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Prevention of nicotine-associated morbidity by smoking cessation counselling in trauma patients in an emergency department

Submission date
11/08/2006

Recruitment status
No longer recruiting

Registration date
29/01/2007

Overall study status
Completed

Last Edited
05/07/2017

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
Emergency departments (EDs) are suitable settings for screening and health promotion. A number of studies showed effective strategies for the prevention of the negative consequences of alcohol consumption. There is little evidence about the benefits of screening and prevention programs for tobacco use. Therefore, the aim of this study is to find out whether smokers in an emergency department benefit from a tobacco control program.

Who can participate?
Patients aged over 18 in an emergency department

What does the study involve?
Participants are randomly allocated to one of two groups. One group receives a motivational interview on site and up to four booster telephone calls intended to motivate smoking patients to quit. They also receive an information leaflet and, if desired, nicotine patches and gum. The other group receives the information leaflet only. Smoking rates are compared between the two groups. As there is evidence from other settings that tobacco control interventions show positive effects not only in the short term (some weeks or months) but also in the long-term (several years), all participants receive a postal questionnaire 10 years later to assess the long-term effects of the intervention.

What are the possible benefits and risks of participating?
All participants undergo screening for tobacco use and receive the information leaflet. Those participants allocated to the tobacco control program also receive a motivational interview. Participants in the control group are offered this program at the end of the study. There are no risks reported in regard to tobacco control programs.

Where is the study run from?
Charité – Universitätsmedizin Berlin (Germany)

When is the study starting and how long is it expected to run for?
October 2005 to June 2016

Who is funding the study?
German Cancer Aid

Who is the main contact?
Dr Bruno Neuner
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Prevention of nicotine-associated morbidity by smoking cessation counselling in trauma patients in an emergency department

Acronym
TED study (Tobacco control in an urban Emergency Department)

Study objectives
The aim of this study is to investigate whether a 20 to 30 minutes counselling in smokers followed by four 5 to 15 minutes booster session by telephone leads to a significant reduction in the number of cigarettes in smokers ambivalent concerning their smoking and a significant rate of abstaining in those smokers who actively try to quit smoking.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Original study: Ethics Committee of the Charité Universitätsmedizin, Berlin, 19/11/2004, ref: EA1/23/2004
2. 10 years follow-up postal survey: Ethics Committee of the Charité Universitätsmedizin, Berlin, 08/09/2015, ref: EA1/238/15

Study design
Randomised controlled trial (TED study) and postal survey (10-years follow-up)

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Smoking addiction

Interventions
Participants are randomised to receive either:
1. A 20 to 30 minutes counselling session followed by four 5 to 15 minutes booster session by telephone
2. Care as usual

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Significant rates of abstainers in those smokers who actively try to quit smoking

Key secondary outcome(s))
Reduction in the number of cigarettes in smokers ambivalent concerning their smoking

Completion date
30/06/2016

Eligibility

Key inclusion criteria
1. Patients in an emergency department
2. Aged over 18

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Under 18 years of age
2. Altered mental status that precluded consent
3. Medically unstable
4. In significant pain
5. Were intoxicated by alcohol or drugs
6. Were non-German speaking

Date of first enrolment
01/10/2005

Date of final enrolment
21/12/2006

Locations

Countries of recruitment
Germany

Study participating centre
Charité – Universitätsmedizin Berlin
Department of Anaesthesiology and Operative Intensive Care Medicine
Campus Charité Mitte
Charitéplatz 1
Berlin
Germany
10117

Sponsor information

Organisation
Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (Germany)

ROR

https://ror.org/001w7jn25

Funder(s)

Funder type
Charity

Funder Name
Deutsche Krebshilfe Grant-No.: DKH-106730 (TED-study) and DKH-111507 (10-years follow-up)

Alternative Name(s)
Stiftung Deutsche Krebshilfe, German Cancer Aid

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2009		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes