

Trial Description

Title

Impact of a smoking cessation program on smoking prevalence and food security among food pantry users - a study protocol for a cluster-randomized pragmatic controlled trial

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Many food pantry users are food insecure and smoke. Probably, smoking and food insecurity are related to one another. A study will be conducted to evaluate the impact of a smoking cessation program adapted to food pantry users on the smoking status and on the food security level among food pantry users.

In the first phase, a group discussion with food pantry users and telephone interviews with smoking cessation trainers, social workers and psychologists will be conducted. In the second phase, at least 32 food pantries (clusters) with 416 participating food pantry users in Berlin, Germany, shall be split into an intervention and a control group. The intervention will consist of the behavioural group program for smoking cessation previously adapted to food pantry users as well as optional nicotine replacement therapy and non-smoker friendly measures in the food pantries. The waiting list control group will receive the intervention around nine months after the intervention group. Participants will be asked to fulfil a questionnaire and to measure exhaled carbon monoxide three times.

Brief Summary in Scientific Language

Among food pantry users there is a high prevalence of both smoking and food insecurity, which may be related to one another. This study aims to evaluate the impact of a smoking cessation program carried out in food pantries on the smoking status and the food security status of food pantry users.

In the first phase, a mixed method approach will be used to develop the intervention. Food pantry users and workers as well as other experts, such as smoking cessation trainers, social workers, and psychologists, will be involved, using the world café technique and telephone interviews. In the second phase, the impact of the intervention on the smoking status and on food insecurity will be investigated by a cluster randomised controlled trial. A total of 416 food pantry users across 32 clusters (food pantries) in Berlin, Germany, should be recruited and randomly assigned to either the intervention group or the waiting list control group. The intervention will consist of a behavioural group counselling program for smoking cessation, specially tailored for food pantry users, as well as optional nicotine replacement therapy and the implementation of environmental smoking reduction measures in the food pantries. The primary outcomes six months after

the treatment will be self-reported continuous smoking abstinence, validated by exhaled carbon monoxide (< 10 ppm of carbon monoxide), and increased food security level (the percentage of participants with an improved food security level).

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

No

Description IPD sharing plan

Due to the sensibility and intimacy of the data.

Organizational Data

- DRKS-ID: **DRKS00020037**
- Date of Registration in DRKS: **2020/04/29**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: [---]* , **Ethikkommission der Universität Hohenheim**

Secondary IDs

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **The intervention will consist of the smoking cessation program previously designed for food pantry users as well as optional nicotine replacement therapy and the implementation of ecological non-smoker friendly measures in the food pantries.**
- Arm 2: **The control group will be provided with the usual food pantry supply and will receive the intervention when the last data collection period will be finished (waiting list control group).**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Control group receives no treatment**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Primary outcomes are the continuous smoking abstinence and increased food security level (the percentage of participants with an improved food security level) six months after the treatment. Smoking cessation is defined as the self-reported continuous smoking cessation (≤ 5 cigarettes since the defined day of stopping smoking) validated by exhaled carbon monoxide (< 10 ppm). Food insecurity is categorized in food security, mild food insecurity, moderate food insecurity, and severely food insecurity according to the Food and Agriculture Organization of the United Nations.

Secondary Outcome

Secondary outcomes at one and/or six months post-intervention include the point prevalence abstinence, the mean number of smoked cigarettes per day, the mean number of affirmative responses at the FIES, and the health-related quality of life.

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- other **Tafel Ausgabestellen, Berlin**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2021/10/15**
- Target Sample Size: **416**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

Users of any of the participating food pantries who reported to smoke at least one cigarette or cigarillo per day and are able to sufficiently understand and speak German.

Exclusion criteria

Non-smokers and individuals smoking less than daily as well as individuals who do not use any of the participating food pantries; individuals who are 17 years of age or less, are unable to understand and speak German or are illiterate; individuals who only use e-cigarettes or tobacco heating systems

Addresses

■ Primary Sponsor

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■ Collaborator, Other Address

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

**Verband der Ersatzkassen e.V. (vdek)
Askanischer Platz 1
10963 Berlin
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- **Private sponsorship (foundations, study societies, etc.)**

**Deutsche Krebshilfe gGmbH
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53113 Bonn
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URL: [---]*

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": [---]*

DRKS-ID: **DRKS00020037**

Date of Registration in DRKS: **2020/04/29**

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

- 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

* *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.*