

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

<b>Submission date</b> 11/08/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 29/01/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/07/2017	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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**  
Dr Bruno Neuner

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

### **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 measure**

Significant rates of abstainers in those smokers who actively try to quit smoking

**Secondary outcome measures**

Reduction in the number of cigarettes in smokers ambivalent concerning their smoking

**Overall study start date**

01/10/2005

**Completion date**

30/06/2016

**Eligibility****Key inclusion criteria**

1. Patients in an emergency department
2. Aged over 18

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

1044

**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)

**Sponsor details**

c/o Dr Bruno Neuner and Prof. Claudia Spies

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**Sponsor type**

University/education

**Website**

<https://anaesthesieintensivmedizin.charite.de/>

**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

**Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal.

**Intention to publish date**

31/10/2017

**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?
<a href="#">Results article</a>	results	01/08/2009		Yes	No