in outcomes with good precision.
- The decrease in quit probability we observed occurred within the group of people who enrolled in the pre-pandemic period, and is therefore unlikely to result from case-mix changes linked to the pandemic itself.
- Treatment in participating clinics changed at the beginning of the pandemic; it is therefore unclear whether changes are due to changes in the care provided or to the wider context of the pandemic.

## Introduction

The reported effects of the COVID-19 pandemic on tobacco addiction and its treatment are complex and sometimes contradictory. Survey data suggest that smokers in some countries have increased their use of tobacco since the pandemic began[1-3], but also that interest in quitting[4 5] (but see also[6]), quit attempts, and successful cessation have risen[7]. Heavy drinking and high psychological distress, both intimately linked with tobacco use, also seem to have become more prevalent in the COVID-19 era,[8 9] and there is some evidence that the same may be true of substance use disorders in general, partly due to relapse among former users[10].

Some of these changes are likely to be due to contextual changes. Public health restrictions have reduced social contact and mobility[11], while job losses and the shift to remote work may have blunted the effects of smoking restrictions in workplaces and public spaces. Changes in smoking behaviour may also be influenced by reported associations between COVID and smoking[12], including suggestions that smoking may protect against infection[13], but is also associated with more severe illness[14 15].

The pandemic has also had marked effects on medical care. Public health messaging has encouraged people to delay non-urgent care, and providers have had to restrict contacts with and among patients, to acquire and use personal protective equipment, and to divert resources to test and treat potential COVID-19 cases. In Ontario, Canada, which is the region of interest in this report, total primary care visits fell sharply early in the pandemic, and in-person contacts were rapidly displaced by virtual care[16].

Although one small study has suggested that abstinence did not change during the pandemic for people treated previously[17], the net effect of pandemic-era changes on the effectiveness of care for smoking cessation is largely unknown. In this study, we examine pandemic-related changes in outcomes from a long-running primary care smoking cessation treatment program.

## Methods

The Smoking Treatment for Ontario Patients (STOP) program provides free counseling and nicotine replacement therapy (NRT)[18], with direct care provided principally by nurses and pharmacists. We analyzed data from 226 family health teams that participated in the program during the study period. Family health teams are physician-led primary care practices with defined rosters of patients.

Ontario family health teams largely transitioned to remote care in the early months of the pandemic[16]. However, each STOP clinic responded to the crisis independently, and in ways that varied over time. Clinic adaptations were discussed in a teleconference with representatives from 99 participating organizations in June, 2020. Broadly, providers had reduced in-person clinic visits, performed consultations by phone or videoconference where possible, and either shipped NRT to participants or arranged for distanced pickup.

STOP participants are followed up by email at 3 months and by email, phone, or at a clinical contact at 6 months and 12 months after baseline. Our outcome was self-reported past 7-day abstinence from cigarettes at the 6-month follow-up, with abstinence defined as a "no" response to the question, "have you smoked a cigarette, even a puff, in the last 7 days". We use the 6-month follow-up because this is the program's primary reported outcome, and efforts to contact participants are most intensive (and follow-up rates highest) at this time. As 85-90% of follow-ups are done remotely, objective verification of smoking status using biochemical validation was not feasible. However, the validity of self-reported smoking status has generally been shown to be good[19 20].

In Ontario, substantial numbers of COVID-19 cases were first detected in March, 2020[21]. The provincial government declared a state of emergency on March 17, 2020, mandating the closure of schools and many business and indoor public spaces. Following the state of emergency declaration, STOP enrolments immediately fell by 70%. By January, 2021, they had recovered to 30% below normal levels. Changes in restrictions after March, 2020 had no clear effects on enrolments. We use the state of emergency declaration on March 17 as the primary break-point in our analysis, as it marks the beginning of public health restrictions and, more approximately, of the epidemic itself. We refer to times before and after this date as the "pre-pandemic" and "pandemic" periods, respectively.

We included participants enrolled from April 11, 2016, when the STOP surveys were expanded to include several important variables, to July 16, 2020, which is the latest date for which 6-

month follow-ups were available. These follow-ups were done between November 11, 2016 and February 16, 2021. From the 58,292 such enrolments, we removed 4314 (7.4%) people who were not daily smokers at baseline and 521 (0.9%) without recorded clinical visits. People are also allowed to re-enroll in STOP after their full one-year treatment eligibility period has expired. We used probabilistic deduplication to identify repeat enrolments, and kept only the most recent enrolment for each person. This meant removing a further 9948 (17.1%) records, almost all of which (9555; 96%) were followed up in the pre-pandemic period. The final analysis sample included 43,509 unique participants from 226 clinics.

To understand the effects of pandemic-related changes on smoking cessation treatment outcomes, we examined change in the probability of successful cessation by date of enrolment. For enrolments in the 6M before the pandemic, we interpret change over time primarily as a continuous measure of exposure to the pandemic environment. People enrolling at the beginning of this period will have experienced the pandemic for only a short time before their follow-up; and, as the total length of treatment is usually less than 6 months[22], only a few will have received treatment during the pandemic. Conversely, those enrolling just before the state of emergency declaration will have usually made their quit attempt(s), and received most of their treatment, after pandemic-related restrictions were imposed.

**Patient involvement**

This was a secondary analysis of program data, without direct involvement of patients in the design of the study or the interpretation of results.

## Ethics approval

The STOP Program is funded by the Ontario Ministry of Health and Long-term Care, and its procedures were approved by the Research Ethics Board at the Centre for Addiction and Mental Health (protocol numbers 058-2011 and 154-2012). Participants provided informed, written consent for use of data for research at the time of the baseline interview.

## Analysis

We first produced descriptive statistics. We then fit a piecewise mixed-effects logistic regression model that estimates one slope for date of enrolment for enrolments from April 11, 2016 to September 16, 2019 and another for those from September 17, 2019 until March 17, 2020. To test for changes after this date, we initially included both another slope and an indicator variable that was 1 for people who enrolled after March 17, 2020, and 0 otherwise. The indicator captures any overall change for these participants, while we included a slope to explore the possibility of further gradual change.

This model allows for different time effects for each of 3 groups of participants: 1) those followed up before the pandemic (n=35,385); 2) those enrolling before the pandemic but followed up after it began (n=6109); and 3) those enrolling during the pandemic (n=1815). As noted, it is change by date of enrolment within the second group that is of greatest interest. We included a random intercept for study site, and evaluated time effects for linearity by examining

monthly means. To obtain absolute adjusted differences (AADs) between pairs of time points, we used post-estimation procedures on estimated marginal means.

We adjusted for possible changes in case-mix by including a set of baseline participant characteristics, selected a priori, that are known to be associated with treatment outcome. These were: age, sex/gender, cigarettes per day, time to first cigarette after waking, previous lifetime quit attempts, motivation to quit (1-10), confidence in ability to quit (1-10), and lifetime diagnosis of a physical (heart disease, cancer, stroke, diabetes, or COPD), mental health (anxiety, depression, bipolar disorder, or schizophrenia), or non-tobacco substance-related condition (drug use disorder or alcohol use disorder).

To examine the possibility that any changes in outcome were associated with changes in the type or amount of treatment used, we fit a further model that included 1) the total number of clinical visits attended in the first 6M of treatment; 2) the type of NRT initially dispensed (no NRT, short-acting forms only, patch only, or short-acting and patch in combination); and 3) the total number of weeks of NRT provided.

Finally, previous work with STOP data has shown that treatment outcomes show modest seasonal variation[23]. It is not clear, however, that the factors underlying seasonal differences continued to operate in the same way during the pandemic, which disrupted holiday-taking, socializing, and other activities. As a result, we treated this question as a sensitivity analysis, and fit a further model including dummy-coded month of year. We used Stata 16 for all analyses[24].

*Missing data*

Most baseline variables include some missing data (Table 1). The outcome was also available only for 27,541 (64%) participants who completed the 6M follow-up survey. This level of completeness compares favourably to other large, observational studies of smoking cessation treatment (e.g., [25 26]). We addressed missing data using multiple imputation with chained equations, with 50 imputed datasets. We included all variables from our substantive models, including treatment variables. As auxiliary variables, we included quit status at 3M follow-up (where available), quit status at the last clinical contact before 6M, and the number of previous enrolments, if any. We do not impute missing outcomes to "smoking", because this would bias the quit proportion downwards, and would also bias effects of any variables, including time, that are associated with loss to follow-up[27 28].

Multiple imputation reduces bias by taking into account observed associations between non-response and the variables measured, but does not exclude the possibility that quit status itself is independently associated with response at follow-up. This is a potential concern for our analysis of change over time, because our follow-up rate rose from 61% before the pandemic to 75% for people followed up after it began. This was partly due to a higher response rate for phone surveys, and partly because efforts to reach participants were intensified. However, the follow up rate after the pandemic began was approximately constant, and it is variation in outcomes for these participants that are of primary interest.

## Results

Descriptive statistics are shown in Table 1, and the overall proportion of participants successfully quitting, by month of enrolment, in Figure 1.

Model results are shown in Table 2, and the corresponding marginal predictions in Figure 2. From the initial model, we removed the slope term for post-pandemic enrolments, number of clinical visits, type of NRT, and weeks of NRT dispensed, all of which were non-significant and did not meaningfully change estimates of change over time.

In the final model, there was no change over time in the probability of cessation for people who were followed up before the pandemic. For people who enrolled pre-pandemic and were followed up during it, however, the probability of cessation fell with date of enrolment. Predicted probabilities were 31.2% (95% CI = 30.0% to 32.5%) for people followed up immediately after the state of emergency and 24.1% (95% CI = 22.1% to 26.2%) for those enrolling immediately before the state of emergency and followed up 6M later. This is a decrease of 6.5% (95% CI = 3.9% to 9.0%).

