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Evaluating the effectiveness and cost-effectiveness of Tobacco Cessation services in Swedish primary healthcare targeting socioeconomically disadvantaged areas in Stockholm - the "Motivation 2 Quit" (M2Q) study

Submission date
07/01/2016

Registration date
11/01/2016

Last Edited
02/12/2022

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The aim of this study is to test whether a new method to help people quit their tobacco use is better than the methods currently offered by primary health care providers (i.e. family doctors) in Sweden. The method specifically targets primary healthcare centres in Stockholm where tobacco use is more common, where the local population are likely to be poorly paid, not be as well-educated and suffer from poorer health when compared to the general population. The study also aims to determine whether this new method is worth its cost.

Who can participate?
Adult Swedish or Arabic speaking patients with Swedish social security numbers and permanent resident permits, without cognitive impairment, who use tobacco on a daily basis, visit participating primary healthcare centres and who are not already undergoing treatment for tobacco cessation.

What does the study involve?
The primary healthcare centres participating in this study are assigned to either the intervention or control group. Participants who attend centres in the control group are given their usual treatment. This includes counselling and drug (nicotine replacement) therapy. Participants who attend centres in the intervention group are treated according to the “tobacco cessation on prescription” programme. The main difference between the treatment for this group and the control group is that the counselling and drug therapy services offered are individually prescribed. They are also given information on other ways to help them quit their tobacco use (for example, doing exercise and finding other ways to cope with withdrawal symptoms) and self-help resources (such as smartphone apps, web-based counseling and websites that have more information and support). All participants are followed up after 6 and 12 months to see whether they have quit their tobacco use.

What are the possible benefits and risks of participating?
Participants will be offered support to quit their tobacco use. Quitting tobacco use can be a stressful experience since it can cause short term withdrawal symptoms and psychological stress. However, counselling on coping strategies and therapies that can help ease withdrawal symptoms will be given to avoid discomfort for participants. Participants that successfully quit their tobacco use should experience an improvement in both short and long-term health and quality of life.

Where is the study run from?
14-20 primary healthcare centres located in socioeconomically disadvantaged areas in Stockholm County (Sweden)

When is the study starting and how long is it expected to run for?
January 2015 to August 2019

Who is funding the study?
1. Stockholm County Council (Sweden)
2. Skandia Life Insurance (Sweden)
3. The Public Health Agency of Sweden (Folkhälsomyndigheten) (Sweden)

Who is the main contact?
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Contact information

Type(s)
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Evaluating the effectiveness and cost-effectiveness of Tobacco Cessation on Prescription in Swedish primary healthcare targeting socioeconomically disadvantaged areas in Stockholm - the "Motivation 2 Quit" (M2Q) study, a cluster-randomised controlled trial

Acronym
M2Q

Study objectives
Compared to standard treatment tobacco cessation on prescription is an effective and cost-effective treatment in achieving 7-day abstinence from tobacco use at 6 months after intervention among tobacco users visiting primary healthcare centres located in socioeconomically disadvantaged areas in Stockholm.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board in Stockholm, April 2015, ref: 2015/207-31, 2015-1226-32, 2016/2080-32

Study design
An interventional pragmatic cluster-randomised controlled trial.

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Smoking

Interventions
Participants are randomly allocated to either tobacco cessation on prescription or standard treatment according to which primary healthcare centre (PHC) they attend.

1. Tobacco cessation on prescription is defined as:
1.1. Tobacco cessation counselling (minimum 10 minutes) provided by a qualified healthcare professional in combination with
1.2. A prescription for individualised tobacco cessation treatment, including options for:
1.2.1. Further counselling (referral to healthcare provider with more competence or the Swedish Quit Smoking Line)
1.2.2. Pharmacotherapy (nicotine replacement therapy, varenicline, bupropion)
1.2.3. Other measures for tobacco cessation (physical activity and other strategies to cope with withdrawal symptoms)
1.2.4. Follow-up (by telephone or revisit)
1.2.5. Support for self-management (reference to mobile applications, web-based counselling and websites for more information and support). The approach will be individualised in the sense that providers will discuss the available treatment options, contraindications, preferences and other relevant circumstances with the patient and then decide together on which treatment alternative(s) suit the individual best.
3. Follow-up of the prescription by the prescriber on at least one occasion is also included in the intervention.

Standard treatment is defined as:
Current treatment practices for tobacco cessation at the participating PHC in the control group and include different types of counselling and pharmacotherapy. The major difference between the trial conditions is how the counselling is administered (with or without a prescription form).

Participating PHC centres will be randomised with a 1:1 ratio to either intervention- or control conditions. Cluster-randomisation will be employed at the PHC centre level, meaning that all study participants recruited from a particular PHC centre will receive the same treatment (tobacco cessation treatment either with or without tobacco cessation on prescription).

Intervention Type
Mixed

Primary outcome measure
Point prevalence of 7-day abstinence (total abstinence from tobacco use during the 7 days preceding follow-up) at 6 months after the intervention

Secondary outcome measures
1. Point prevalence of 7-day abstinence at 12 months after the intervention
2. Daily tobacco consumption (number of cigarettes), at 6 and 12 months after the intervention
3. Number of quit attempts and health-related quality of life (on a scale from 0-1 where 0 represents death and 1 represents perfect health) at 6 and 12 months after the intervention
4. Cost effectiveness, measured as the incremental cost per quality-adjusted life year

All outcomes will be based on self-reports from patient questionnaires.

Overall study start date
01/01/2015

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Swedish or Arabic speaking daily tobacco users with Swedish social security number and permanent resident permit
2. Over 18 years of age
3. Visiting participating primary health care centres in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
14-20 primary healthcare centres with 43 participants from each centre

Total final enrolment
250

Key exclusion criteria

1. Ongoing treatment for tobacco cessation
2. Cognitive impairment affecting ability to participate in the study on a voluntary basis

Date of first enrolment
01/02/2016

Date of final enrolment
31/08/2018

Locations

Countries of recruitment
Sweden

Study participating centre
Valsta Medical Centre (Valsta Vårdcentral)
Hammargatan 6
Märsta
Sweden
195 53

Study participating centre
Norrtälje Northern Medical Centre (Norrtälje Norra Vårdcentral)
Lasarettsgatan 6
Norrtälje
Sweden
761 45

Study participating centre
Hallstaviks Medical Centre (Hallstaviks Vårdcentral)
Carl Wahrens väg 24
Hallstavik
Sweden
763 34

Study participating centre
Capio Primary Care Centre Hagsätra (Capio Vårdcentral Hagsätra)
Hagsätra torg 7B
Bandhagen
Sweden
124 73

Study participating centre
Capio Primary Care Centre Wasa (Capio Vårdcentral Wasa)
Prästgårdsvägen 4
Södertälje
Sweden
151 61

Study participating centre
Cevita Care - Rimbo-Edsbro family doctors (Husläkarna Rimbo-Edsbro)
Stockholmsvägen
Rimbo
Sweden
762 31

Study participating centre
Capio Primary Care Centre Skogås (Capio Vårdcentral Skogås)
Melodivägen 6
Skogås
Sweden
142 40

Study participating centre
Capio Primary Care Centre Vårberg (Capio Vårdcentral Vårberg)
Vårbergstorget 5
Skärholmen
Sweden
127 43

Study participating centre
Handens Medical Centre (Handens Vårdcentral)
Dalarövägen 6
Handen
Sweden
136 46

Study participating centre
Family Doctors Husby (Familjeläkarna Husby)
Edvard Griegsgången 13
Kista

Sweden
164 32

Study participating centre
Hallonbergens Medical Centre (Hallonbergens Vårdcentral)
Hallonbergsplan 7
Sundbyberg
Sweden
174 52

Study participating centre
Fisksätra Medical Centre (Fisksätra Vårdcentral)
Fisksätra torg 20
Saltsjöbaden
Sweden
133 41

Study participating centre
The Health Medical Centre Tensta (Hälsans Vårdcentral Tensta)
Tenstagången 18
Spånga
Sweden
163 64

Study participating centre
Liljeholmens Medical Centre (Liljeholmens Vårdcentral)
Liljeholmstorget 7
Stockholm
Sweden
117 63

Study participating centre
Rinkeby Medical Centre (Rinkeby Vårdcentral)
Skårbygränd 3
Spånga
Sweden
163 72

Study participating centre

Vårbergs Medical Centre (Vårbergs Vårdcentral)
Vårbergsplan 31
Skärholmen
Sweden
127 43

Study participating centre
Skärholmens Medical Centre (Skärholmens Vårdcentral)
Storholmsgatan 19
Skärholmen
Sweden
127 48

Study participating centre
Solna City Medical Centre (Solna Centrum Vårdcentral)
Hotellgatan 3
Solna
Sweden
171 45

Sponsor information

Organisation
Karolinska Institute (Karolinska Institutet) (Sweden)

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Sponsor type
University/education

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ROR
https://ror.org/056d84691

Funder(s)

Funder type
Government

Funder Name
Stockholms Läns Landsting

Alternative Name(s)
Stockholm County Council

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Funder Name
Skandia Life Insurance (Livförsäkringsbolaget Skandia)

Funder Name
The Public Health Agency of Sweden (Folkhälsomyndigheten)

Results and Publications

Publication and dissemination plan
The trialists intend to publish the study protocol during the spring of 2016 and the study results in the beginning of 2019. The cost-effectiveness analysis is expected to be published in 2020. In addition to publications in scientific journals, the results will be disseminated to the scientific community through presentations at national and international conferences. The results will also be disseminated to study participants, funders, policy makers and the general public through oral presentations, written reports and popular scientific summaries.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available because the trialists do not have consent to share this information.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	16/09/2016		Yes	No
Results article		01/12/2022	02/12/2022	Yes	No