

Influence of counselor on the effectiveness of a brief motivational intervention on heavy drinking in young adults

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Registration date 23/08/2013	Overall study status Completed	<input type="checkbox"/> Protocol
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		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Brief motivational intervention (BMI), an adaptation of motivational interviewing, has the potential to reach adolescents and young adults because it includes acceptance of individual autonomy, avoidance of argumentation and hostile confrontation, and avoids giving lectures or ultimatums. BMI research with young adults has shown promising results. The best time to address young adult substance use is during army recruitment procedures in countries where it is mandatory. In Switzerland, virtually all non-institutionalized men are called for army recruitment at the age of 20. An initial investigation among this population showed a roughly 20% drinking reduction at 6-month follow-up in the BMI condition compared to a control group receiving no intervention.

This study aims at better understanding brief motivational intervention (BMI) mechanisms by investigating the influence of counselors on BMI effectiveness in reducing alcohol use among young men.

Who can participate?

Young men screened as hazardous drinkers.

What does the study involve?

Participants will be randomly allocated to receive a single BMI conducted by one of 18 counselors performing 12 BMIs each or to receive no intervention (control group). Counselors will be selected to maximize differences in several of their characteristics (e.g. background, clinical and motivational interviewing experience). The intervention will be a 20 to 30-minute BMI addressing alcohol use, its related consequences, and per client agreement, eventual change perspectives. First analyses will compare reduction in alcohol use between the control and intervention group 3 months after inclusion. Next, several links between counselor characteristics, BMI content (i.e. within-session counselor and subject behaviors and working alliance), and alcohol use will be assessed at the 3-month follow-up.

What are the possible benefits and risks of participating?

All studies so far have found decreases in substance use even in the control group with

assessment only. Thus, beneficial effects are expected even in the control group with assessment only. Though some studies show no effect of brief interventions, no study so far has demonstrated any negative effects of a brief intervention. Thus, there seem to be no danger of negative effects in the experimental group.

Where is the study run from?

This study will take place at the Recruitment Center of Lausanne, which serves the French-speaking part of Switzerland. At all research stages, participants will be reminded that the research staff has no connection with the army and that all information will be kept confidential.

When is the study starting and how long is it expected to run for?

The study started in September 2010 and ran until March 2011.

Who is funding the study?

Swiss National Science Foundation.

Who is the main contact ?

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Influence of counselor on the effectiveness of a brief motivational intervention on heavy drinking in young adults: a randomized controlled trial

Study objectives

1. A single 20-30 minutes brief motivational intervention (BMI) will result in reduction alcohol use among 20-year, non treatment seeking, heaving drinking young men, when compared to no intervention (assessment only).
2. Our second set of hypotheses is that certain therapist characteristics will predict alcohol outcomes. Specifically, greater drinking reductions will be associated with higher levels of clinical experience, particularly in motivational interviewing (MI), as well as to feeling effective when delivering BMI and believing in BMIs potential to reduce alcohol use in the target population. We do not expect general therapist characteristics, such as professional status (psychologist vs. medical doctor) or gender to influence outcomes. We also hypothesize that therapist within-session behaviors will predict outcome. Specifically, better outcomes will be related to therapists showing more MI proficiency, as measured by the Motivational Interviewing Skill Code (MISC), version 2.1 (Miller et al, 2008), than less MI proficiency.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee for Clinical Research of the Lausanne University Medical School (Protocol No. 15/07)

Study design

Single center non-blinded randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

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

Heavy alcohol use / Hazardous drinking

Interventions

All conscripts in the Swiss Army Recruitment Center of Lausanne during study period are eligible for participation unless they have a priority army assessment during the study inclusion period. A sub-group of conscripts will be first randomized to participate in the study. They will be asked to read an information sheet and to sign a consent form. Consenting conscripts will then be asked to fill out a self-administrated assessment questionnaire; the research staff providing assistance if needed. The assessment questionnaire will include the Alcohol Use Disorders Identification Test Consumption (AUDIT-C) (Bush et al, 1998), which will be used to screen hazardous drinkers (score greater or equal to 4).

Hazardous drinkers will be randomized to a BMI condition or to a control condition receiving no intervention.

The intervention will be a single 20 to 30-minute BMI addressing alcohol use, its related consequences, and per client agreement, eventual change perspectives. As a purpose of the study is to examine therapist within-session behaviors, no specific guidelines will be provided regarding the content of individual interventions, but all therapists will be familiar with the brief intervention format and with MI spirit and basic techniques.

Follow-up procedures will take place 3 months after baseline and will be conducted by telephone by interviewers blinded to group allocation and baseline answers.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Alcohol use: usual number of drinking days per week, usual number of drinks (defined as 10 grams of alcohol such as 100 ml of wine, 250 ml of beer or 25 ml of spirits) per drinking day, and frequency of binge drinking episodes (6 drinks or more) over the last year (measured on a 0-4 scale with 0=never, 1=less than monthly, 2=monthly, 3=weekly, and 4=almost daily).

Secondary outcome measures

Alcohol-related consequences (9 item questionnaire assessing the occurrence of a series of consequences (e.g., argue with friends, miss a class, engage in unplanned sexual activity, get into trouble with police) based on Wechsler et al. (1994). Alcohol Use Disorder Identification Test (AUDIT, Babor et al, 2001).

Overall study start date

01/09/2010

Completion date

01/03/2011

Eligibility

Key inclusion criteria

1. Young men aged 19-20 and participating in the Swiss Army mandatory conscription process in the Recruitment Center of Lausanne.
2. Those who do not have a priority army assessment during the study period.

Participant type(s)

Patient

Age group

Adult

Sex

Male

Target number of participants

432 (216 intervention, 216 control)

Key exclusion criteria

1. Non-hazardous drinkers

Date of first enrolment

01/09/2010

Date of final enrolment

01/03/2011

Locations**Countries of recruitment**

Switzerland

Study participating centre

Lausanne University Hospital

Lausanne

Switzerland

1011

Sponsor information**Organisation**

The Swiss National Science Foundation (Switzerland)

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Sponsor type

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Funder(s)

Funder type

Research organisation

Funder Name

The Swiss National Science Foundation (Grant Ref: FN 33CSC0-122679) (Switzerland)

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