Adjusting for seasonality did not meaningfully change effects for pre-pandemic enrolments (Figure 2). However, this adjustment did increase the coefficient for enrolment during the pandemic period, and lowered the corresponding p-value to 0.03. As this effect was not significant in our main model, the evidence for a change in quit success for these enrolments is

ambiguous. Even in the seasonality-adjusted model, however, the predicted probability of quitting smoking remained lower for pandemic-era enrolments than it was for people who enrolled before the pandemic began (AAD = -3.8%, 95% CI = -6.5% to -1.0%).

## Discussion

In this large, primary care smoking cessation program, the COVID-19 pandemic was associated with a clinically meaningful decrease in the proportion of patients who quit successfully. The quit probability fell linearly with date of enrolment, which is consistent with an effect of "exposure" to the pandemic environment: people who spent more of their follow-up period, and received more of their treatment, during the pandemic period were less likely to quit smoking. This change was not accounted for by seasonal variation, by changes in the known characteristics of enrolling participants, or by differences in the type or amount of treatment provided.

Ontario's public health measures changed over the study period, and beliefs and behaviours of program participants may also have varied. The probability of successful smoking cessation, however, declined approximately linearly with enrolment date. This is probably because outcomes reflect the net effects of all influences over the 6 month period, and will not have been sensitive to small or short-term contextual differences. Chance variation and possible seasonal differences also make it difficult to discern small probability variations within this time.

It is not possible to confidently link poorer treatment outcomes to specific causes, because the pandemic brought change in many areas simultaneously. Of potential causes, however, we can usefully distinguish between 1) changes related to the wider pandemic context, and 2) changes in the care provided. As noted, some data suggest that psychological distress and substance use have increased during the pandemic[8 9], and this may have made quitting smoking more difficult for some people. Population survey data from other countries generally do not suggest that cessation rates fell[7], but the evidence on this question is limited, and what is true of the wider population may not be true of smokers in treatment. The effects of contextual factors on treatment outcomes therefore remain unclear.

Despite the difficulty of disentangling causal effects, it is important to consider possible impacts of changes in care provision. In STOP, there were no pandemic-related disruptions at the program level: delivery of NRT supplies to each clinic continued uninterrupted, we placed no restrictions on conduct of remote visits or enrolment of new participants using verbal consent procedures, and our model results show that the amount of treatment received did not meaningfully change estimates of change over time. However, as noted, care in Ontario FHTs was rapidly virtualized following the beginning of the pandemic[16]. Virtual care may have changed the nature of counseling, with group therapy, for example, becoming a technological challenge. Provision of NRT may also have become less timely, and less-tangible influences, such as immediacy and engagement, may also be relevant.

It is therefore possible that the decrease in quit rate is due to virtual treatment for smoking cessation being less effective than in-person care. There is surprisingly little evidence on this question. The overall effectiveness of remote care for smoking cessation, in the form of telephone quitlines[29 30], is well-established[31 32]. However, very few trials have directly compared any form of remote care directly to in-person treatment[33 34]. One such non-inferiority trial from Japan found no difference in outcomes, but was not powered to detect small differences, and provided an intervention that may not be entirely comparable to those offered during the pandemic by smoking cessation clinics[35]. Studies on alcohol[36] and opioid use[37] disorders have also failed to find differences between in-person and virtual care, but the applicability of this research to tobacco cessation is uncertain, and sample sizes were again relatively small. Moreover, the pandemic obliged STOP providers to transition very rapidly to remote care without extensive preparation or training, and this may, in some cases, have made it difficult to provide optimal care.

A further possibility is that the pandemic disrupted existing treatment episodes, with participants accustomed to in-person treatment having to adjust to remote care. In this case, it would not be the new care approaches themselves, but the transition to them, that is important. If this were the case, we would expect to see an increase in quit probability among people enrolling after the pandemic began, as they received all treatment after the shift to remote care had occurred. Our results are ambiguous on this question, due to the uncertain influence of seasonal variation. They do show, however, that the quit probability for these patients did not return to pre-pandemic levels. Disruptions to ongoing care therefore cannot entirely explain the change in quit success.

Although STOP is a single program, it was delivered in 226 team-based primary care practices across Ontario during the study period, and changes in processes and protocols were implemented independently at each clinic. The experience of Ontario during this period was also fairly similar to those of many other developed-world jurisdictions, in terms of the epidemiology of COVID-19 and the public health restrictions that were imposed. We therefore believe that results will be relevant to other contexts. Our findings also suggest that the wider question of the effectiveness of remote treatment in primary care deserves close attention.

**Limitations**

We lack detailed information about how individual clinics adapted to COVID-19. It is also possible that people enrolling during the pandemic differed from those enrolling earlier on unmeasured variables. However, this does not affect the primary results, which rest on time effects for earlier enrolments. A substantial proportion of participants also did not complete their 6M follow-up. Although we have tried to account for missingness in our analysis, it is conceivable that there remained uncaptured associations treatment outcome and other variables. As noted, our follow-up rate also increased for pandemic-era follow-ups. However, this cannot explain change in outcomes over time within the group followed up during this period, because the follow-up rate over this period was approximately constant.

**Conclusion**

The STOP model ensured that smoking cessation treatment continued to be provided in primary care during the COVID-19 pandemic, and this treatment did remain generally effective.

However, the proportion of participants who quit successfully declined meaningfully during this time. As the number of people receiving this care was also reduced by public health restrictions, reduced smoking cessation through formal treatment can be numbered among the important negative secondary effects of the pandemic. There is a need for research on the effectiveness and further optimization of virtual care for smoking cessation.

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Data sharing: Requests for access to anonymized patient-level data will be considered in consultation with the supervising privacy and ethics bodies. Enquiries should be made to the corresponding author.

[Figure1]

[Figure2]

Table 1. Descriptive statistics.

| | Enrolment date | | | |
|---|---|---|---|---|
| | Historical controls[1] | 6M before COVID[2] | COVID era[3] | Total |
| Sex | | | | |
| Male | 16,696 (47%) | 2,857 (46.9%) | 825 (45.5%) | 20,378 (46.8%) |
| Female | 18,806 (53%) | 3,235 (53.1%) | 987 (54.5%) | 23,028 (53.1%) |
| "Other" or Missing | 83 (0.2%) | 17 (0.3%) | 3 (0.2%) | 103 (0.2%) |
| Age | | | | |
| <35 | 5,041 (14.2%) | 750 (12.3%) | 224 (12.3%) | 6,015 (13.8%) |
| 35 to 54 | 13,818 (38.8%) | 2,205 (36.1%) | 652 (35.9%) | 16,675 (38.4%) |
| 55+ | 16,709 (47%) | 3,150 (51.6%) | 939 (51.7%) | 20,798 (47.8%) |
| Missing | 17 (0%) | 4 (0.1%) | 0 (0%) | 21 (0.1%) |
| Past week employment status | | | | |
| Not working | 14,244 (42%) | 2,415 (41.9%) | 731 (45.9%) | 17,390 (42.2%) |
| Employed | 15,300 (45.1%) | 2,581 (44.8%) | 512 (32.1%) | 18,393 (44.6%) |
| Employed but absent | 1,362 (4%) | 238 (4.1%) | 162 (10.2%) | 1,762 (4.3%) |
| Permanently unable to work | 3,023 (8.9%) | 525 (9.1%) | 189 (11.9%) | 3,737 (9.1%) |
| Missing | 1,656 (4.7%) | 350 (5.7%) | 221 (12.2%) | 2,227 (5.1%) |
| Education | | | | |
| <Secondary | 7,897 (24%) | 1,251 (22.8%) | 358 (24.1%) | 9,506 (23.5%) |
| Secondary | 8,790 (26.7%) | 1,475 (26.8%) | 406 (27.4%) | 10,671 (26.4%) |
| Some post-secondary | 5,596 (17%) | 927 (16.9%) | 217 (14.6%) | 6,740 (16.7%) |
| Post-secondary | 10,582 (32.2%) | 1,842 (33.5%) | 503 (33.9%) | 12,927 (32.0%) |
| Missing | 2,720 (7.6%) | 614 (10.1%) | 331 (18.2%) | 3,665 (8.4%) |
| Household income | | | | |
| <=$20,000 | 6,158 (28.1%) | 982 (28.6%) | 259 (29.3%) | 7,399 (28.2%) |
| $20,001 to $60,000 | 8,935 (40.8%) | 1,346 (39.2%) | 364 (41.1%) | 10,645 (40.6%) |
| >$60,000 | 6,811 (31.1%) | 1,108 (32.2%) | 262 (29.6%) | 8,181 (31.2%) |
| Missing | 13,681 (38.4%) | 2,673 (43.8%) | 930 (51.2%) | 17,284 (39.7%) |

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|---|---|---|---|---|
| Mental health diagnosis[4] | | | | |
| No | 17,581 (54%) | 2,838 (52.1%) | 710 (45.5%) | 21,129 (53.2%) |
| Yes | 14,981 (46%) | 2,613 (47.9%) | 850 (54.5%) | 18,444 (46.8%) |
| Missing | 3,023 (8.5%) | 658 (10.8%) | 255 (14%) | 3,936 (9.1%) |
| Physical health diagnosis[5] | | | | |
| No | 18,443 (57.6%) | 2,952 (55%) | 746 (49%) | 22,141 (56.2%) |
| Yes | 13,550 (42.4%) | 2,413 (45%) | 778 (51%) | 16,741 (43.2%) |
| Missing | 3,592 (10.1%) | 744 (12.2%) | 291 (16%) | 4,627 (10.6%) |
| Substance use disorder diagnosis[6] | | | | |
| No | 29,998 (89.2%) | 4,968 (87.9%) | 1,344 (84.7%) | 36,310 (88.2%) |
| Yes | 3,616 (10.8%) | 685 (12.1%) | 243 (15.3%) | 4,544 (11.1%) |
| Missing | 1,971 (5.5%) | 456 (7.5%) | 228 (12.6%) | 2,655 (6.1%) |
| Previous lifetime quit attempts | | | | |
| None | 3,203 (9.2%) | 507 (8.4%) | 127 (7.1%) | 3,837 (9%) |
| 1 to 5 times | 21,884 (62.6%) | 3,749 (62.4%) | 1,095 (61.4%) | 26,728 (62.4%) |
| 6 to 10 times | 5,464 (15.6%) | 968 (16.1%) | 323 (18.1%) | 6,755 (15.8%) |
| 11 or more times | 4,406 (12.6%) | 783 (13%) | 238 (13.3%) | 5,427 (12.7%) |
| Missing | 628 (1.8%) | 102 (1.7%) | 32 (1.8%) | 762 (1.8%) |
| Quit date specified | | | | |
| No | 16,121 (45.3%) | 2,807 (45.9%) | 927 (51.1%) | 19,855 (45.8%) |
| Yes | 19,464 (54.7%) | 3,302 (54.1%) | 888 (48.9%) | 23,654 (54.4%) |
| Missing | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| First cigarette after waking | | | | |
| Within 5 mins | 12,940 (36.6%) | 2,161 (35.6%) | 678 (37.7%) | 15,779 (36.6%) |
| 6 to 30 mins | 14,431 (40.8%) | 2,551 (42.1%) | 726 (40.3%) | 17,708 (41%) |
| 31 to 60 mins | 4,646 (13.1%) | 760 (12.5%) | 211 (11.7%) | 5,617 (13%) |
| More than 60 mins | 3,329 (9.4%) | 591 (9.7%) | 185 (10.3%) | 4,105 (9.5%) |
| Missing | 239 (0.7%) | 46 (0.8%) | 15 (0.8%) | 300 (0.7%) |
| Cigarettes per day | | | | |
| <10 | 4,599 (13%) | 864 (14.2%) | 251 (13.8%) | 5,714 (13.2%) |
| 10 to 19 | 13,001 (36.6%) | 2,205 (36.1%) | 643 (35.4%) | 15,849 (36.7%) |

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| 20 to 29 | 13,248 (37.3%) | 2,295 (37.6%) | 658 (36.3%) | 16,201 (37.2%) |
| 30 to 39 | 2,500 (7%) | 379 (6.2%) | 134 (7.4%) | 3,013 (6.9%) |
| 40+ | 2,157 (6.1%) | 360 (5.9%) | 129 (7.1%) | 2,732 (6.3%) |
| Missing | 80 (0.2%) | 6 (0.1%) | 0 (0%) | 86 (0.2%) |
| Confidence in ability to quit | | | | |
| Low (1-4) | 2,771 (7.9%) | 425 (7%) | 130 (7.2%) | 3,326 (7.7%) |
| Moderate (5-7) | 13,705 (38.9%) | 2,374 (39.3%) | 681 (38%) | 16,760 (38.6%) |
| High (8-10) | 18,749 (53.2%) | 3,235 (53.6%) | 983 (54.8%) | 22,967 (53.1%) |
| Missing | 360 (1%) | 75 (1.2%) | 21 (1.2%) | 456 (1.1%) |
| Importance of quitting | | | | |
| Low (1-4) | 281 (0.8%) | 51 (0.8%) | 13 (0.7%) | 345 (0.8%) |
| Moderate (5-7) | 3,352 (9.5%) | 556 (9.2%) | 145 (8.1%) | 4,053 (9.4%) |
| High (8-10) | 31,699 (89.7%) | 5,451 (90%) | 1,642 (91.2%) | 38,792 (89.7%) |
| Missing | 253 (0.7%) | 51 (0.8%) | 15 (0.8%) | 319 (0.7%) |

[1] April 11, 2016 to September 16, 2019.
[2] September 17, 2019 to March 16, 2020.
[3] March 17, 2020 to July 16, 2020.
[4] Lifetime diagnosis of depression, anxiety, bipolar disorder, or schizophrenia.
[5] Lifetime diagnosis of heart disease, stroke, diabetes, cancer, or chronic obstructive pulmonary disease.
[6] Lifetime diagnosis of non-tobacco substance use disorder.

Table 2. Time terms from final mixed-effects logistic regression models.

| | OR (95% CI) | p |
|---|---|---|
| Main model | | |
| Time: Apr 11, 2016 to Sep 16, 2019[1] | 1.000 (0.997, 1.002) | 0.77 |
| Time: Sep 17, 2019 to Mar 17, 2020[1] | 0.940 (0.918, 0.962) | <0.001 |
| Post-March 17, 2020 | 1.09 (0.93, 1.28) | 0.28 |
| With seasonality adjustment | | |
| Time: Apr 11, 2016 to Sep 16, 2019[1] | 1.000 (0.998, 1.002) | 0.98 |
| Time: Sep 17, 2019 to Mar 17, 2020[1] | 0.942 (0.919, 0.965) | <0.001 |
| Post-March 17, 2020 | 1.22 (1.02, 1.46) | 0.03 |

[1] Per 30 days.

Figure 1. Proportion of patients abstinent from cigarettes for 7 days at 6-month follow up, by month of enrolment, with 95% confidence intervals.

Figure 2. Predicted probability of being abstinent from cigarettes for 7 days at 6-month follow-up, by date of enrolment. Solid line shows results from primary model, dotted line results adjusting for seasonality.

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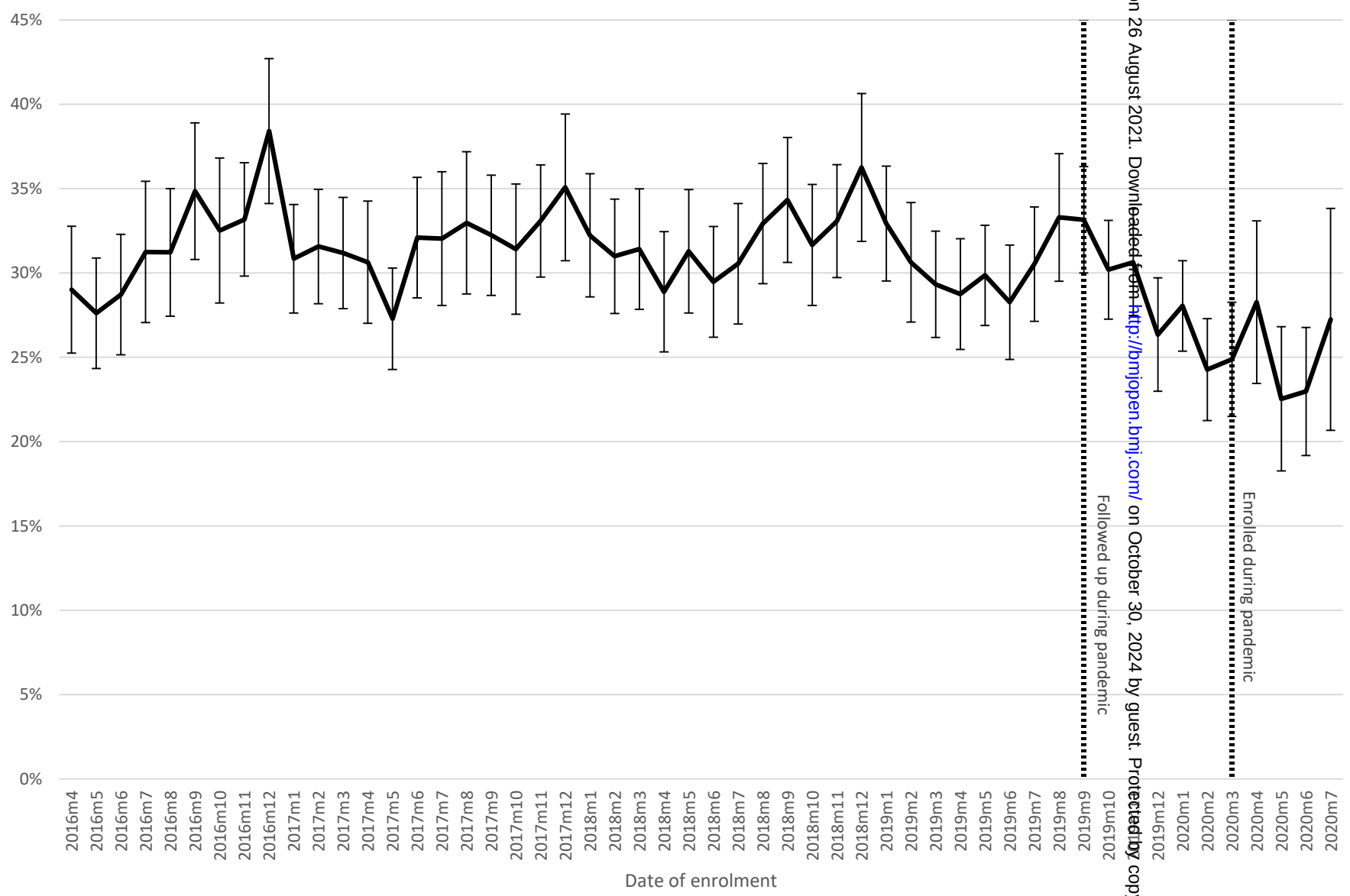

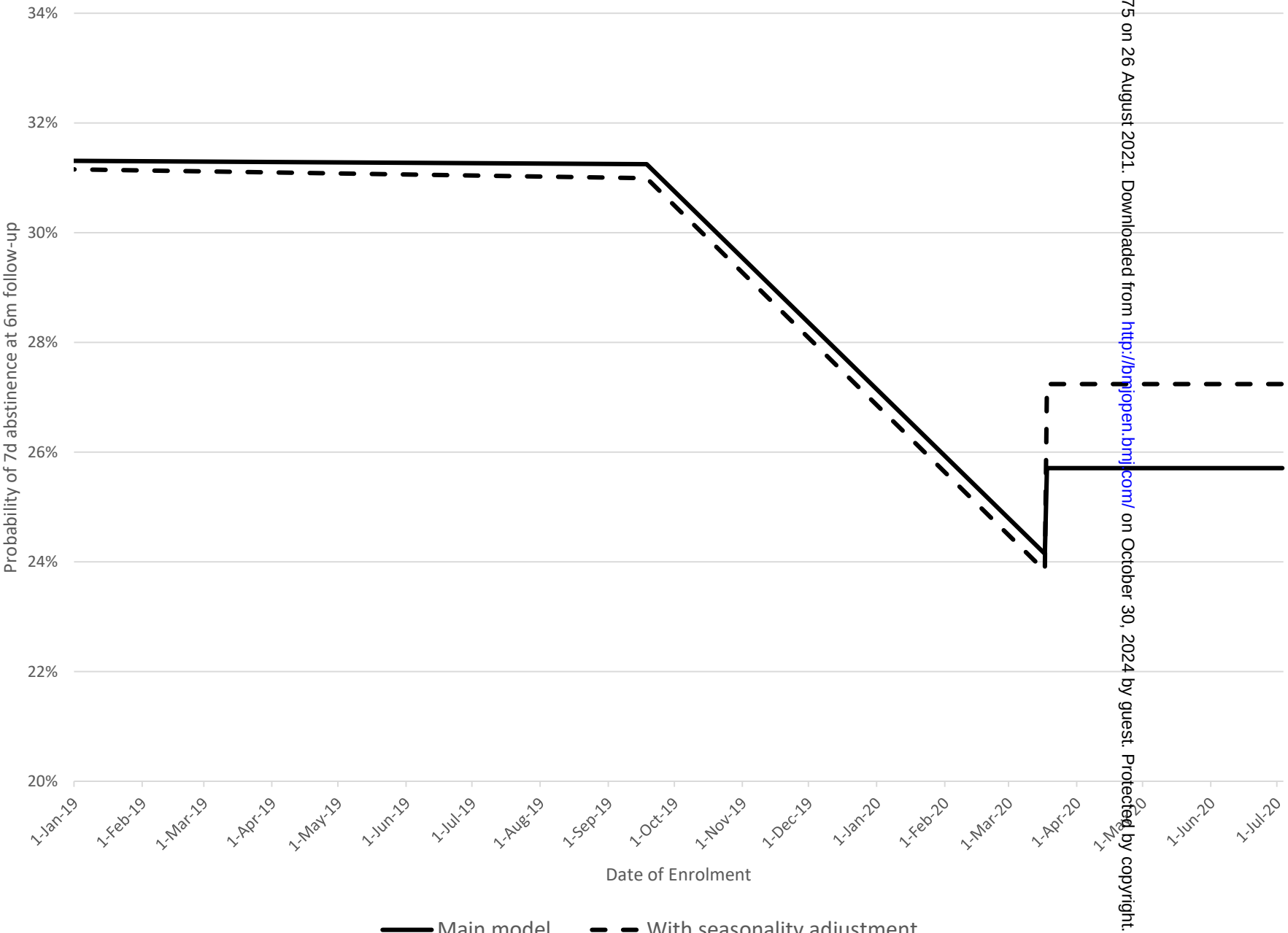

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

| | Item No | Recommendation | Page No |
|---|---|---|---|
| **Title and abstract** | 1 | (*a*) Indicate the study's design with a commonly used term in the title or the abstract | 3 |
| | | (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found | 3-4 |
| **Introduction** | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | 5-6 |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | 6 |
| **Methods** | | | |
| Study design | 4 | Present key elements of study design early in the paper | 6-7 |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 6-7 |
| Participants | 6 | (*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up | 7-8 |
| | | (*b*) For matched studies, give matching criteria and number of exposed and unexposed | N/A |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 8-9 |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | 8-9 |
| Bias | 9 | Describe any efforts to address potential sources of bias | 10 |
| Study size | 10 | Explain how the study size was arrived at | 7-8 |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 9-10 |
| Statistical methods | 12 | (*a*) Describe all statistical methods, including those used to control for confounding | 9-11 |
| | | (*b*) Describe any methods used to examine subgroups and interactions | N/A |
| | | (*c*) Explain how missing data were addressed | 10-11 |
| | | (*d*) If applicable, explain how loss to follow-up was addressed | N/A |
| | | (*e*) Describe any sensitivity analyses | 10 |
| **Results** | | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | 8 |
| | | (b) Give reasons for non-participation at each stage | 8-9 |
| | | (c) Consider use of a flow diagram | N/A |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | 18 |
| | | (b) Indicate number of participants with missing data for each variable of interest | 18 |
| | | (c) Summarise follow-up time (eg, average and total amount) | 7 |
| Outcome data | 15* | Report numbers of outcome events or summary measures over time | 12 |

| | | | |
|---|---|---|---|
| Main results | 16 | (*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included<br>(*b*) Report category boundaries when continuous variables were categorized<br>(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | 21<br>N/A<br>12 |
| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | 12 |
| **Discussion** | | | |
| Key results | 18 | Summarise key results with reference to study objectives | 12-13 |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | 15 |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 12-15 |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | 14-15 |
| **Other information** | | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | 2 |

*Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

BMJ Open

# The effect of COVID-19 on smoking cessation outcomes in a large primary care treatment program: an observational study

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Title: The effect of COVID-19 on smoking cessation outcomes in a large primary care treatment program: an observational study

Scott Veldhuizen[1], Ph.D. (email: scott.veldhuizen@camh.ca; ORCID: 0000-0003-3969-2756)
Peter Selby[1,2,3,4,5], MBBS, CCFP(AM), FCFP, dip ABAM, MHSc (email: peter.selby@camh.ca; ORCID 0000-0001-5401-2996)
Benjamin Wong[1], MPH (email: benjamin.wong@camh.ca; ORCID: 0000-0002-7745-6271)
Laurie Zawertailo[1,2,6], Ph.D. (email: laurie.zawertailo@camh.ca; ORCID: 0000-0002-4547-1565)

1 Nicotine Dependence Service, Centre for Addiction and Mental Health, 175 College St, Toronto, ON M5T 1P7, Canada
2 Department of Family and Community Medicine, University of Toronto, 500 University Ave, Toronto, ON M5G 1V7, Canada
3 Campbell Family Mental Health Research Institute, Centre for Addiction and Mental Health, 60 White Squirrel Way, Toronto, ON M6J 1H4, Canada
4 Dalla Lana School of Public Health, University of Toronto, 155 College, Toronto, ON M5T 3M7, Canada
5 Department of Psychiatry, University of Toronto, 250 College Street, Toronto, ON M5T 1R8, Canada
6 Department of Pharmacology and Toxicology, University of Toronto, 1 King's College Cir, Toronto, ON M5S 1A8, Canada

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Correspondence: scott.r.veldhuizen@gmail.com

Objectives

The COVID-19 pandemic has changed patterns of smoking, other substance use, and other health-related behaviours, leading to a virtualization of non-urgent medical care. In this study, we examine associated changes in outcomes of smoking-cessation treatment.

Design

Observational study.

Setting

Data are drawn from 221 physician-led primary care practices participating in a smoking cessation program in Ontario, Canada.

Participants

43,509 patients (53% female), comprising 35,385 historical controls, 6109 people enrolled before the pandemic and followed up during it, and 1815 people enrolled after the pandemic began.

Intervention

Nicotine-replacement therapy (NRT) with counseling.

Primary outcome measure

7-day self-reported abstinence from cigarettes at a follow-up survey 6 months after entry.

Results

For people followed up in the 6M after the pandemic began, quit probability declined with date of enrolment. Predicted probabilities were 31.2% (95% CI=30.0%, 32.5%) for people enrolled in smoking cessation treatment 6 months prior to the emergency declaration and followed up immediately after the state of emergency was declared, and 24.1% (95% CI=22.1%, 26.2%) for those enrolled in treatment immediately before the emergency declaration and followed up 6M later (difference = -6.5%, 95% CI=-9.0%, -3.9%). Seasonality and total treatment use did not explain this decline.

Conclusion

The probability of successful smoking cessation following treatment fell during the pandemic, with the decline consistent with an effect of "exposure" to the pandemic-era environment. As many changes happened simultaneously, specific causes cannot be identified; however, the possibility that virtual care has been less effective than in-person treatment should be explored.

## Article summary

### Strengths and limitations of this study

- This is the first large study to evaluate changes in outcomes of smoking cessation treatment during the COVID-19 pandemic.
- The large sample size and the treatment of time effects made it possible to measure changes in outcomes with good precision.
- The decrease in quit probability we observed occurred within the group of people who enrolled in the pre-pandemic period, and is therefore unlikely to result from case-mix changes linked to the pandemic itself.
- Treatment in participating clinics changed at the beginning of the pandemic; it is therefore unclear whether changes are due to changes in the care provided or to the wider context of the pandemic.

## Introduction

The reported effects of the COVID-19 pandemic on tobacco addiction and its treatment are complex and sometimes contradictory. Survey data suggest that smokers in some countries have increased their use of tobacco since the pandemic began[1-3], but also that interest in quitting[4 5] (but see also[6]), quit attempts, and successful cessation have risen[7]. Heavy drinking and high psychological distress, both intimately linked with tobacco use, also seem to have become more prevalent in the COVID-19 era,[8 9] and there is some evidence that the same may be true of substance use disorders in general, partly due to relapse among former users[10].

Some of these changes are likely to be due to contextual changes. Public health restrictions have reduced social contact and mobility[11], while job losses and the shift to remote work may have blunted the effects of smoking restrictions in workplaces and public spaces. Changes in smoking behaviour may also be influenced by reported associations between COVID and smoking[12], including suggestions that smoking may protect against infection[13], but is also associated with more severe illness[14 15].

The pandemic has also had marked effects on medical care. Public health messaging has encouraged people to delay non-urgent care, and providers have had to restrict contacts with and among patients, to acquire and use personal protective equipment, and to divert resources to test and treat potential COVID-19 cases. In Ontario, Canada, which is the region of interest in this report, total primary care visits fell sharply early in the pandemic, and in-person contacts were rapidly displaced by virtual care[16].

Although one small study has suggested that abstinence did not change during the pandemic for people treated previously[17], the net effect of pandemic-era changes on the effectiveness of care for smoking cessation is largely unknown. Given the global nature of the pandemic, and the importance of tobacco use as a public health issue, this is a question of some urgency. In this study, we examine changes during the pandemic period in the probability of achieving abstinence from cigarettes among participants in a long-running primary care smoking cessation treatment program. To our knowledge, this is the earliest attempt to understand the effects of the pandemic on the outcomes of formal treatment for tobacco addiction.

## Methods

### Design

We use longitudinal data from a clinical program to study changes over time in treatment outcomes before and during the COVID-19 pandemic. Our outcome is self-reported past 7-day abstinence from cigarettes at the 6-month follow-up, with abstinence defined as a "no" response to the question, "have you smoked a cigarette, even a puff, in the last 7 days". We consider changes over time in the probability of a "no" response to this question for 3 groups of participants: 1) those enrolled and followed up before the state of emergency declaration on March 17, 2020 (n=35,385); 2) those enrolling before this time, but followed up after it (n=6,109); and 3) those enrolling after March 17, 2020 (n=1,815).

Setting

The Smoking Treatment for Ontario Patients (STOP) program provides free counseling and nicotine replacement therapy (NRT)[18], with direct care provided principally by nurses and pharmacists. We analyzed data from 226 family health teams that participated in the program during the study period. Family health teams are physician-led primary care practices with defined rosters of patients. Participants are eligible to receive up to 26 weeks of NRT over a one-year period, and are typically seen every 2-4 weeks. Smoking status and heaviness, as well as other clinically-relevant data, are ascertained by self-report. Some sites also perform carbon monoxide or cotinine verification at clinical contacts, but this is not a feature of the core program.

Ontario family health teams largely transitioned to remote care in the early months of the pandemic[16]. However, each STOP clinic responded to the crisis independently, and in ways that varied over time. Clinic adaptations were discussed in a teleconference with representatives from 99 participating organizations in June, 2020. Broadly, providers had reduced in-person clinic visits, performed consultations by phone or videoconference where possible, and either shipped NRT to participants or arranged for distanced pickup.

Data

STOP participants are followed up by email at 3 months and by email, phone, or at a clinical contact at 6 months and 12 months after baseline. We use the 6-month follow-up because this is the program's primary reported outcome, and efforts to contact participants are most intensive

(and follow-up rates highest) at this time. As 85-90% of follow-ups are done remotely, objective verification of smoking status using biochemical validation was not feasible. However, the validity of self-reported smoking status has generally been shown to be good[19 20]. The general follow-up approach did not change during the pandemic, with most participants continuing to be reached by phone.

Context

In Ontario, substantial numbers of COVID-19 cases were first detected in March, 2020[21]. The provincial government declared a state of emergency on March 17, 2020, mandating the closure of schools and many business and indoor public spaces. Following the state of emergency declaration, STOP enrolments immediately fell by 70%. By January, 2021, they had recovered to 30% below normal levels. Changes in restrictions after March, 2020 had no clear effects on enrolments. We use the state of emergency declaration on March 17 as the primary break-point in our analysis, as it marks the beginning of public health restrictions and, more approximately, of the epidemic itself. We refer to times before and after this date as the "pre-pandemic" and "pandemic" periods, respectively.

Participants

We included participants enrolled from April 11, 2016, when the STOP surveys were expanded to include several important variables, to July 16, 2020, which is the latest date for which 6-month follow-ups were available. These follow-ups were done between November 11, 2016 and February 16, 2021. From the 58,292 such enrolments, we removed 4314 (7.4%) people who

were not daily smokers at baseline and 521 (0.9%) without recorded clinical visits. People are also allowed to re-enroll in STOP after their full one-year treatment eligibility period has expired. We used probabilistic deduplication to identify repeat enrolments, and kept only the most recent enrolment for each person. This meant removing a further 9948 (17.1%) records, almost all of which (9555; 96%) were followed up in the pre-pandemic period. The final analysis sample included 43,509 unique participants from 226 clinics (see supplementary file).

Analytic approach

To understand the effects of pandemic-related changes on smoking cessation treatment outcomes, we conduct an individual-level analysis of change in the probability of successful cessation by date of enrolment. For enrolments in the 6M before the pandemic, we interpret change over time primarily as a continuous measure of exposure to the pandemic environment. People enrolling at the beginning of this period will have experienced the pandemic for only a short time before their follow-up; and, as the total length of treatment is usually less than 6 months[21], only a few will have received treatment during the pandemic. Conversely, those enrolling just before the state of emergency declaration will have usually made their quit attempt(s), and received most of their treatment, after pandemic-related restrictions were imposed.

**Patient involvement**

This was a secondary analysis of program data, without direct involvement of patients in the design of the study or the interpretation of results.

## Ethics approval

The STOP Program is funded by the Ontario Ministry of Health and Long-term Care, and its procedures were approved by the Research Ethics Board at the Centre for Addiction and Mental Health (protocol numbers 058-2011 and 154-2012). Participants provided informed, written consent for use of data for research at the time of the baseline interview.

## Analysis

We first produced descriptive statistics. We then fit a piecewise mixed-effects logistic regression model that estimates one slope for date of enrolment for enrolments from April 11, 2016 to September 16, 2019 and another for those from September 17, 2019 until March 17, 2020. To test for changes after this date, we initially included both another slope and an indicator variable that was 1 for people who enrolled after March 17, 2020, and 0 otherwise. The indicator captures any overall change for these participants, while we included a slope to explore the possibility of further gradual change.

This model allows for different time effects for each of our 3 groups of participants: those enrolled and followed up before the state of emergency declaration; those enrolled before this time, but followed up after it; and those enrolled after this point. As noted, it is change by date of enrolment within the second group that is of greatest interest. We included a random intercept for study site, and evaluated time effects for linearity by examining monthly means. To obtain

absolute adjusted differences (AADs) between pairs of time points, we used post-estimation procedures on estimated marginal means.

We adjusted for possible changes in case-mix by including a set of baseline participant characteristics, selected a priori, that are known to be associated with treatment outcome. These were: age, sex/gender, cigarettes per day, time to first cigarette after waking, previous lifetime quit attempts, motivation to quit (1-10), confidence in ability to quit (1-10), and lifetime diagnosis of a physical (heart disease, cancer, stroke, diabetes, or COPD), mental health (anxiety, depression, bipolar disorder, or schizophrenia), or non-tobacco substance-related condition (drug use disorder or alcohol use disorder).

To examine the possibility that any changes in outcome were associated with changes in the type or amount of treatment used, we fit a further model that included 1) the total number of clinical visits attended in the first 6M of treatment; 2) the type of NRT initially dispensed (no NRT, short-acting forms only, patch only, or short-acting and patch in combination); and 3) the total number of weeks of NRT provided.

Finally, previous work with STOP data has shown that treatment outcomes show modest seasonal variation[22]. It is not clear, however, that the factors underlying seasonal differences continued to operate in the same way during the pandemic, which disrupted holiday-taking, socializing, and other activities. As a result, we treated this question as a sensitivity analysis, and fit a further model including dummy-coded month of year. We used Stata 16 for all analyses[23].

*Missing data*

Most baseline variables include some missing data (Table 1). The outcome was also available only for 27,541 (64%) participants who completed the 6M follow-up survey. This level of completeness compares favourably to other large, observational studies of smoking cessation treatment (e.g., [24 25]). We addressed missing data using multiple imputation with chained equations, with 50 imputed datasets. We included all variables from our substantive models, including treatment variables. As auxiliary variables, we included quit status at 3M follow-up (where available), quit status at the last clinical contact before 6M, and the number of previous enrolments, if any. We do not impute missing outcomes to "smoking", because this would bias the quit proportion downwards, and would also bias effects of any variables, including time, that are associated with loss to follow-up[26 27].

Multiple imputation reduces bias by taking into account observed associations between non-response and the variables measured, but does not exclude the possibility that quit status itself is independently associated with response at follow-up. This is a potential concern for our analysis of change over time, because our follow-up rate rose from 61% before the pandemic to 75% for people followed up after it began. This was partly due to a higher response rate for phone surveys, and partly because efforts to reach participants were intensified. However, the follow up rate after the pandemic began was approximately constant, and it is variation in outcomes for these participants that are of primary interest.

## Results

Descriptive statistics are shown in Table 1, and the overall proportion of participants successfully quitting, by month of enrolment, in Figure 1.

Model results are shown in Table 2, and the corresponding marginal predictions in Figure 2. From the initial model, we removed the slope term for post-pandemic enrolments, number of clinical visits, type of NRT, and weeks of NRT dispensed, all of which were non-significant and did not meaningfully change estimates of change over time.

In the final model, there was no change over time in the probability of cessation for people who were followed up before the pandemic. For people who enrolled pre-pandemic and were followed up during it, however, the probability of cessation fell with date of enrolment. Predicted probabilities were 31.2% (95% CI = 30.0% to 32.5%) for people enrolled 6 months prior to the emergency declaration and followed up immediately before the state of emergency was declared and 24.1% (95% CI = 22.1% to 26.2%) for those enrolled in treatment immediately before the emergency declaration and followed up 6M later. This is a decrease of 6.5% (95% CI = 3.9% to 9.0%).

Adjusting for seasonality did not meaningfully change effects for pre-pandemic enrolments (Figure 2). However, this adjustment did increase the coefficient for enrolment during the pandemic period, and lowered the corresponding p-value to 0.03. As this effect was not

significant in our main model, the evidence for a change in quit success for these enrolments is ambiguous. Even in the seasonality-adjusted model, however, the predicted probability of quitting smoking remained lower for pandemic-era enrolments than it was for people who enrolled before the pandemic began (AAD = -3.8%, 95% CI = -6.5% to -1.0%).

## Discussion

In this large, primary care smoking cessation program, the COVID-19 pandemic was associated with a clinically meaningful decrease in the proportion of patients who quit successfully. The quit probability fell linearly with date of enrolment, which is consistent with an effect of "exposure" to the pandemic environment: people who spent more of their follow-up period, and received more of their treatment, during the pandemic period were less likely to quit smoking. This change was not accounted for by seasonal variation, by changes in the known characteristics of enrolling participants, or by differences in the type or amount of treatment provided. For people enrolled after the state of emergency, the probability of cessation may have increased slightly, but neither varied strongly nor returned to its pre-pandemic level, which is consistent with the continued operation of factors associated with the pandemic.

Ontario's public health measures changed over the study period, and beliefs and behaviours of program participants may also have varied. The probability of successful smoking cessation, however, declined approximately linearly with enrolment date. This is probably because outcomes reflect the net effects of all influences over the 6-month period, and will not have been

sensitive to small or short-term contextual differences. Chance variation and possible seasonal differences also make it difficult to discern small probability variations within this time.

It is not possible to confidently link poorer treatment outcomes to specific causes, because the pandemic brought change in many areas simultaneously. Of potential causes, however, we can usefully distinguish between 1) changes related to the wider pandemic context, and 2) changes in the care provided. As noted, some data suggest that psychological distress and substance use have increased during the pandemic[8 9], and this may have made quitting smoking more difficult for some people. Population survey data from other countries generally do not suggest that cessation rates fell[7], but the evidence on this question is limited, and what is true of the wider population may not be true of smokers in treatment. The effects of contextual factors on treatment outcomes therefore remain unclear.

Despite the difficulty of disentangling causal effects, it is important to consider possible impacts of changes in care provision. In STOP, there were no pandemic-related disruptions at the program level: delivery of NRT supplies to each clinic continued uninterrupted, we placed no restrictions on conduct of remote visits or enrolment of new participants using verbal consent procedures, and our model results show that the amount of treatment received did not meaningfully change estimates of change over time. However, as noted, care in Ontario FHTs was rapidly virtualized following the beginning of the pandemic[16]. Virtual care may have changed the nature of counseling, with group therapy, for example, becoming a technological

challenge. Provision of NRT may also have become less timely, and less-tangible influences, such as immediacy and engagement, may also be relevant.

It is therefore possible that the decrease in quit rate is due to virtual treatment for smoking cessation being less effective than in-person care. There is surprisingly little evidence on this question. The overall effectiveness of remote care for smoking cessation, in the form of telephone quitlines[28 29], is well-established[30 31]. However, very few trials have directly compared any form of remote care directly to in-person treatment[32 33]. One such non-inferiority trial from Japan found no difference in outcomes, but was not powered to detect small differences, and provided an intervention that may not be entirely comparable to those offered during the pandemic by smoking cessation clinics[34]. Studies on alcohol[35] and opioid use[36] disorders have also failed to find differences between in-person and virtual care, but the applicability of this research to tobacco cessation is uncertain, and sample sizes were again relatively small. Moreover, the pandemic obliged STOP providers to transition very rapidly to remote care without extensive preparation or training, and this may, in some cases, have made it difficult to provide optimal care.

A further possibility is that the pandemic disrupted existing treatment episodes, with participants accustomed to in-person treatment having to adjust to remote care. In this case, it would not be the new care approaches themselves, but the transition to them, that is important. If this were the case, we would expect to see an increase in quit probability among people enrolling after the pandemic began, as they received all treatment after the shift to remote care had occurred. Our

results are ambiguous on this question, due to the uncertain influence of seasonal variation. They do show, however, that the quit probability for these patients did not return to pre-pandemic levels. Disruptions to ongoing care therefore cannot entirely explain the change in quit success; and it is likely that the factors underlying the poorer outcomes among pre-COVID enrolments continued to affect people who enrolled after the state of emergency.

Although STOP is a single program, it was delivered in 226 team-based primary care practices across Ontario during the study period, and changes in processes and protocols were implemented independently at each clinic. The experience of Ontario during this period was also fairly similar to those of many other developed-world jurisdictions, in terms of the epidemiology of COVID-19 and the public health restrictions that were imposed. We therefore believe that results will be relevant to other contexts. Our findings also suggest that the wider question of the effectiveness of remote treatment in primary care deserves close attention.

**Limitations**

We lack detailed information about how individual clinics adapted to COVID-19. It is also possible that people enrolling during the pandemic differed from those enrolling earlier on unmeasured variables. However, this does not affect the primary results, which rest on time effects for earlier enrolments. A substantial proportion of participants also did not complete their 6M follow-up. Although we have tried to account for missingness in our analysis, it is conceivable that there remained uncaptured associations between treatment outcome and other variables. As noted, our follow-up rate also increased for pandemic-era follow-ups. However,

this cannot explain change in outcomes over time within the group followed up during this period, because the follow-up rate over this period was approximately constant.

## Conclusion

The STOP model ensured that smoking cessation treatment continued to be provided in primary care during the COVID-19 pandemic, and this treatment did remain generally effective. However, the proportion of participants who quit successfully declined meaningfully during this time. As the number of people receiving this care was also reduced by public health restrictions, reduced smoking cessation through formal treatment can be numbered among the important negative secondary effects of the pandemic. There is a need for research on the effectiveness and further optimization of virtual care for smoking cessation.

Contributors: SV designed and performed the analysis and drafted and revised the manuscript. He is guarantor. BW assisted with the analysis of the data and revised the paper. LZ and PS initiated and manage the STOP program, supervised data collection, and drafted and revised the paper.

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Data sharing: Requests for access to anonymized patient-level data will be considered in consultation with the supervising privacy and ethics bodies. Enquiries should be made to the corresponding author.

[Figure1]

[Figure2]

Table 1. Descriptive statistics.

| | Enrolment date | | | |
|---|---|---|---|---|
| | Historical controls[1] | 6M before COVID[2] | COVID era[3] | Total |
| Sex | | | | |
| Male | 16,696 (47%) | 2,857 (46.9%) | 825 (45.5%) | 20,378 (46.8%) |
| Female | 18,806 (53%) | 3,235 (53.1%) | 987 (54.5%) | 23,028 (53.1%) |
| "Other" or Missing | 83 (0.2%) | 17 (0.3%) | 3 (0.2%) | 103 (0.2%) |
| Age | | | | |
| <35 | 5,041 (14.2%) | 750 (12.3%) | 224 (12.3%) | 6,015 (13.8%) |
| 35 to 54 | 13,818 (38.8%) | 2,205 (36.1%) | 652 (35.9%) | 16,675 (38.4%) |
| 55+ | 16,709 (47%) | 3,150 (51.6%) | 939 (51.7%) | 20,798 (47.8%) |
| Missing | 17 (0%) | 4 (0.1%) | 0 (0%) | 21 (0.1%) |
| Past week employment status | | | | |
| Not working | 14,244 (42%) | 2,415 (41.9%) | 731 (45.9%) | 17,390 (42.2%) |
| Employed | 15,300 (45.1%) | 2,581 (44.8%) | 512 (32.1%) | 18,393 (44.6%) |
| Employed but absent | 1,362 (4%) | 238 (4.1%) | 162 (10.2%) | 1,762 (4.3%) |
| Permanently unable to work | 3,023 (8.9%) | 525 (9.1%) | 189 (11.9%) | 3,737 (9.1%) |
| Missing | 1,656 (4.7%) | 350 (5.7%) | 221 (12.2%) | 2,227 (5.1%) |
| Education | | | | |
| <Secondary | 7,897 (24%) | 1,251 (22.8%) | 358 (24.1%) | 9,506 (23.5%) |
| Secondary | 8,790 (26.7%) | 1,475 (26.8%) | 406 (27.4%) | 10,671 (26.4%) |
| Some post-secondary | 5,596 (17%) | 927 (16.9%) | 217 (14.6%) | 6,740 (16.7%) |
| Post-secondary | 10,582 (32.2%) | 1,842 (33.5%) | 503 (33.9%) | 12,927 (32.0%) |
| Missing | 2,720 (7.6%) | 614 (10.1%) | 331 (18.2%) | 3,665 (8.4%) |
| Household income | | | | |
| <=$20,000 | 6,158 (28.1%) | 982 (28.6%) | 259 (29.3%) | 7,399 (28.2%) |
| $20,001 to $60,000 | 8,935 (40.8%) | 1,346 (39.2%) | 364 (41.1%) | 10,645 (40.6%) |
| >$60,000 | 6,811 (31.1%) | 1,108 (32.2%) | 262 (29.6%) | 8,181 (31.2%) |
| Missing | 13,681 (38.4%) | 2,673 (43.8%) | 930 (51.2%) | 17,284 (39.7%) |

| | | | | |
|---|---|---|---|---|
| Mental health diagnosis[4] | | | | |
| No | 17,581 (54%) | 2,838 (52.1%) | 710 (45.5%) | 21,129 (53.2%) |
| Yes | 14,981 (46%) | 2,613 (47.9%) | 850 (54.5%) | 18,444 (46.8%) |
| Missing | 3,023 (8.5%) | 658 (10.8%) | 255 (14%) | 3,936 (9.1%) |
| Physical health diagnosis[5] | | | | |
| No | 18,443 (57.6%) | 2,952 (55%) | 746 (49%) | 22,141 (56.2%) |
| Yes | 13,550 (42.4%) | 2,413 (45%) | 778 (51%) | 16,741 (43.2%) |
| Missing | 3,592 (10.1%) | 744 (12.2%) | 291 (16%) | 4,627 (10.6%) |
| Substance use disorder diagnosis[6] | | | | |
| No | 29,998 (89.2%) | 4,968 (87.9%) | 1,344 (84.7%) | 36,310 (88.2%) |
| Yes | 3,616 (10.8%) | 685 (12.1%) | 243 (15.3%) | 4,544 (11.1%) |
| Missing | 1,971 (5.5%) | 456 (7.5%) | 228 (12.6%) | 2,655 (6.1%) |
| Previous lifetime quit attempts | | | | |
| None | 3,203 (9.2%) | 507 (8.4%) | 127 (7.1%) | 3,837 (9%) |
| 1 to 5 times | 21,884 (62.6%) | 3,749 (62.4%) | 1,095 (61.4%) | 26,728 (62.4%) |
| 6 to 10 times | 5,464 (15.6%) | 968 (16.1%) | 323 (18.1%) | 6,755 (15.8%) |
| 11 or more times | 4,406 (12.6%) | 783 (13%) | 238 (13.3%) | 5,427 (12.7%) |
| Missing | 628 (1.8%) | 102 (1.7%) | 32 (1.8%) | 762 (1.8%) |
| Quit date specified | | | | |
| No | 16,121 (45.3%) | 2,807 (45.9%) | 927 (51.1%) | 19,855 (45.9%) |
| Yes | 19,464 (54.7%) | 3,302 (54.1%) | 888 (48.9%) | 23,654 (54.4%) |
| Missing | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) |
| First cigarette after waking | | | | |
| Within 5 mins | 12,940 (36.6%) | 2,161 (35.6%) | 678 (37.7%) | 15,779 (36.6%) |
| 6 to 30 mins | 14,431 (40.8%) | 2,551 (42.1%) | 726 (40.3%) | 17,708 (41%) |
| 31 to 60 mins | 4,646 (13.1%) | 760 (12.5%) | 211 (11.7%) | 5,617 (13%) |
| More than 60 mins | 3,329 (9.4%) | 591 (9.7%) | 185 (10.3%) | 4,105 (9.5%) |
| Missing | 239 (0.7%) | 46 (0.8%) | 15 (0.8%) | 300 (0.7%) |
| Cigarettes per day | | | | |
| <10 | 4,599 (13%) | 864 (14.2%) | 251 (13.8%) | 5,714 (13.2%) |
| 10 to 19 | 13,001 (36.6%) | 2,205 (36.1%) | 643 (35.4%) | 15,849 (36.7%) |

| | | | | |
|---|---|---|---|---|
| 20 to 29 | 13,248 (37.3%) | 2,295 (37.6%) | 658 (36.3%) | 16,201 (37.3%) |
| 30 to 39 | 2,500 (7%) | 379 (6.2%) | 134 (7.4%) | 3,013 (6.9%) |
| 40+ | 2,157 (6.1%) | 360 (5.9%) | 129 (7.1%) | 2,732 (6.3%) |
| Missing | 80 (0.2%) | 6 (0.1%) | 0 (0%) | 86 (0.2%) |
| Confidence in ability to quit | | | | |
| Low (1-4) | 2,771 (7.9%) | 425 (7%) | 130 (7.2%) | 3,326 (7.7%) |
| Moderate (5-7) | 13,705 (38.9%) | 2,374 (39.3%) | 681 (38%) | 16,760 (38.6%) |
| High (8-10) | 18,749 (53.2%) | 3,235 (53.6%) | 983 (54.8%) | 22,967 (53.1%) |
| Missing | 360 (1%) | 75 (1.2%) | 21 (1.2%) | 456 (1.1%) |
| Importance of quitting | | | | |
| Low (1-4) | 281 (0.8%) | 51 (0.8%) | 13 (0.7%) | 345 (0.8%) |
| Moderate (5-7) | 3,352 (9.5%) | 556 (9.2%) | 145 (8.1%) | 4,053 (9.4%) |
| High (8-10) | 31,699 (89.7%) | 5,451 (90%) | 1,642 (91.2%) | 38,792 (89.7%) |
| Missing | 253 (0.7%) | 51 (0.8%) | 15 (0.8%) | 319 (0.7%) |

[1] April 11, 2016 to September 16, 2019.
[2] September 17, 2019 to March 16, 2020.
[3] March 17, 2020 to July 16, 2020.
[4] Lifetime diagnosis of depression, anxiety, bipolar disorder, or schizophrenia.
[5] Lifetime diagnosis of heart disease, stroke, diabetes, cancer, or chronic obstructive pulmonary disease.
[6] Lifetime diagnosis of non-tobacco substance use disorder.

Table 2. Time terms from final mixed-effects logistic regression models.

| | OR (95% CI) | p |
|---|---|---|
| Main model | | |
| Time: Apr 11, 2016 to Sep 16, 2019[1] | 1.000 (0.997, 1.002) | 0.77 |
| Time: Sep 17, 2019 to Mar 17, 2020[1] | 0.940 (0.918, 0.962) | <0.001 |
| Post-March 17, 2020 | 1.09 (0.93, 1.28) | 0.28 |
| With seasonality adjustment | | |
| Time: Apr 11, 2016 to Sep 16, 2019[1] | 1.000 (0.998, 1.002) | 0.98 |
| Time: Sep 17, 2019 to Mar 17, 2020[1] | 0.942 (0.919, 0.965) | <0.001 |
| Post-March 17, 2020 | 1.22 (1.02, 1.46) | 0.03 |

[1] Per 30 days.

Figure 1. Proportion of patients abstinent from cigarettes for 7 days at 6-month follow up, by month of enrolment, with 95% confidence intervals.

Figure 2. Predicted probability of being abstinent from cigarettes for 7 days at 6-month follow-up, by date of enrolment. Solid line shows results from primary model, dotted line results adjusting for seasonality.

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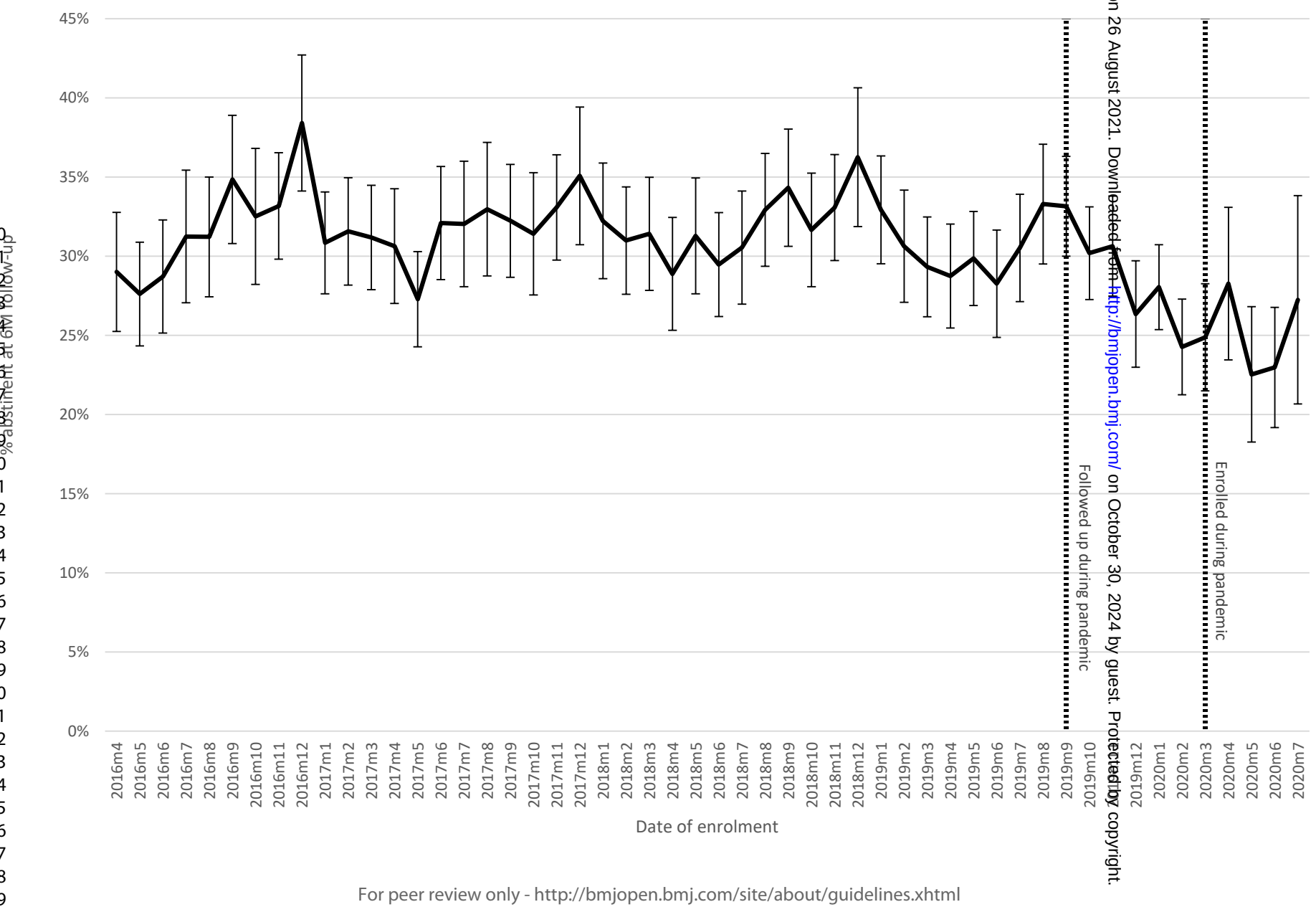

