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Promoting tobacco treatment uptake among health plan members

Submission date	Recruitment status	[_] Prospectively registered
11/01/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/01/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/02/2018	Respiratory	

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
https://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

Protocol serial number
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

Study type(s)
Other

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(s)
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

Key secondary outcome(s))
There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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

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

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?
Results article	results	08/02/2018		Yes	No