A Smoking Cessation Intervention for People with Severe Mental Illness

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29433

Source
Nationaal Trial Register

Brief title
KISMET

Health condition

Severe mental illness (Schizophrenia, schizotypical/schizoaffective disorder, mood/bipolar disorder, psychotic disorders); Addiction

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

• CO-levels

Secondary outcome

• Fagerström Test for Nicotine Dependence (FTND)
• Health of the Nation Outcome Scales (HoNOS)
• Hospital Anxiety and Depression Scale (HADS)
• 12 item Short Form-12 (SF-12) mental and physical component scores
• WHO Alcohol, Smoking and Substance Involvement Screening Test (WHO-ASSIST)
• Patient Activation Measure (PAM-13)

Study description

Background summary

This study aims to evaluate the effectiveness and implementation of a smoking cessation intervention tailored for people with severe mental illness, such as schizphrenia or psychotic disorders. The intervention consists of three core components: 1. Pharmacological treatment; 2. Behavioural counselling (based on cognitive-behavioural therapy and motivational interviewing) and 3. Peer support. It was designed based on the outcomes of a Delphi study with five experts from the field.

Study objective

It is hypothesised that the bespoke smoking intervention is more effective than usual care to reduce nicotine dependence and smoking for people with severe mental illness in FACT-teams in the Netherlands.

Study design

Baseline, 3-months, 6-months, 12-months

Intervention

An integrative intervention consisting of behavioural counselling (cognitive-behavioural therapy and motivational interviewing) pharmacological treatment and peer support groups.

Contacts

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Eligibility criteria

Inclusion criteria

• Documented diagnosis of SMI
• Age ≥18
• Being treated in a FACT-team in the Netherlands
• Current smoker (≥ 5 cigarettes) without a quit attempt in the prior month
• Expresses an interest in stopping smoking
• Willing and able to sign informed consent

Exclusion criteria

• Contra-indications for participation due to acute psychiatric crisis or somatic diseases (e.g. surgery, cancer)
• Documented primary diagnosis of substance abuse disorder according to the DSM-5 (with exception of cannabis use disorder)
• Subjects with a cognitive impairment sufficient to interfere with their ability to provide informed consent, complete study questionnaires, or participate in the intervention
• Women who are pregnant or breastfeeding at the time of inclusion
• Subjects not able to communicate in the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-01-2022
Enrollment:	318
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-10-2021
Application type:	First submission

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
NTR-new	NL9783
Other	METc VUmc : 2021.0158

Study results