

## Offering nicotine patches to all households in a community with high smoking rates: Pilot test of a population-based approach to promote tobacco cessation

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### Abstract

#### Background

The objective of this project is to determine the effectiveness of targeting a community with a high smoking rate with the distribution of free-of-charge nicotine patches in order to promote tobacco cessation.

#### Methods/Design

One small community with an elevated smoking rate (compared to national and provincial averages) has been identified. All households in the community will be sent a letter offering one smoker (18 years or older; 10 or more cigarettes per day) in the household a free-of-charge mailed five-week supply of nicotine patches (up to a total of 800 five-week kits will be available for distribution). Participants receiving nicotine patches will be asked to complete a six-month follow-up survey assessing tobacco cessation defined as 30-day point prevalence abstinence. In addition, attempts will be made to employ ongoing national population surveys containing cigarette smoking variables to compare changes in smoking prevalence in the target community to other communities with similar characteristics.

#### Discussion

We will examine whether the concentrated distribution of mailed nicotine patches will result in a measurable reduction in smoking rates in the target community. If demonstrated, this would provide support for the targeted population-level distribution of an effective individual-level public health intervention.

#### Clinical Trials registration

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#### Keywords

smoking; tobacco cessation; nicotine patches; NRT; mass distribution

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## Introduction

One of the potentially important considerations for tobacco control initiatives is that there is regional variation in rates of smoking. For example, in Canada, rates of smoking vary substantially by province and territory, ranging from 17% in British Columbia to 63% in Nunavut [1, 2]. Further, there appears to be variation by regions within a province as well, with smoking rates ranging from 15.4% to 44.7% between municipalities in the province of Ontario [3]. This variation is important because targeting interventions to communities with higher smoking rates may be an effective means of maximizing the impact of limited public health resources and result in a substantial increase in the number of people quitting smoking.

The current project will explore whether the concentrated distribution of free-of-charge nicotine replacement therapy patches (henceforth as nicotine patches) will lead to larger reductions in smoking rates in a community where smoking is common. There is an extensive research base demonstrating the efficacy of nicotine patches in clinical trials [4, 5]. There have also been a number of mass distribution initiatives of free-of-charge nicotine replacement therapy (NRT) [6–10]. Further, a randomized controlled trial has demonstrated that nicotine patches delivered by postal mail promote higher rates of short-term (6 months) tobacco cessation compared to a no intervention control group (30-day abstinence: 7.6% vs. 3.0%; odds ratio (OR), 2.65; 95% CI, 1.44 - 4.89,  $p = 0.002$ ) [11]. However, while the mass distribution of nicotine patches has been judged to be a cost effective intervention using standard clinical criteria at the individual level (cost per quitter Can\$1720) [10], substantial financial resources are needed if this intervention is to be made available on a large scale. In order to make use of limited public health dollars, mass distributing nicotine patches to communities with high smoking rates may be a greater value for money, if it can be demonstrated that distribution to these areas would lead to large reductions in overall smoking rates. Thus, in the present project, we seek to determine if concentrating this distribution to an area that has a higher rate of tobacco smoking leads to a significant impact on the cessation rate in the community under study.

## Specific research questions to be addressed

Question 1: Will the concentrated distribution of nicotine patches in a community with a high smoking prevalence lead to large reductions in smoking rate? We define a large reduction based on the findings of our previous trial where there was a medium sized increase (OR of 2.6) overall but what appeared to be a large reduction (OR of 9.6) in some regions (estimate unstable due to small sample size) [12, 13]. Odds Ratios of this magnitude are discussed as large in the context of epidemiological studies [13].

Question 2: What individual characteristics are related to successful tobacco cessation (30-day abstinence) at 6-month follow-up?

Question 3: How does the wording of the cover letter inviting people to participate in the study influence the number of people who will contact the study team to request nicotine patches?

## Methods

### Study procedure

For this pilot innovation project, one intervention municipality with high smoking rates was selected using data from the two most recently available Canadian Community Health Survey conducted by Statistics Canada (2013/14 and 2015/16 CCHS) data sets [1, 14]. For the purposes of this study, a high smoking rate was defined as a municipal smoking prevalence in the top quartile of the region under study. The site was chosen by identifying those municipalities (census subdivision) in the top quartile of smoking rates among people 18 years or older on the 2015/16 data set. We then checked to see if the municipality was also listed on the 2013/14 dataset and selected a community where the reported smoking rate was similar on both surveys and had a prevalence rate that was defined by Statistics Canada as 'releasable.' We note that the CCHS sampling procedure was not constructed for this sort of use. In addition, this procedure did not result in the selection of a municipality with high smoking rates at random. However, as this is a pilot innovation project and funds were limited, we judged this method to be a good way to use available data to identify a suitable municipality for the research study.

One further detail regarding the selection of a target municipality, the trial was budgeted based on the estimate that 800 nicotine patch kits would be distributed. Thus, a small community (approximately 7200 residents) in a largely rural area was selected to allow for sufficient nicotine patch kit offers to be sent to all households in the municipality. We will also attempt to identify several other municipalities with similar characteristics to the intervention municipality as comparison municipalities. The primary matching variables for the comparison municipalities will be smoking prevalence and population size. No other factors such as proximity to the author's institution, or other administrative factors, played a role in the selection of the municipality.

All households in the intervention community will be mailed a letter offering free-of-charge nicotine patches. The letter and accompanying information sheet will explain the purpose of the study. Each letter will contain a unique code number. Those interested (one per household) will be asked to register and answer a brief baseline survey to determine if they are eligible to receive nicotine patches. The survey can be completed online or by calling the telephone number provided and responding to an automated telephone version of the same survey (survey only available in English). The letter will contain an expiry date of two months post-mailing in order to promote timely redemption. The letter also contains the information that participants will be offered a \$20 cheque to complete a 6-month follow-up survey to assess changes in smoking. Prospective participants will first be asked to provide consent to participate in the study as described in the mailed information sheet before answering any eligibility questions. Prior to providing consent, participants will be asked if they have read the information sheet. Those who have not read the information sheet will be shown an online copy, or for those who call in by telephone, the option to have the information sheet read to them will be provided. Upon providing consent, they will be asked to provide the unique code printed on the letter sent to them (only one person per

household can participate in the study). If the majority of nicotine patches have not been distributed via this recruitment method, a larger advertising strategy will be conducted in local newspapers and websites to promote recruitment into the study.

Eligible participants consist of those who speak and understand English, are 18 years or older, are primary residents of the study community, have smoked 10 or more cigarettes per day for at least the last three months, and do not have any health contraindications for using nicotine patches without the supervision of a doctor (i.e. allergy to tape, pregnant or intending to become pregnant, currently breastfeeding, serious heart or circulation problems not including high blood pressure). Those who complete the eligibility survey online will also be asked to provide contact information (name, phone number, mailing address, and email), while those who complete the automated telephone survey will be asked to contact research staff to provide this information. Only participants who are interested in receiving nicotine patches, and provide their contact information to receive the patches will be formally enrolled into the study.

The mailing of the community letters started in October 2020, and we expect the data collection to be completed by July 2020.

### **There will be four versions of the cover letter**

In order to establish whether the wording of the cover letter can influence the number of people who request nicotine patches, letters sent out will be randomized to one of four different versions in a two by two design – contains text that has a positive or a negative framing for why it is good to quit smoking [15]; and having the text of the letter edited to ensure that it is at a grade 8 or lower reading comprehension level versus not editing the letter. The unique code on each letter will allow us to match those participants requesting nicotine patches to the version of the letter they received.

### **Items included in the nicotine patch kit**

Participants will receive a 5-week step-down program of nicotine patches by postal mail. The 5-week program will consist of 3 weeks of Step 1 [21 mg of nicotine]; 1 week of Step 2 [14 mg of nicotine]; and 1 week of Step 3 [7 mg of nicotine]. There is sufficient evidence from our previous research to indicate that a 5 week supply of nicotine patches increases the chances of tobacco cessation [11] The kit will also contain a letter that advises participants to talk to their doctor if they have questions or concerns about the use of nicotine patches, a frequently asked questions section, and a list of additional local treatment resources.

### **Ethical approval**

The research methods to be used in this study have been approved by the standing ethics review committee of the Centre for Addiction and Mental Health (CAMH – REB Protocol #122/2019).

## **Outcome measures**

### **Primary outcome measure**

The primary outcome measure will be self-reported 30-day point prevalence abstinence at 6 months post-intervention. There is sufficient evidence of the reliability of self-reported tobacco cessation without biochemical validation [16–18].

### **Content of baseline survey**

Participants who request nicotine patches will be asked: a) number of cigarettes smoked per day; b) level of nicotine dependence using the revised Fagerstrom test for nicotine dependence [19]; c) ability to use nicotine patches (e.g. no contraindications to its use); and d) demographic characteristics – age, sex, family income, marital status, employment status, and ethnic origin. Further, in order to assess the potential household impact of offering nicotine patches (and to control for household smokers' impact on participants' cessation outcomes), participants will also be asked how many adults are in the household and, of these adults, how many currently smoke.

### **Content of 6-month post-intervention follow-up survey**

Participants will be asked their current smoking status, including length of time without smoking in order to assess the primary outcome variable. Further questions will be asked about participants' experience with nicotine patches and use of other stop smoking medications. Finally, use of other tobacco or nicotine containing products (including electronic cigarettes) will also be assessed.

