

# Promoting tobacco treatment uptake among health plan members

<b>Submission date</b> 11/01/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/01/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/02/2018	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Nearly 17% of adults smoke and tobacco use remains the leading preventable cause of death and illness in the U.S. Smoking kills an estimated 480,000 Americans annually and results in more than \$300 billion in direct health care costs and lost productivity each year. Treatment for nicotine dependence is cost-effective and is recommended for all smokers, more than half of whom make an attempt to quit smoking each year. Unfortunately, most smokers fail to utilize evidence-based treatment when trying to quit. Less than one third use a medication approved by the Food and Drug Administration and less than 10% use behavioral treatment. Best practice and clinical guidelines dictate smokers should be offered a combination of these interventions, but less than 6% of smokers utilize this comprehensive care. Thus, improving uptake of evidence-based smoking cessation treatment is an important public health goal. Health care systems and health insurers are particularly well positioned to support this goal within the patient populations they serve. As such, it is important to evaluate population-level interventions to promote treatment utilization which can be broadly disseminated within these organizations. Therefore, the aim of this study is to see if mailed letters with different information can encourage patients to stop smoking or join a smoking treatment program.

### Who can participate?

Adults aged 18 to 60 years old who are smokers/tobacco users.

### What does the study involve?

Participants are randomly allocated to one of five groups. Those in the first group receive no letter. Those in the second group receive a referral only letter. Those in the third group receive a health motivation letter. Those in the fourth group receive a money motivation letter and those in the last group receive a personal values motivator letter. Participants receive only one letter and there is not further contact. The amount of participants who enrolled in the smoking treatment program five months after receiving their letter is collected.

### What are the possible benefits and risks of participating?

Participants who sought treatment for nicotine dependence, as recommended, could quit smoking, save money, and experience positive health benefits associated with not smoking. There were no known risks to study participation.

Where is the study run from?  
Kaiser Permanente Washington (USA)

When is the study starting and how long is it expected to run for?  
January 2016 to August 2016

Who is funding the study?  
Group Health Foundation (USA)

Who is the main contact?  
Dr Jennifer McClure (Scientific)

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Jennifer McClure

**ORCID ID**  
<http://orcid.org/0000-0002-2094-9147>

**Contact details**  
Kaiser Permanente Washington Health Research Institute  
1730 Minor Ave, Suite 1600  
Seattle, WA  
United States of America  
98101

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
215146

## Study information

**Scientific Title**  
Evaluation of a population-level strategy to promote tobacco treatment use among insured smokers: a pragmatic, randomized trial

**Study objectives**

1. Proactively mailed letters would encourage greater smoking cessation treatment enrollment than usual care referral strategies (i.e., no letter) among smokers enrolled in a large mixed-model US health plans
2. The impact on future treatment enrollment would vary based on the content in the letters (motivational vs. referral only)
3. The results would differ between people who receive both medical care and coverage from the health plan message source versus those who receive insurance coverage alone

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

This work deemed Exempt Research under 45 CFD 46.101(b(4) by the Kaiser Permanente Washington Institutional Review Board and granted a waiver of written consent.

## **Study design**

Pragmatic single-centre randomised parallel trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised parallel trial

## **Study setting(s)**

Home

## **Study type(s)**

Other

## **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

## **Health condition(s) or problem(s) studied**

Uptake of services for smoking cessation

## **Interventions**

Within strata defined by age, sex, and coverage plan, selected participants are randomly assigned to one of five treatment conditions in equal proportions: no letter (NL), referral only letter (ROL), health motivation letter (HML), money motivation letter (MML), or personal values motivator letter (VML). Mailed letters are chosen because email addresses are not available for all health plan members and, as a policy, the health plan does not communicate with members via unsecure email.

Each letter is of similar length (one page) and formatting, advised smokers to quit, instructed them how to enroll in the covered treatment program, was signed by a single health plan physician, and printed on health plan letterhead. Three letters include additional brief motivational content, as reflected in each letter name. The motivational themes are chosen to reflect key reasons people quit smoking and are designed to encourage people to consider

quitting based on these factors. The HML points out to the positive health benefits of quitting (e.g., to reduce risk of cardiovascular disease, cancer, or oral disease; prevent impotence; improve appearance, etc.) and that it is never too late to quit. The MML points out the amount of money one could save in one month, one year, 5 years, and 10 years if they smoke a pack a day and spend on average \$8 per pack. The VML acknowledges that every person has different reasons for wanting to quit, which may include their health, finances, desire to set an example for loved ones, or other reason. Participants are encouraged to think about their own personal reasons for wanting to quit. In accordance with Prospect Theory, which predicts that gain-framed messages will be more influential for changing preventative health behaviors than are loss-framed messages, the motivational letters are written in a gain-framed tone (e.g., quitting smoking can help you stay strong and vibrant, prevent disease, or save money). In contrast, the ROL instructs people how to enroll in the covered treatment program, but did not include gain-framed or motivational content.

Each participant receive a single letter. There is no additional intervention contact.

### **Intervention Type**

Other

### **Primary outcome measure**

Enrolment in the covered tobacco cessation program was determined using automated treatment enrolment records assessed during the 5 month period following the letter mail date for each participant

### **Secondary outcome measures**

There are no secondary outcome measures

### **Overall study start date**

01/01/2016

### **Completion date**

30/08/2016

## **Eligibility**

### **Key inclusion criteria**

1. Health plan members in the integrated group practice division and the health plan network
2. Aged 18 to 60 years old
3. Evidence of tobacco use based on ICD codes (all members) or a smoking flag in their electronic medical record (group practice members only)
4. Had not enrolled in the health plan's covered comprehensive smoking cessation program in the prior year

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

5,000

**Key exclusion criteria**

1. No evidence of recent smoking in their medical records based on ICD codes or other tobacco status flags
2. Enrolled in the covered smoking cessation program in the prior year
3. Dis-enrolled from the health plan at the time the intervention letters were mailed

**Date of first enrolment**

03/02/2016

**Date of final enrolment**

04/05/2016

## **Locations**

**Countries of recruitment**

United States of America

**Study participating centre**

**Kaiser Permanente Washington**

Seattle, Washington

United States of America

98101

## **Sponsor information**

**Organisation**

Kaiser Permanente Washington Health Research Institute

**Sponsor details**

1730 Minor Ave

Suite 1600

Seattle, WA

United States of America

98101

**Sponsor type**

Research organisation

ROR

<https://ror.org/0027frf26>

## Funder(s)

### Funder type

Charity

### Funder Name

Group Health Foundation

### Alternative Name(s)

GHF

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Trusts, charities, foundations (both public and private)

### Location

United States of America

## Results and Publications

### Publication and dissemination plan

Planned publication in an open-access, peer-reviewed, public health journal.

### Intention to publish date

28/02/2018

### Individual participant data (IPD) sharing plan

Participant level data will not be made publically available because we do not have consent to share this information. Moreover, only limited participant level data were collected for this pragmatic trial (e.g., participant identity, age, gender, smoking status, health plan details, and whether they enrolled in the covered smoking cessation program), so this data has little utility for other research purposes.

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	08/02/2018		Yes	No

