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Development and evaluation of the efficacy of a brief motivational intervention among young adults admitted in the Emergency room while being alcohol intoxicated

Submission date
26/11/2016

Recruitment status
No longer recruiting

Registration date
30/11/2016

Overall study status
Completed

Last Edited
03/05/2024

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 08/08/2018:
Background and study aims
Harmful alcohol use among young adults is a major public health concern and accounts for a significant portion of disease burden in Switzerland and worldwide. In Switzerland, Emergency Room admissions for alcohol intoxication have increased substantially over the past decade, particularly among adolescents and young adults. Brief motivational interventions (short programs which aim to motivate people to change their behaviour) for young adults conducted in the Emergency Room have shown promising but inconsistent results. The aim of this study is to test the effectiveness of a new motivational intervention model for young adults admitted in the ER with alcohol intoxication.

Who can participate?
Patients aged 18-35 who have been admitted in the Lausanne University Hospital Emergency Room for any cause and having alcohol intoxication.

What does the study involve?
At the start of the study, participants are asked to complete a 10 minute questionnaire, participate in an interview with a research clinician to discuss alcohol use, as well as change in alcohol use if they wish so, and complete a short feedback questionnaire about the interview (3 minutes). They are then randomly allocated to one of two groups. Those in the first group take part in the brief motivational intervention. The programme is delivered while in the ER by a qualified research clinician and takes between 20 and 60 minutes. The programme aims to help participants to help change their drinking behaviour by looking at the discrepancies between their current behaviour and where their broader life goals. After the session, they are sent a letter summing up the discussion (i.e., context, discussion, aims and encouragements). Based on participant's agreement, booster session by phone is conducted after 1 week, 1 month, and 3 months. Those in the second group receive 5-10 minutes of brief advice in the ER to cut down on drinking. Participants in both groups are contacted by phone 1, 3, 6 and 12 months later in order

to complete another questionnaire on alcohol use and related consequences. Each contact lasts for around 15 minutes. In addition, a sample of hair is collected and tested for alcohol use at the start of the study and then again after 6 and 12 months. Medical records are also reviewed after 12 months to find out if any participants have been readmitted to hospital while intoxicated with alcohol.

What are the possible benefits and risks of participating?
There may be no direct benefit to participants. That being said, potential benefits to participants include the possibility to reduce alcohol consumption and related problem; participants also may benefit from clinical assessment, monitoring and referrals as necessary. They might also take advantage of an interview with a trained psychologist to think about their behaviors and their life values and better get to know themselves. The risks of serious adverse consequences as a result of study participation are relatively low. It is possible that some participants will find the interviewing tiresome. They might also have concerns about confidentiality of sensitive information addressed during the intervention. The sensitive nature of some of the questions (e. g., alcohol-related) may cause participants discomfort.

Where is the study run from?
Lausanne University Hospital (Switzerland)

When is the study starting and how long is it expected to run for?
December 2016 to August 2020 (updated 17/06/2019, previously: May 2019)

Who is funding the study?
Swiss National Science Foundation (Switzerland)

Who is the main contact?
Dr Jacques Gaume
jacques.gaume@chuv.ch

Previous plain English summary:
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Who is funding the study?
Health Technology Assessment Programme, National Institute for Health Research (UK)

Who is the main contact?
Dr Jacques Gaume

Contact information

Type(s)
Scientific

Contact name
Dr Jacques Gaume

Contact details
Lausanne University Hospital
Avenue de Beaumont 21 bis – P2
Lausanne
Switzerland
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Additional identifiers

Protocol serial number
Grant 105319_163123, Swiss National Science Foundation

Study information

Scientific Title
A Process study and Randomized controlled trial examining the Efficacy and Mechanisms of Motivational interviewing for alcohol Intoxicated young adults admitted to the Emergency Room

Acronym
PREMMIER

Study objectives
The primary aim of this trial is to test the efficacy of a brief motivational intervention model (developed in the first part of the PREMMIER project) by comparing it to a control condition receiving a minimal intervention (structured brief advice).

Null hypothesis:
Both interventions have comparable effects in reducing
1. The number of Heavy drinking days (HDD, i.e. the number of days with 6 standard drinks or more, equivalent to 60 grams of pure alcohol or more, over the last month)
2. Alcohol-related problems as measured by the Short Inventory of Problems (SIP) total score over 3 the follow-up times (3, 6, and 12 months after intervention)

Alternative hypothesis:
Participants in the Brief motivational intervention group (experimental condition – intervention model developed in the first phase of the project) reduce
1. The number of Heavy drinking days (HDD, i.e. the number of days with 6 standard drinks or more, equivalent to 60 grams of pure alcohol or more, over the last month)
2. Alcohol-related problems as measured by the Short Inventory of Problems (SIP) total score, more then participants in the control group (structured brief advice) over the 3 follow-up times (3, 6, and 12 months after intervention)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Commission cantonale d'éthique de la recherche sur l'être humain (Ethics Committee of Canton Vaud), 01/11/2016, ref: 2016-01476

Study design
Single-center two-arm randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Alcohol intoxication

Interventions
Participants will be randomised to one of two groups using an algorithm implemented in the same software used to collect baseline assessment (secuTrial).

Intervention group: The experimental treatment will be a brief motivational intervention (BMI) developed and pre-tested in the first phase of project PREMMIER. BMI will be delivered while in the ER by a qualified research clinician (psychologist, clinical social worker, or nurse) and will last between 20 to 60 minutes. The intervention will use 3 main ingredients, in particular:
1. Relational factors (e.g., empathy, acceptance, collaboration, avoidance of confrontation)
2. Evoking participants' change talk and strengthening their ability and commitment to change
3. Providing information while supporting participants' autonomy.
Overall, the intervention aims at increasing participants' motivation to change their drinking behaviours by enhancing discrepancy between their current behaviour and their broader life goals and values. The intervention focuses on helping participants to resolve the latter discrepancy through evoking and planning behaviour change. When necessary, interventionist will discuss and facilitate referral to alcohol treatment. After the session, the interventionist sends a letter summing up the discussion (i.e., context, discussion, aims and encouragements) to the participant. Based on participant's agreement, booster session by phone will be conducted after 1 week, 1 month, and 3 months.

Control group: The control intervention will be a minimal intervention - Brief advice. Brief advice will be delivered in approximately 5 to 10 minutes. It will led by the same research clinicians and will consist of a standardized brief structured feedback and advice to cut down drinking, with referral to specialist services for the more severe patients (based on the Alcohol Use Disorders Identification Test score included in the baseline assessment).

Participants will complete a short post-session questionnaire while in the ER, and will then be contacted for follow-up assessments at 1, 3, 6, and 12 months post-baseline. Research assistants will conduct follow-up interviews by phone, using a computer assisted program directly recording data electronically in the eCRF (secuTrial). The interview will last 15 to 30 minutes.

Intervention Type
Behavioural

Primary outcome(s)
Number of Heavy drinking days over the last month (HDD, i.e. the number of days with 6 standard drinks or more, equivalent to 60 grams of pure alcohol or more) measured using a 30-day Timeline Follow-back technique (TLFB) and the Short Inventory of Problems (SIP) total score at 3, 6 and 12 months post-intervention.

Key secondary outcome(s))
1. Weekly drinking amount (i.e. number of drinks per week) derived from the Timeline Follow-back technique (TLFB) at 3, 6 and 12 months post-intervention
2. Frequency of alcohol-related consequences will be derived from 4 alcohol-related consequences at 3, 6 and 12 months post-intervention
3. Alcohol-related problems are assessed using SIP sub-dimension scores (Physical, Social, Intra-personal, Inter-personal, and Impulse control) at 3, 6 and 12 months post-intervention
4. Proportion of patients with hazardous or harmful drinking status is assessed using the Alcohol

use disorder identification test (AUDIT) at baseline and 12 months
5. Proportion of patients who started alcohol treatment and of patients readmitted to the ER over the 12-month follow-up period will be measured by specific self-report questions at 3, 6 and 12 months post-intervention
6. Proportion of patients who started alcohol treatment and of patients readmitted to the ER is measured using Lausanne University Hospital medical records at 12 months post-intervention
7. Heavy drinking is assessed by measuring to Ethyl glucuronide (EtG) concentration in head hair at baseline, 6 and 12 months post-intervention

Completion date
31/08/2020

Eligibility

Key inclusion criteria
1. Aged between 18 and 35
2. Admitted in the Lausanne University Hospital ER (for any cause) and having alcohol intoxication (>0.5 gram/liter BAC or clinical indication of alcohol intoxication)
3. Informed consent as documented by signature

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
344

Key exclusion criteria
1. Life threatening conditions
2. Detainees or medico-legal admissions
3. Not being fluent in French
4. Currently receiving another alcohol or substance use treatment
5. Psychiatric or medical contra-indications preventing patients understanding informed consent, fulfilling questionnaires, and participating in the intervention (evaluated using an adaptation of the University of California, San Diego Brief Assessment of Capacity to Consent)

Date of first enrolment
01/12/2016

Date of final enrolment
31/08/2019

Locations

Countries of recruitment
Switzerland

Thailand

Study participating centre
Lausanne University Hospital
Rue du Bugnon 46
Lausanne
Thailand
1011

Sponsor information

Organisation
Lausanne University Hospital

ROR
https://ror.org/05a353079

Funder(s)

Funder type
Research organisation

Funder Name
Swiss National Science Foundation

Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, The Swiss National Science Foundation (SNSF), SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/10/2022	24/10/2022	Yes	No
Other publications	Secondary analysis	28/03/2024	02/04/2024	Yes	No
Other publications	Young adults' change talk within brief motivational intervention in the emergency department and booster sessions is associated with a decrease in heavy drinking over 1 year	01/05/2024	03/05/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes