Smoking cessation among people with severe mental illness: a study on effectiveness and implementation

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Primary objectives (after 1 year): - to improve smoking cessation- to reduce number of smoked cigarettes Secondary objectives (after 1 year): - to reduce psychiatric symptoms such as depression, psychotic symptoms and anxiety- to improve physical...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON54435

Source
ToetsingOnline

Brief title
KISMET

Condition

- Other condition
- Schizophrenia and other psychotic disorders

Synonym
Severe Mental Illness, Smoking Cessation

Health condition

Addiction

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: ZonMw;Stichting tot Steun VCVGZ

Intervention

Keyword: Addiction, CBT, Severe mental illness, Smoking cessation

Outcome measures

Primary outcome

The main study parameter is smoking cessation after 12 months. This outcome will be validated by measuring the exhaled carbon monoxide (CO) level with a CO monitor. The measurement of CO level provides an immediate, non-invasive method of assessing smoking status. We defined smoking cessation as a CO reading less than 10 ppm. Additional smoking cessation parameters are the number of cigarettes smoked (reported by the patient) and scores on the Fagerström Test for Nicotine Dependence (FTND).

Secondary outcome

Secondary study parameters are physical health (physical fitness (6 minute walk test) and cardiovascular risk (i.e. blood pressure, lipid profile and glucose metabolism); mental health, including psychiatric symptoms (depression, anxiety and psychotic symptoms) and use of psychopharmaca, quality of life and self-efficacy. Finally, we will calculate BMI to assess weight change after the start of the smoking cessation intervention.

Study description

Background summary

Smoking among adults with serious mental illness (SMI) is highly prevalent and strongly associated with poor health. About 50-80% people with SMI smoke, which is at least three times the rate in the general population.Smoking is the leading cause of preventable morbidity and mortality,with reduced life expectancy. Smoking cessation is the single most powerful intervention for reducing these health inequalities. A limited number of studies shows that pharmacological treatment combined with behavioural support interventions significantly improves outcomes for smokers with SMI. However, more studies are needed focusing on both the implementation and the effectiveness of smoking cessation intervention, with the active engagement of both mental health professionals and individuals with SMI.
In the Netherlands, treatment for these patients is mainly offered by Flexible Assertive Community Treatment (FACT) teams. These FACT-teams form an unique possibility to deliver and support smoking cessation interventions.

Study objective

Primary objectives (after 1 year):
- to improve smoking cessation
- to reduce number of smoked cigarettes

Secondary objectives (after 1 year):
- to reduce psychiatric symptoms such as depression, psychotic symptoms and anxiety
- to improve physical health (physical fitness and cardiovascular risks)
- to improve quality of life and health related self-efficacy

Study design

The study will consist of a cluster randomized controlled clinical trial with a 1 year follow-up period. Effectiveness of the intervention will be evaluated in comparison with usual care. Eligible participants will be randomly allocated to the smoking cessation intervention or usual care. This multicentre study will recruit the 216 participants form approximately 21 FACT-teams across the Netherlands. Including inclusion of participants, analysis and reporting phase, the total duration of the study will be 48 months.

Intervention

The provided intervention consists of three components:
1. Pharmacotherapy (Nicotine replacements: patches and gum; other registered medication for smoking cessation: Varenicline and Bupropion)
2. Cognitive Behavioural Therapy (CBT); in groups
3. Peer Support Groups.

The intensity and frequency of individual behavioural support (CBT), and the

dosage of the pharmacotherapy are determined individually according to the patients' needs. Over the course of the intervention, the intensity will decrease, i.e. the frequency of CBT sessions will decrease and the dose of medication will be reduced. The following scheme is proposed:

1. Treatment period (12 weeks): 1x per week group CBT, individual consultation as desired; 1x per week peer support; medication dosage as prescribed by a psychiatrist
2. Treatment period (16 weeks): 1x per month group CBT, individual consultation as desired; 1x every two weeks peer support; medication dosage as prescribed by a psychiatrist
3. Treatment period (20 weeks): 1x per month group CBT, individual consultation as desired; 1x per month peer support; medication dosage as prescribed by a psychiatrist

The intervention group is compared with a control group that receives care as usual in a FACT-team ('treatment as usual') and will have access to all standard smoking cessation aids.

Study burden and risks

Benefits:
By participating, patients have the opportunity to overcome their addiction and improve their mental and physical health by quitting smoking. In addition, patients can gain deeper insights into their smoking behaviour and underlying emotional difficulties, which may have a positive effect on their psychological treatment.

Burden:
Participation in the intervention proposed in this research means that patients will voluntarily commit to follow a complex programme. This might be perceived as a burden, especially in the more intensive starting phase during which some patients might struggle more with withdrawal symptoms after smoking cessation. During this study, the subjects will be assessed at four timepoints (Baseline, 3-, 6- and 12-month follow-up) and a selection of participants will participate in qualitative interviews. At 3-month follow-up assessment only the primary study parameters will be registered (smoking status, carbon monoxide level, nicotine dependence questionnaire). Furthermore, the process of quitting to smoke can be experienced as mentally and physically challenging due to physical and psychological withdrawal.

Risks:
A number of risks are known when using nicotine replacements and medication for nicotine addiction. According to the package insert, possible side effects (in 10-30 in 100 people) of medication include headache, dry mouth, insomnia and nausea.
The nicotine replacements that will be offered in this intervention are patches

and chewing gum. Known risks of nicotine patches and chewing gum are mild skin irritation, dizziness, headache and nausea. We don't expect any risks associated with therapeutic group sessions and peer support.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Above 18 years old
- Smoker (>= 5 cigarettes) and wish to quit smoking
- Documented diagnosis of schizophrenia, other psychotic disorder and/or disorders defined as severe mental illness according to Delespaul consensusgroup at Maastricht University
- Dutch language skills

Exclusion criteria

- Contra-indications (determined by a psychiatrist/physician) for participation due to acute psychiatric crisis or somatic disease
- Pregnancy or breastfeeding in women at the time of inclusion
- Primary alcohol or other substance use disorder, with exception of cannabis use disorder
- Lacking capacity to consent, to complete questionnaires, or participate in peer support group session
- Non-Dutch speaking

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-10-2022
Enrollment:	318
Type:	Actual

Ethics review

Approved WMO

Date:	23-09-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	05-07-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL76469.029.21