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Intensive smoking cessation treatment among patients with a primary mental disorder

Submission date
15/04/2024

Recruitment status
No longer recruiting

Registration date
01/05/2024

Overall study status
Ongoing

Last Edited
02/07/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Tobacco consumption is a leading global risk factor for premature death, with about six million premature deaths annually. Smokers with psychiatric diagnoses have higher levels of tobacco dependence, about twice as high as the general population.
Research indicates that stopping smoking has long-term positive effects on mental health, comparable to antidepressant treatments. Integration of tobacco cessation into psychotherapeutic interventions may be necessary for long-term success. The current care for smoking in patients with primary psychiatric diagnoses is considered inadequate. Uncertainty remains regarding therapy-optimizing factors, such as session frequency.
This study aims to examine an intensive smoking cessation treatment, consisting of six behaviorally oriented sessions combined with a digital health application, compared to a control condition, in outpatient psychotherapeutic patients with harmful use or dependence. This study will investigate whether a smoking cessation treatment is more effective than treatment as usual (TAU) at improving mental health status, such as perceived quality of life, changes in symptom severity of a primary diagnosis and nicotine dependence.

Who can participate?
Adult tobacco smokers who exhibit either harmful use of tobacco or dependence, fulfil the criteria for a psychiatric primary diagnosis and are currently in psychotherapeutic treatment

What does the study involve?
Participants will be randomly assigned to either the experimental group (diagnostic session + three regular therapy sessions + a six-session smoking cessation program + self-guided app treatment) or the treatment as usual (TAU) control condition (diagnostic session + three regular therapy sessions).

What are the possible benefits and risks of participating?
One possible benefit is that the smoking cessation program might reduce dependence and improve mental health next to physical health benefits related to smoking cessation. Implementing smoking interventions in standard psychotherapy might improve overall treatment effects on long-term symptom reduction.

Where is the study run from?
University of Siegen (Germany)

When is the study starting and how long is it expected to run for?
December 2023 to January 2027

Who is funding the study?
University of Siegen (Germany)

Who is the main contact?
Esra Otto, esra.otto@uni-siegen.de

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
1

Study information

Scientific Title
Intensive smoking cessation treatment among patients with a primary mental disorder: a randomized controlled trial

Study objectives
The researchers expect a treatment effect on nicotine dependence and symptom severity of a primary mental disorder and general mental health status. Precisely, it is expected that smokers in the experimental condition will experience a significantly higher reduction of dependence and symptom severity than patients in the control condition during the post-treatment and follow-up measures when compared to the baseline measures. The researchers also expect a

significantly higher reduction in the primary diagnosis' severity, such as depression or anxiety severity, in the experimental condition versus the control condition when comparing baseline assessment to follow-up assessment.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 28/01/2024, Ethics Committee of the University of Siegen (Adolf-Reichwein-Str. 2a, Siegen, 57076, Germany; +49 (0)271 740-4819; ethikrat@uni-siegen.de), ref: ER_10_2024

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Intensive smoking cessation treatment for outpatient psychotherapeutic patients with nicotine dependence

Interventions
The study is a single-center randomized controlled trial. Relative changes in dependence symptoms and symptoms of a mental disorder (post vs baseline, follow-up vs post, follow-up vs baseline) will be compared between a group receiving an intensive behavioral smoking cessation treatment and a control group will be compared in a superiority design. The study employs a 2 (condition: smoking treatment vs control treatment) x 4 (time: baseline assessment, post assessment, 6-weeks-follow-up), 6-months-follow-up design.

Eligible participants will be randomly assigned to either the experimental group (diagnostic session + three psychotherapeutic sessions + six-session smoking cessation program + self-guided app treatment) or the TAU control condition (diagnostic session + three psychotherapeutic sessions).
Participants will undergo random allocation to either the experimental or control group at a 1:1 ratio. Given the study's design, participant blinding or therapist blinding post-allocation is not feasible. To mitigate bias during data assessment and analysis, research assistants involved in enrollment and data analysis will remain blinded to participants' group allocations. The duration of the intervention is 3 weeks. 6 weeks and 6 months after completion, follow-up measures occur.

Intervention Type
Behavioural

Primary outcome(s)
1. Nicotine dependence is measured using:
1.1. The Fagerström Test for Nicotine Dependence at baseline (t0), post (t0 + 3 weeks) and both follow-up assessments (post + 6 weeks/ post + 6 months)
1.2. The measured carbon monoxide (CO) level in exhaled breath at baseline (t0), post (t0 + 3

weeks) and both follow-up assessments (post + 6 weeks/ post + 6 months)
1.3. Cotinin by self-applied urine tests at baseline (t0), post (t0 + 3 weeks) and both follow-up assessments (post + 6 weeks/ post + 6 months)
1.4. The WHO ASSIST questionnaire at baseline (t0), post (t0 + 3 weeks) and both follow-up assessments (post + 6 weeks/ post + 6 months)
1.5. The ICD-10 criteria for dependence at baseline (t0), post (t0 + 3 weeks) and both follow-up assessments (post + 6 weeks/ post + 6 months)
2. Symptom severity of the primary diagnosis is measured by specific questionnaires that target both disorder-specific symptoms (such as the Becks Depression Inventory-Revised) and diagnostic questionnaries across disorders such as the Brief Symptom Check List and the WHO Qualitiy of Life questionnaires. All questionnaires will be assessed at baseline (t0), post (to + 3 weeks),and both follow-up assessments (t0 + 6 weeks; t0 + 6 months).

Key secondary outcome(s))
1. Self-efficacy is measured using the Generalized Self-Efficacy Scale and the Self-Efficacy Scale for Smoking at baseline (t0), post (t0 + 3 weeks) and both follow-up assessments (post + 6 weeks/ post + 6 months)
2. Patients' motivation is measured by the Motivation to Quit Scale and the German version of the URICA (FEVER), the Scale for Stages of Change at baseline (t0), post (t0 + 3 weeks) and both follow-up assessments (post + 6 weeks/ post + 6 months)
3. Attitudes towards digital health applications measured using the Attitudes towards Psychological Online Interventions (APOI) questionnaire at baseline (t0), post (t0 + 3 weeks) and both follow-up assessments (post + 6 weeks/ post + 6 months)

Completion date
01/01/2027

Eligibility

Key inclusion criteria
1. >18 years of age
2. Exhibition of either harmful use of tobacco (F17.1 according to ICD-10) or tobacco dependence (F17.2 according to ICD-10)
3. Psychiatric primary diagnosis (F-Diagnosis according to ICD-10)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Acute suicidality
2. Acute psychotic epsiode

Date of first enrolment
01/02/2024

Date of final enrolment
01/01/2026

Locations

Countries of recruitment
Germany

Study participating centre
Psychotherapeutische Hochschulambulanz der Universität Siegen (Psychotherapeutic outpatient clinic of the University of Siegen)
Siegen
Germany
57072

Sponsor information

Organisation
University of Siegen

ROR
https://ror.org/02azyry73

Funder(s)

Funder type
University/education

Funder Name
Universität Siegen

Alternative Name(s)
University of Siegen

Funding Body Type

Government organisation

Funding Body Subtype
Universities (academic only)

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan
The dataset will be available upon request from the corresponding author (Esra Otto, Esra.otto@uni-siegen.de). The data will be available after the overall trial end.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		01/07/2025	02/07/2025	Yes	No