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FOllow-up and Brief Intervention of Conscripts in Lausanne, Switzerland

Submission date	Recruitment status	[ ] Prospectively registered
13/12/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/02/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/05/2013	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

FOllow-up and Brief Intervention of Conscripts in Lausanne, Switzerland: a single-centre randomised controlled trial

Acronym
FOBIC

Study objectives
Testing the effectiveness of brief interventions on alcohol, tobacco, and cannabis use and related risks outside a clinical setting and delivering it to a large majority of men in the French speaking region of Switzerland. A first phase will concentrate on alcohol use intervention, a second on tobacco, and a third on all substances addressed together.

Research questions are:
1. Are brief interventions among young men effective in reducing hazardous alcohol use and substance use in general?
2. Are booster sessions more effective than single brief intervention sessions?
3. Does a brief intervention in one domain (e.g., alcohol) show cross-effects in another domain (e. g., tobacco)?
4. Are interventions simultaneously provided for multiple risks more effective than an intervention focusing on one risk behaviour at the time?
5. Can simple assessment of problematic use (without brief motivational interviewing [BMI]) be seen as an effective minimal intervention? This can be demonstrated by comparing conscripts of the randomised trial that received
5.1. BMI with those who did not receive BMI but for which substance use was measured during assessment, and
5.2. By comparing the assessment only group with a second control group that received only screening without further assessment and without BMI

As of 13/02/2009 this record was updated to include amended trial dates; the initial trial dates at the time of registration were as follows:
Initial anticipated start date: 30/01/2007
Initial anticipated end date: 31/12/2010

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 13/02/09: Ethics Committee for Clinical Research of the Lausanne University Medical School gave approval on the 2nd April 2007 (ref: 15/07)

Study design
Single-centre randomised controlled trial

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Alcohol, tobacco, and cannabis use

Interventions
This trial comprises three separate studies:
1. Study on alcohol use (600 participants)
2. Study on tobacco use (600 participants)
3. Study on the use of alcohol, tobacco and cannabis assessed together (600 participants)

Within each study, the participants will be allocated to one of the following three groups:
Group 1: Screening only (200 participants)
Group 2: Screening + assessment (200 participants)
Group 3: Screening + assessment + BMI (200 participants)

The screening questionnaire takes approximately 5 minutes to complete. The assessment questionnaire takes approximately 15 minutes to complete. BMI is intended to enforce the motivation to change behaviour. Interventions are conducted by experienced psychologists trained in motivational interviewing and in providing brief motivational interventions. Interventions last approximately 30 minutes. The same psychologists provide booster brief motivational intervention sessions 3 months after the first session by telephone. Booster sessions last approximately 20 minutes. Follow-up will be carried out at 6 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Alcohol, tobacco and cannabis use 6 months after baseline, measured by the following:
1. Alcohol use:
1.1. Quantity/frequency questionnaires
1.2. Retrospective diary
1.3. Alcohol Use Disorder Identification Test
2. Tobacco use:
2.1. Quantity/frequency questionnaires
2.2. Cigarette Dependence Scale
3. Cannabis use:
3.1. First three questions of the Cannabis Use Disorder Identification Test

Secondary outcome measures
1. Reduction of related risks 6 months after baseline. Related risks are measured using several tests:

1.1. Wechsler Alcohol Consequences
1.2. Questionnaire on dinking and driving
1.3. Attitudes Towards Smoking Scale, or questionnaire for cannabis use consequences
2. Cross-over effects:
2.1. Reduction in at-risk use of tobacco and cannabis use during the alcohol study at 6 months after baseline
2.2. Reduction in at-risk use of alcohol and cannabis use during the tobacco phase at 6 months after baseline.
2.3. Substance use, measured as described above
3. Readiness to change at 6 months after baseline, measured using 10-points Visual Analogue Scale (1 = not ready to change, 10 = extremely ready to change)

Overall study start date
30/01/2007

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. 19-year old males with a Swiss citizenship enrolling during the mandatory army recruitment process in the French-speaking part of Switzerland
2. Informed consent
3. Provision of a contact address

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
1,800 participants. Target number of recruitment may be increased if additional funding becomes available.

Key exclusion criteria
Lack of informed consent and provision of contact address.

Date of first enrolment
30/01/2007

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Switzerland

Study participating centre
Mont Paisible 16
Lausanne
Switzerland
1011

Sponsor information

Organisation
Swiss Alcohol Research Foundation (Fondation Suisse De Recherche Sur L'alcool) (Switzerland)

Sponsor details
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Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

Funder Name
Swiss Foundation for Alcohol Research (Switzerland) - funding for the alcohol study phase

Funder Name
Swiss Tobacco Prevention Funds (Switzerland) - funding obtained in 2008 for the tobacco study phase

Funder Name

Swiss National Science Foundation (Switzerland) - application to be submitted in 2010 for the funding of the multi-substance study phase

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Other publications	findings of the screening porcedure	01/11/2008		Yes	No
Results article	results	29/08/2012		Yes	No