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The effectiveness of a standardized tobacco cessation program on addiction patients undergoing long-term rehabilitation

Submission date
06/03/2024

Recruitment status
No longer recruiting

Registration date
07/03/2024

Overall study status
Completed

Last Edited
14/05/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
This research explores the effectiveness of a specific program designed to help people stop smoking within a group of patients receiving long-term treatment for addiction. The goal is to see if this program can reduce their reliance on tobacco and improve both psychological and physical health aspects.

Who can participate?
Tobacco dependent adults over 18 years old who are receiving inpatient treatment for addiction and want to quit smoking can join the study. There are no other strict requirements for participation.

What does the study involve?
Participants are divided into two groups: one group takes part in a six-week tobacco cessation program, while the other receives usual care without this specific program. We will compare changes in tobacco use and dependence, craving, self-efficacy, psychopathological symptoms, and heart rate variability before and after the program.

What are the possible benefits and risks of participating?
Participants might reduce their tobacco use and improve self-confidence and physical health indicators. There are minimal risks involved, mainly related to the emotional and physical challenges of quitting smoking.

Where is the study run from?
The study is conducted at the Schloss Johnsdorf addiction clinic, operated by the Grüner Kreis society (Austria)

When is the Study Starting and How Long is it Expected to Run For?
November 2022 to March 2023

Who is Funding the Study?
The Grüner Kreis Society (Austria)

Who is the Main Contact?
Prof. DDr. Human-Friedrich Unterrainer
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The effectiveness of a standardized tobacco cessation program on psychophysiological parameters in addiction patients undergoing long-term rehabilitation: a quasi-experimental pilot study

Acronym
SToP-PLaRe

Study objectives
Primary Outcomes Hypotheses:
Hypothesis 1 (Tobacco Dependence): There will be a difference in tobacco dependence between participants in the intervention group (IG), who undergo the standardized tobacco cessation program, and the control group receiving Treatment As Usual (TAUG).
Hypothesis 2 (Cigarettes Per Day (CPD)): There will be a difference in the number of smoked cigarettes per day (CPD) between participants in the IG and participants in the TAUG.
Hypothesis 3 (Craving): There will be a difference in craving between participants in the IG and participants in the TAUG.

Secondary Outcomes Hypotheses:
Hypothesis 4 (Heart Rate Variability (HRV)): There will be a difference in HRV measurements between participants in the IG and the TAUG.
Hypothesis 5 (Comorbid Psychiatric Symptoms): There will be a difference in the severity of comorbid psychiatric symptoms between participants in the IG and the TAUG.
Hypothesis 6 (self-efficacy): There will be a difference in the self-efficacy between participants in the IG and the TAUG.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/12/2022, Ethikkommission der Universität Graz (Universitätsplatz 3, Graz, 8010, Austria; +43 (0) 316 / 380-1052; ethikkommission@uni-graz.at), ref: GZ. 39/30/63 ex 2022/23

Study design
Non-randomized interventional study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Tobacco addiction in patients diagnosed with Mental and behavioral disorders due to multiple drug use and use of other psychoactive substances, dependence syndrome (F19.2)

Interventions

This non-randomized interventional study examines the potential benefit of a standardized tobacco cessation program in a group of patients undergoing long-term addiction treatment. An intervention group (IG; participants in the program) and a control group receiving Treatment As Usual Group (TAUG; non-participants in the program) in an inpatient addiction clinic (single center). The study design was a quasi-experimental controlled trial, without random assignment. None of the participants took part in previous smoking cessation programs. No additional smoking cessation medication was implemented in the study.

Treatment as usual: Addiction treatment in a therapeutic community specialized for the treatment of F19.2.
Intervention group: The “smoke free in 6 weeks” program is a standardized behavioral therapy intervention that takes place once a week for 1.5 hours over six weeks and is provided by the Austrian health insurance provider Österreichische Gesundheitskasse (ÖGK). Held in the therapeutic community, it employed behavioral therapy coupled with personalized recommendations for nicotine replacement. The Austrian Health Insurance standard for therapy guided the program's content, which was tailored for inpatient clients. Various behavioral therapy techniques, including building motivation, behavioral observation, stimulus and self-control, as well as operant methods were applied in the group sessions. The primary aim was to help clients achieve smoking cessation, favoring this approach over gradual reduction methods. To support ongoing abstinence and motivation, participants were directed to additional resources such as the Smoke-Free App, Smoke-Free Phone, and regional outpatient cessation services. This program was led by a clinical psychologist.

Intervention Type
Behavioural

Primary outcome(s)
1. Tobacco dependence is measured by the The Fagerström Test for Cigarette Dependence (FTND) at baseline and 1,5 weeks after the intervention.
2. Smoked cigarettes per day is measured by the The Fagerström Test for Cigarette Dependence (FTND) at baseline and 1,5 weeks after the intervention.
3. Craving is measured by the Mannheim Craving Scale (MaCS) at baseline and 1,5 weeks after the intervention.

Key secondary outcome(s))
1. Heart Rate Variability is measured using Electrocardiography at baseline and 1,5 weeks after the intervention.
2. Psychiatric Symptoms are measured using the Brief Symptom Inventory (BSI-18) at baseline and 1,5 weeks after the intervention.
3. Self-efficacy is measured using the Self-Efficacy Scale (SWE) at baseline and 1,5 weeks after the intervention.

Completion date
20/04/2023

Eligibility

Key inclusion criteria
1. voluntary participation
2. a current tobacco dependence (F17.2)
3. a current poly-drug use disorder (F19.2)

4. the desire to quit smoking
5. an age > 18 years.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
56

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/11/2022

Date of final enrolment
01/03/2023

Locations

Countries of recruitment
Austria

Study participating centre
Grüner Kreis Schloss Johnsdorf
Johnsdorf 1
Johnsdorf Brunn
Austria
8350

Sponsor information

Organisation

University of Vienna

ROR
https://ror.org/03prydq77

Funder(s)

Funder type
Charity

Funder Name
Grüner Kreis Society

Results and Publications

Individual participant data (IPD) sharing plan
The datsets generated during and/or analysed during the current study will be available upon request to Prof. DDr. Human-Friedrich Unterrainer (human.unterrainer@univie.ac.at)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2024	14/05/2024	Yes	No
Basic results			22/04/2024	No	No