

Trial Description

Title

**Investigation of a positive care effect of the NichtraucherHelden App (Medicine):
Implementation of a Randomized Controlled Trial (RCT).**

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The NichtraucherHelden App is used to treat and alleviate a diagnosed tobacco addiction. Through a cognitive-behavioral therapy approach, patients are encouraged to overcome their tobacco dependence. The aim of this study is to investigate the effectiveness of the app in smoking cessation together with a brief medical consultation.

Brief Summary in Scientific Language

The aim of this study is the scientific evaluation of the NichtraucherHelden App (Medicine) in combination with brief advice from a physician. The effectiveness of the NichtraucherHelden App (Medicine) in combination with brief advice (intervention group, IG) is tested in comparison to a control group (KG), which only receives brief advice. The following parameters will be evaluated as part of the study:

- **7-day point prevalence of smoking abstinence 6 months after smoking cessation.**
- **prolonged smoking abstinence**
- **objective smoking abstinence measured by cotinine detection in saliva**
- **changes in health-related quality of life**
- **influence on shortness of breath**
- **influence on cough**

Do you plan to share individual participant data with other researchers?

No

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00025933**
- Date of Registration in DRKS: **2021/07/30**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **Eth-52/20 , Ethik-Kommission der Ärztekammer Berlin**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1268-2181**

Health condition or Problem studied

- ICD10: **F17.2 - Mental and behavioural disorders due to use of tobacco; Dependence syndrome**

Interventions/Observational Groups

- Arm 1: **Intervention Group (IG). Subjects receive a 3-minute, brief medical consultation and the NichtraucherHelden App (Medicine). At the end of the study, successful non-smokers provide a saliva sample for cotinine measurement.**
- Arm 2: **Control group (CG). Subjects receive a 3-minute, brief medical consultation, but no app.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Other**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

7-day point prevalence of smoking abstinence 6 months after smoking cessation

Secondary Outcome

- **prolonged smoking abstinence**
- **objective smoking abstinence measured by cotinine detection in saliva**
- **changes in health-related quality of life**
- **influence on shortness of breath**
- **influence on cough**

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- **other mehrere Allgemeinarzt- + Pneumologie-Praxen in Berlin + Baden Württemberg**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2021/08/31**
- Target Sample Size: **640**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- **diagnosed tobacco dependence according to ICD-10 F17.2**
- **intention to quit smoking**
- **age \geq 18 years**
- **device for use of the NichtraucherHelden App (Medicine)**
- **resident (primary residence) in Germany**
- **valid private e-mail address**

Exclusion criteria

- **concomitant alcohol, pill, or illicit drug addiction**
- **acutely symptomatic psychiatric illness**
- **severe cognitive impairment**
- **dementia-related illnesses**
- **lack of German language skills**
- **work in 24h shifts (e.g. rescue service, fire department)**
- **participation in another tobacco cessation program**
- **use of another smartphone app for tobacco cessation**

Addresses

■ Primary Sponsor

NichtraucherHelden GmbH
Im Himmel 20
70569 Stuttgart
Germany

Telephone: **0711 / 21 959 343**

Fax: **0711 / 21 959 348**

E-mail: **info at nichtraucherhelden.de**

URL: **<https://www.nichtraucherhelden.de/>**

■ Contact for Scientific Queries

NichtraucherHelden GmbH
Ms. Dr. Maddalena Angela Di Lellis
Im Himmel 20
70569 Stuttgart
Germany

Telephone: **0711 / 21 959 343**

Fax: **0711 / 21 959 348**

E-mail: **maddalena.di-lellis at nichtraucherhelden.de**

URL: **<https://www.nichtraucherhelden.de/>**

■ Contact for Public Queries

NichtraucherHelden GmbH
Ms. Dr. Maddalena Angela Di Lellis
Im Himmel 20
70569 Stuttgart
Germany

Telephone: **0711 / 21 959 343**

Fax: **0711 / 21 959 348**

E-mail: **maddalena.di-lellis at nichtraucherhelden.de**

URL: **<https://www.nichtraucherhelden.de/>**

■ **Collaborator, Other Address**

novineon CRO GmbH
Friedrich-Miescher-Straße 9
72076 Tübingen
Germany

Telephone: **07071-98 979-139**

Fax: **07071-98 979-230**

E-mail: **nichtraucherhelden at novineon.de**

URL: [---]*

Sources of Monetary or Material Support

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

NichtraucherHelden GmbH
Im Himmel 20
70569 Stuttgart
Germany

Telephone: **0711 / 21 959 343**

Fax: **0711 / 21 959 348**

E-mail: **info at nichtraucherhelden.de**

URL: **https://www.nichtraucherhelden.de/**

Status

■ Recruitment Status: **Recruiting planned**

■ Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruiting started": [---]*

■ Reason, if Reason for Recruiting Stop "Other": [---]*

■ Study Closing (LPLV): [---]*

■ Number of Participants in Germany after Recruiting complete: [---]*

■ Total Number of Participants (all Sites worldwide) after Recruiting complete: [---]*

Trial Publications, Results and other documents

DRKS-ID: **DRKS00025933**

Date of Registration in DRKS: **2021/07/30**

Date of Registration in Partner Registry or other Primary Registry: [---]*

* *This entry means the parameter is not applicable or has not been set.*

*** *This entry means that data is not displayed due to insufficient data privacy clearing.*