### **Community characteristics**

Relevant community characteristics for the proposed analyses will be generated from the existing Canadian Community Health Survey (CCHS) data set (or other available general population data sets; average smoking rate, region, population density, age and gender distribution, average SES) and will be merged with the baseline and follow-up data collected as part of this trial. Health services availability will be generated based on publicly available data on the number of physicians by location, as well as other public health service locations.

## **Data analyses**

### **Question 1: To assess the proportion of participants who quit smoking**

*Method 1:* The proportion of participants who report 30-day point prevalence abstinence at 6-month follow-up out of the total number of participants who were mailed the nicotine patch kits. Participants lost to follow-up will be assumed to still be current smokers.

*Method 2:* Calculated as the proportion of participants who quit (as reported on the 6-month follow-up survey) out of the total number of participants who smoke in the municipality (the latter estimated from municipal level data of the number of adults living in the municipality and the prevalence who smoke – as assessed on the CCHS).

*Method 3:* CCHS data collected in the years before the trial, and CCHS data collected in the year after the trial (or two years after – depends on the timing of the next CCHS survey), will be used to explore any sustained impact of the reduction in smoking rates in the intervention municipality.

*Method 4:* Comparison of the rates of smoking, and tobacco cessation over time, in the intervention municipality as compared to matched municipalities with similar characteristics.

### **Question 2: What individual characteristics are related to successful tobacco cessation (30-day abstinence) at 6-month follow-up?**

*Method 1:* Logistic regression analyses will be employed to identify participants' demographic and severity of smoking characteristics related to smoking cessation at 6-month follow-up.

*Method 2:* Multi-level logistic regression models will be used to explore characteristics of the intervention municipality, and of the matched comparison municipalities [prevalence of smoking, health service availability, age and gender distribution, average SES, population density, tobacco retailer density, NRT distributor (e.g., pharmacy, grocery store) density], to identify contextual factors important in determining the size of the impact of the intervention as measured by the individual-level outcome data. Individual demographic and severity of smoking characteristics will be included in order to identify individual-level factors relevant to the impact of the intervention.

### **Question 3: Does the wording of the cover letter inviting people to participate in the study influence the number of people who request nicotine patches?**

Chi-square analyses will relate the version of the letter each household receives to whether a resident from that household called to take part in the study.

## **Discussion**

Quitting smoking is the most effective way to reduce the risk of cancer [20]. The proposed research will investigate ways to most efficiently use public resources to promote the largest number of people quitting smoking and consequently, lower the incidence of cancer and cancer-related morbidity and mortality. If the study finds that providing free nicotine patches to all households in a municipality with high smoking prevalence leads to large reductions in smoking in the community, it would provide evidence to move forward with policies designed to target mass distributions of nicotine patches to areas where smoking is most common.

## **Limitations**

We would like to address that this study will have some limitations. Firstly we should mention that as the municipality is not chosen at random, the generalizability of results will be limited. Nonetheless, we feel that the results of this trial will help inform policy and provide the preliminary evidence to conduct a full trial. Secondly, as we are only offering one

coupon per household, it is possible that the presence of other smokers in the household may negatively impact cessation rates and impact study findings. We propose to control for this in the analyses by collecting data on how many smokers reside with the participant at baseline, and at 6-month follow-up to detect changes. Lastly, it is acknowledged that some of the proposed analyses are dependent upon the release of another report by CCHS which may take a few years, or may contain only a few comparable municipalities which may impact our ability to perform some analyses.

## **Declarations**

### **Ethics approval and consent to participate**

This research was approved by the Ethics Review Board at the Centre for Addiction and Mental Health (No. 122/2019). All participants will provide consent (either online or verbal, over-the-phone) to participate prior to the start of the baseline survey.

### **Competing interests**

JAC, STL, MC, AG, and CS have no conflicts of interest to declare. RFT declares that, in the past three years, she has consulted for Quinn Emanuel and Ethismos Research Inc. and has received unrestricted research funds via GRAND from Pfizer Inc.

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## **Authors' contributions**

All authors have made an intellectual contribution to this research trial. JAC is the principal investigator of the trial, with overall responsibility for the project. He conceived the study and will oversee all aspects of the project. JAC, AG, and CS developed the protocol. JAC wrote the first draft of this manuscript. STL, MC and RFT are co-investigators on the trial and will provide leadership in the interpretation, knowledge exchange and dissemination of the trial findings. All authors have contributed to the manuscript drafting process and have read and approved the final manuscript.

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## Abbreviations

NRT:	nicotine replacement therapy
OR:	Odds ratio
Can:	Canadian
CCHS:	Canadian Community Health Survey
mg:	Milligram
CAMH:	Centre for Addiction and Mental Health
REB:	Research Ethics Board
SES:	Socioeconomic status