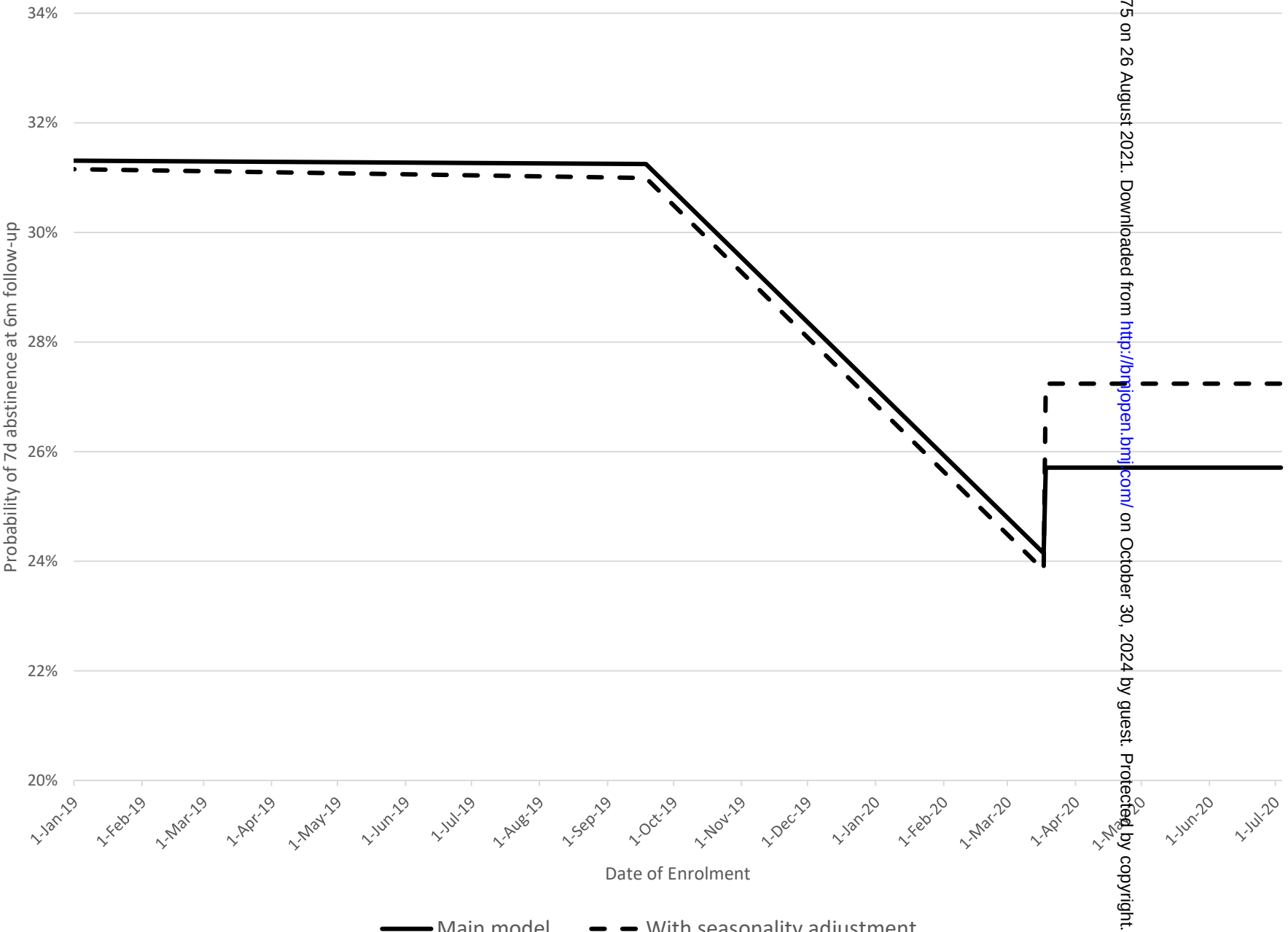

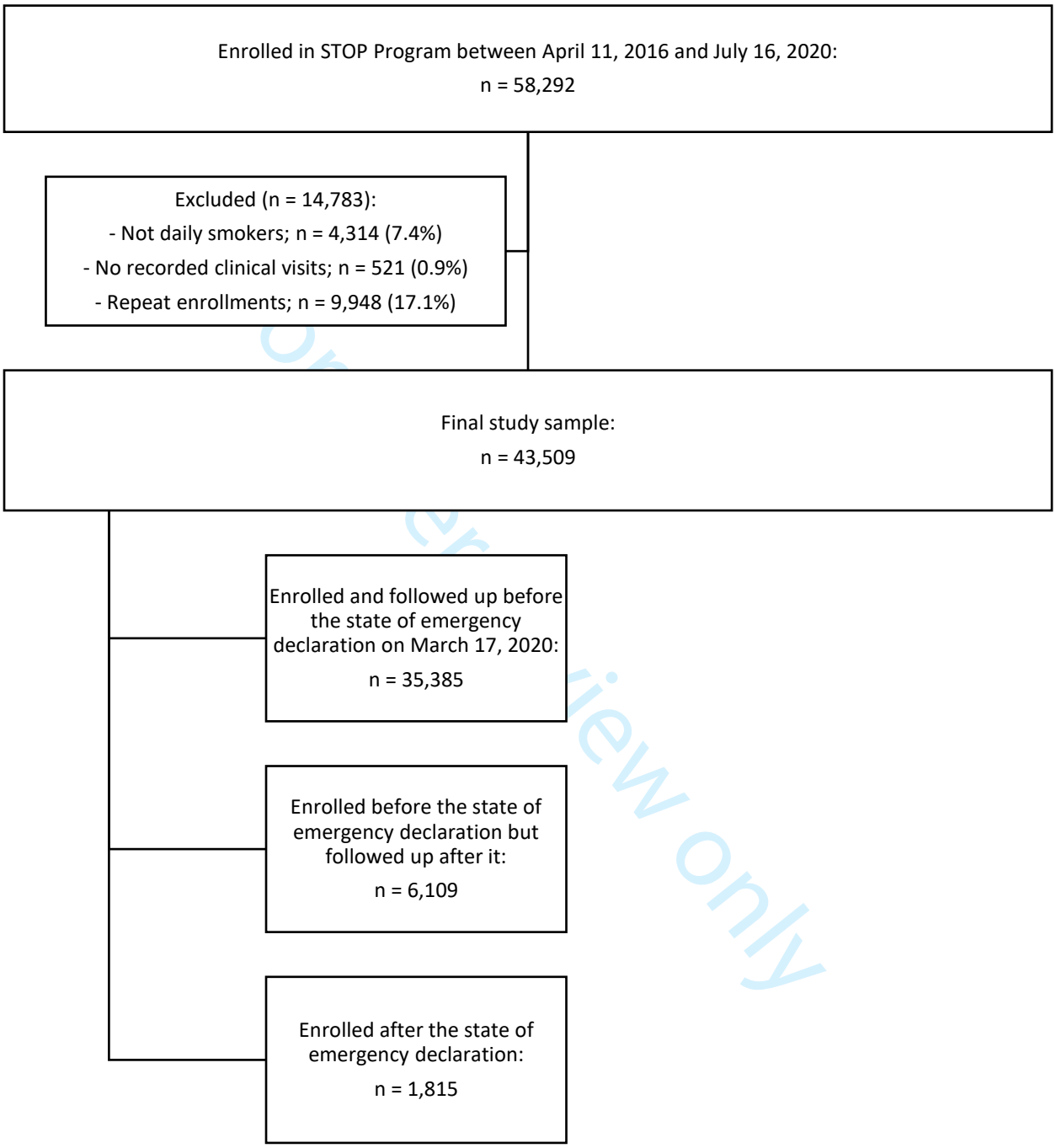

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

| | Item No | Recommendation | Page No |
|---|---|---|---|
| **Title and abstract** | 1 | (*a*) Indicate the study's design with a commonly used term in the title or the abstract | 3 |
| | | (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found | 3-4 |
| **Introduction** | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | 5-6 |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | 6 |
| **Methods** | | | |
| Study design | 4 | Present key elements of study design early in the paper | 6-7 |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 6-7 |
| Participants | 6 | (*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up | 7-8 |
| | | (*b*) For matched studies, give matching criteria and number of exposed and unexposed | N/A |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 8-9 |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | 8-9 |
| Bias | 9 | Describe any efforts to address potential sources of bias | 10 |
| Study size | 10 | Explain how the study size was arrived at | 7-8 |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 9-10 |
| Statistical methods | 12 | (*a*) Describe all statistical methods, including those used to control for confounding | 9-11 |
| | | (*b*) Describe any methods used to examine subgroups and interactions | N/A |
| | | (*c*) Explain how missing data were addressed | 10-11 |
| | | (*d*) If applicable, explain how loss to follow-up was addressed | N/A |
| | | (*e*) Describe any sensitivity analyses | 10 |
| **Results** | | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | 8 |
| | | (b) Give reasons for non-participation at each stage | 8-9 |
| | | (c) Consider use of a flow diagram | N/A |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | 18 |
| | | (b) Indicate number of participants with missing data for each variable of interest | 18 |
| | | (c) Summarise follow-up time (eg, average and total amount) | 7 |
| Outcome data | 15* | Report numbers of outcome events or summary measures over time | 12 |

| | | | |
|---|---|---|---|
| Main results | 16 | (*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included<br>(*b*) Report category boundaries when continuous variables were categorized<br>(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | 21<br>N/A<br>12 |
| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | 12 |
| **Discussion** | | | |
| Key results | 18 | Summarise key results with reference to study objectives | 12-13 |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | 15 |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 12-15 |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | 14-15 |
| **Other information** | | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | 2 |

*Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.