

# Intensive smoking cessation treatment among patients with a primary mental disorder

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
15/04/2024	No longer recruiting	<input checked="" type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
01/05/2024	Ongoing	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
02/07/2025	Mental and Behavioural Disorders	<input checked="" type="checkbox"/> 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

**Contact name**  
Ms Esra Otto

**Contact details**  
Obergraben 23  
Siegen  
Germany  
57072  
+49 (0)271 7404106  
esra.otto@uni-siegen.de

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
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 questionnaires across disorders such as the Brief Symptom Check List and the WHO Quality of Life questionnaires. All questionnaires will be assessed at baseline (t0), post (t0 + 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 episode

**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?
<a href="#">Protocol article</a>		01/07/2025	02/07/2025	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes