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SUN Tirol: Smoking undone naturally in Tirol

Submission date	Recruitment status	[ ] Prospectively registered
20/02/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/03/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/03/2025	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
By 2040, a dramatic increase is expected in the population group over 70 years of age in Tyrol. Austria has one of the highest expenditures on health within the European Union. Nevertheless, the "healthy life years" of Austrians are far below the EU average; specifically, Austrians only live an average of approximately 57 years in perfect health. To underscore this worrying fact, this is 16 years less than the “healthy life years” in Sweden, although both countries have similar expenditures. One conspicuous difference in the Austria-Sweden comparison is that Sweden spends significantly more on preventive care than Austria and this is what needs to change. Health should be promoted to a greater extent before diseases arise, thus allowing people not only to grow older but spend the extra years of life in good health. Therefore, within the framework of the SUN Tirol study, the health-promoting effect of smoking cessation will be investigated.

Who can participate?
People aged between 18 and 75 years old can participate if they are current smokers, they must be motivated to quit smoking and own a smartphone and be familiar with its use.

What does the study involve?
The study is based in Hall in Tirol where each subject will participate for 8 months. After a thorough explanation and the signing of informed consent, participants will be randomly assigned to one out of two groups: half will receive biofeedback on the normalisation of epigenetic markers after smoking cessation but this information will not be divulged to the other half. The reasoning behind this approach is that we want to investigate whether biofeedback makes a difference in the effectiveness of smoking cessation. The classification is purely randomised and cannot be influenced. A total of 5 visits take place within 8 months in our study centre in Hall in Tirol. During the visits, changes in quality of life and sleep, stress, blood values, blood pressure, epigenetic markers, and much more are examined. Participants can expect a lifestyle change through smoking cessation, professional counselling by addiction experts from the addiction support Tyrol, motivation through group sessions and a personal coach, and free medical check-ups.

What are the possible benefits and risks of participating?
We hope to gain new insights into sustainable lifestyle changes for many more people and individual prevention for certain diseases in the future. Participants can expect a lifestyle change

through smoking cessation, professional counselling by addiction experts from the addiction support Tyrol, motivation through group sessions and a personal coach, and free medical check-ups. The risks comprise withdrawal symptoms after smoking cessation and pain and/or bruising during blood collection.

Where is the study run from?
European Translational Oncology Prevention and Screening (EUTOPS) Institute (Austria)

When is the study starting and how long is it expected to run for?
August 2021 to January 2024

Who is funding the study?
1. Standortagentur Tirol (Austria)
2. Horizon 2020 Framework Programme (Belgium)

Who is the main contact?
Prof Martin Widschwendter, martin.widschwendter@uibk.ac.at (Principal Investigator) (Austria)

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
SUN Tirol: Prospective, randomised trial to assess whether biofeedback improves adherence to smoking cessation

Acronym
SUN Tirol

Study objectives
Smoking cessation is more sustainable when subjects receive regular biofeedback on epigenetic markers after smoking cessation compared to those who do not receive such feedback

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/10/2022, Ethics Committee of the Medical University of Innsbruck (Anichstraße 35, 6020 Innsbruck, Austria; +43 (0)50 504-22293; ethikkommission@i-med.ac.at), ref: 1203/2022

Study design
Single-centre prospective randomized longitudinal non-therapeutic intervention study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Primary prevention through smoking cessation

Interventions
Participants quit smoking after a smoke-free-programme provided by the addiction support Tirol

Quitting smoking is one of the most effective preventive health measures. This study aims to find out whether regular biofeedback on the normalisation of epigenetic markers in cells after smoking cessation increases the sustainability of smoking cessation. The method of randomisation was a computer-based age- and gender-stratified block randomisation in groups of four subjects each.

The smoke-free experts from "Suchthilfe Tirol" (addiction support Tyrol) have the following educational backgrounds: psychologists in training, psychologists, clinical and health psychologists and psychotherapists. In addition, all course leaders are certified smoke-free trainers by the Institut für Therapieforschung (IFT) in Munich (Institute for mental health & addiction research). They are trained in the conception of the smoke-free programmes (basic, compact and online versions) and have been taught the scientific principles of psychotherapeutic change on which the programme is based.

The intervention starts with a group session in person. The aim is to have a group of 4-8 people, but if there are some cancellations, the course will take place so as not to demotivate those who want to participate. This is followed, after one and two weeks, by online meetings with the same group and the same coach. At the first online meeting, smoking cessation takes place. The programme also includes two individual telephone calls with the coach.

The intervention mostly takes place at each participant's home since they are supposed to quit smoking. The study center, where the visits take place and the consultation is performed is located in the hospital of Hall in Tirol, Austria, although the rooms are rented and the study itself has nothing to do with the hospital.

Intervention Type
Behavioural

Primary outcome(s)
Effectiveness of the biofeedback method to sustain smoking cessation measured by comparing the number of ‘smoke-free’ participants in the groups with and without biofeedback until at least the end of the study

Key secondary outcome(s))

1. Achievement of the planned number of participants (n=200) in Tirol within 5 months measured using study records of recruitment at 6 months after recruitment initiation
2. Number of participants in the two groups (with and without biofeedback) who have completed the study (regardless of whether they continue smoking) measured using study records from baseline to 6 months of recruitment time
3. Epigenetic alterations as a result of smoking cessation evaluated using DNA methylation signatures associated with age, disease, or exposure, e.g. WID indices (WID-BC, WID-OC, WID-SMKand WID-age), epigenetic clocks, etc. and measured using microarray analysis (Illumina HumanMethylationEPIC) using of buccal and cervical/vaginal smears and blood at baseline and 2, 4, 6 and 8 months after study entry. Per-protocol and intention to treat analyses will be conducted and compared between the two groups at respective timepoints, and separately comparing changes from baseline in each group.
4. Clinical factors, including resting heart rate and blood pressure (measured using the device Boso Medicus X (Bosch + Sohn)) and vascular elasticity (measured using the device Vicorder®) at baseline and 2, 4, 6 and 8 months after study entry. Per-protocol and intention to treat analyses will be conducted and compared between the two groups at respective timepoints, and separately comparing changes from baseline in each group.
5. Quality of life (measured using the WHO quality of life questionnaire (WHOQOL)), quality and duration of sleep (measured using the Pittsburgh Sleep Quality Index (PSQI)) and stress level (measured using the Perceived Stress Scale (PSS-10)) at baseline and 2, 4, 6 and 8 months after study entry. Per-protocol and intention to treat analyses will be conducted and compared between the two groups at respective timepoints, and separately comparing changes from baseline in each group.
6. Blood values, including:
6.1. Blood count and differential blood count measured using flow cytometry on a Sysmex XN-3000 module at baseline and at the end of the study (eight months after study entry). All laboratory parameters are measured using CE-IVD test systems and ISO9001:2015 procedures. Per-protocol and intention to treat analyses will be conducted and compared between the two groups at respective timepoints, and separately comparing changes from baseline in each group.
6.2. LDL, HDL, HbA1c, creatinine and CRP measured using CE-IVD test systems and ISO9001:2015 procedures at baseline and at the end of the study (eight months after study entry): CRP, HDL and LDL are measured by immunologic methods (CLIA) using a Roche Cobas 801 module. HbA1c is measured by an immunologic method (TINIA) using a Roche Cobas 513 analyzer and Creatinine is measured by an enzymatic method using a Roche Cobas c702 analyzer. Per-protocol and intention to treat analyses will be conducted and compared between the two groups at respective timepoints, and separately comparing changes from baseline in each group.
6.3. Analysis of cellular measurements: distribution of the different immune cell populations (% and absolute values) in peripheral blood mononuclear cells (PBMCs); activation levels of monocytes and T-cells and expression of adhesion molecules measured using RT-qPCR, cell culture experiments, or flow cytometry. Per-protocol and intention to treat analyses will be conducted and compared between the two groups at respective timepoints, and separately comparing changes from baseline in each group.
6.4. Inflammatory cytokines and factors and blood (plasma), including IL-1, HMGB-1, RAGE, sASC, and IL-6 measured using enzyme-linked immunosorbent assays (ELISA) or RT-qPCR compared between the two groups at respective timepoints 2, 4, 6, and 8 months after study including and separately comparing changes from baseline in each group.
6.5. Cytotoxicity of peripheral blood mononuclear cells measured using e.g. the xCELLigence assay between the two groups at respective timepoints 2, 4, 6, and 8 months after the study including, and separately comparing change from baseline in each group.

Completion date

15/01/2024

Eligibility

Key inclusion criteria
1. Age 18 to 75 years
2. Current smokers
3. Motivated to quit smoking
3. In possession of a smartphone and familiar with its use

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Total final enrolment
105

Key exclusion criteria
1. Active cancer (exception: non-melanocytic skin cancer)
2. Present and/or past severe psychiatric illnesses
3. Concurrent participation in another interventional study

Date of first enrolment
02/11/2022

Date of final enrolment
30/04/2023

Locations

Countries of recruitment
Austria

Study participating centre

European Translational Oncology Prevention and Screening (EUTOPS) Institute
Milser Straße 10
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Sponsor information

Organisation
Tirol Kliniken

ROR
https://ror.org/028ze1052

Funder(s)

Funder type
Government

Funder Name
Standortagentur Tirol

Alternative Name(s)
Standortagentur Tirol Ltd.

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Austria

Funder Name
Horizon 2020 Framework Programme

Alternative Name(s)
EU Framework Programme for Research and Innovation H2020, Horizon 2020, Horizon 2020 Framework Programme (H2020), Rahmenprogramm Horizont 2020, Horizont 2020, Programa Marco Horizonte 2020, Horizonte 2020, Programme-cadre Horizon 2020, Orizzonte 2020, Programma quadro Orizzonte 2020, H2020

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes