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Alcohol e-Help self-help intervention

Submission date	Recruitment status	[X] Prospectively registered
12/11/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/11/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/11/2022	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
The e-health portal on alcohol and health of the World Health Organization was launched on December 6, 2012. So far there are adapted versions in four countries and four different languages (https://www.infoalcohol.net/, https://www.informalcool.org.br, https://www.alcoholwebindia.in, https://www.saberdealcohol.org.mx/). This portal provides information for policymakers, professionals and the public at large on alcohol and health. It also includes a web-based self-help program to reduce alcohol consumption. Testing the effectiveness of this self-help program is the first step to open the program to other countries worldwide and make it more attractive for authorities in countries not yet involved. The potential public health impact of the expansion of an effective Internet self-help program to many low-income and high-income countries worldwide is enormous. The aim of this study is to test the effectiveness of the web-based self-help program to reduce alcohol consumption.

Who can participate?
People aged between 18 and 75 who live in Brazil, India, Mexico or Belarus.

What does the study involve?
Participants are randomly allocated to one of two groups. One group is given access to the Alcohol e-Health program, while the other group receives general information on alcohol and health, and is given access to the Alcohol e-Health program after the end of the study.

What are the possible benefits and risks of participating?
Participants may learn to reduce or to abstain from alcohol use by participating in the six-week self-help program. According to the experience in former studies, there are no significant health risks in participating in this' study. However, in case participants experience acute alcohol withdrawal or other physical or mental symptoms, they are recommend to see a health professional.

Where is the study run from?
1. The Information and Training Centre of Belarusian Psychiatric Association (Belarus)
2. Universidade Federal de Juiz de Fora, Universidade Federal de Sao Paulo and Universidade Federal do Parana (Brazil)
3. National Drug Dependence Treatment Center (NDDTC) (India)
4. Insituto Nacional de Psiquiatría Ramón de la Fuente Muñiz (Mexico)

When is the study starting and how long is it expected to run for?
January 2016 to June 2017

Who is funding the study?
World Health Organization (Switzerland)

Who is the main contact?
Dr Michael Schaub

Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Alcohol e-Help – a web-based self-help program for the reduction of alcohol use in harmful, hazardous or suggestive dependent drinkers compared to an active waiting list: a cluster randomized controlled four-country trial

Study objectives
The study hypothesizes that participants in the Alcohol e-Health program will show greater reductions in the Alcohol Use Disorders Identification Test score (AUDIT, primary outcome, Babor et al. 2001) at the 6-month follow-up than participants allocated to a waiting list control group. Similar hypotheses are drawn regarding secondary outcomes, the quantity of alcohol measured in weekly standard drinks and the number of alcohol abstinent days of a typical week in the last 6 months. Participants in the program group are also expected to be less harmful or hazardous drinkers (falling below the cut-off of 8 according to the AUDIT score, Babor et al. 2001) at the 6-month follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. WHO Ethics Review Committee, 30/06/2015, ref: RPC756
2. Four relevant country-specific ethics committees in Belarus, Brazil, India, and Mexico

Study design
Cluster randomized controlled four-country intervention trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Harmful, hazardous or suggestive dependent alcohol users

Interventions
The randomization occurs on the individual level but for each country separately. Participants are randomized to either:
1. The Alcohol e-Health program
2. Classical waiting list receiving first general information on alcohol and health and program access only after 6 months

The Alcohol e-Health program is an accessible self-help tool for people who are trying to reduce their use of alcohol or stop drinking entirely. Participants can register and use the program in their own time, at their own pace, and free of charge. Participants are encouraged to complete all parts of the program, to repeat any parts they feel they need or perceive as helpful, and to use the program for a minimum of 6 weeks. Alcohol e-Health provides support for individual participants to think about their drinking, decide whether or not to change their drinking, set goals regarding their drinking, take action regarding reducing or stopping drinking, measure their progress, and to deal with relapse to their previous drinking patterns.

Intervention Type
Behavioural

Primary outcome(s)
The total score of the Alcohol Use Disorders Identification Test (AUDIT, Babor et al. 2001) will be assessed at baseline and the 6-month follow-up

Key secondary outcome(s))
1. Falling below the cut-off of hazardous or harmful alcohol use (below AUDIT score of 8) between baseline and the 6-month follow-up
2. The alcohol use reflected for each weekday of a typical week in the last six months assessed at baseline and the 6-month follow-up
3. Program satisfaction is measured by the Client Satisfaction Questionnaire CSQ-8 assessed at the 6-months follow-up in the intervention group only

Completion date

30/06/2017

Eligibility

Key inclusion criteria
1. Age between 18 and 75 years
2. To be a resident of one of the participating pilot countries
3. To have at least weekly Internet access
4. To have an AUDIT score ≥ 8

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
1400

Key exclusion criteria
1. Current substance abuse treatment
2. Use of opioids, inhalants, cocaine/crack or amphetamine/amphetamine-like stimulants, sedatives during the last month
3. Cannabis or synthetic cannabinoids for more than 4 days during the last month

Date of first enrolment
01/09/2016

Date of final enrolment
01/03/2017

Locations

Countries of recruitment
Belarus

Brazil

India

Mexico

Study participating centre
The Information and Training Centre of Belarusian Psychiatric Association
Republican Mental Health Research and Practice Centre

Belarus
987654321

Study participating centre
Associação Fundo de Incentivo à Pesquisa
Universidade Federal de Juiz de Fora, Universidade Federal de Sao Paulo and Universidade Federal do Parana
Rua Botucatu, 862 - 1º andar - Edifício de Ciências Biomédicas
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04023062

Study participating centre
National Drug Dependence Treatment Center (NDDTC)
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201002

Study participating centre
Insituto Nacional de Psiquiatría Ramón de la Fuente Muñiz
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14370

Sponsor information

Organisation
World Health Organization (Switzerland)

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Other

Funder Name
World Health Organization

Alternative Name(s)
, , Всемирная организация здравоохранения, Organisation mondiale de la Santé, Organización Mundial de la Salud, WHO, , ВОЗ, OMS

Funding Body Type
Government organisation

Funding Body Subtype
International organizations

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/08/2021	31/08/2021	Yes	No
Protocol article	protocol	01/02/2018	19/09/2019	Yes	No
Abstract results		26/09/2019	30/11/2022	No	No
Abstract results		29/06/2022	30/11/2022	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes