

# Alcohol e-Help self-help intervention

<b>Submission date</b> 12/11/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 13/11/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/11/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## 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 recommended 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. Instituto Nacional de Psiquiatria 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

### **Study website**

Please refer to the Plain English Summary field above

## **Contact information**

**Type(s)**  
Public

**Contact name**  
Dr Michael P Schaub

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8031

## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

### **Secondary study design**

Cluster randomised trial

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

Internet/virtual

### **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**

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 measure**

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

### **Secondary outcome measures**

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

### **Overall study start date**

04/01/2016

### **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  $\geq 8$

### **Participant type(s)**

Mixed

### **Age group**

Mixed

### **Sex**

Both

### **Target number of participants**

640

### **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

Vila Clementino

São Paulo, SP

Brazil

04023062

**Study participating centre**

**National Drug Dependence Treatment Center (NDDTC)**

All India Institute of Medical Sciences

Kamla Nehru Nagar

Ghaziabad

Uttar Pradesh

India

201002

**Study participating centre**

**Instituto Nacional de Psiquiatría Ramón de la Fuente Muñiz**

Calzada Mexico Xochimilco #101

Tlalpan

Huipulco

Ciudad de México, D.F.

Mexico

14370

## **Sponsor information**

**Organisation**

World Health Organization (Switzerland)

**Sponsor details**

Management of Substance Abuse

Department of Mental Health and Substance Abuse

20 Avenue Appia

Geneva

Switzerland

1211

**Sponsor type**

Other

**Website**

[http://www.who.int/substance\\_abuse/activities/ehealth/en/](http://www.who.int/substance_abuse/activities/ehealth/en/)

**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**

Private sector organisation

**Funding Body Subtype**

International organizations

**Location**

Switzerland

## Results and Publications

**Publication and dissemination plan**

There will be a study protocol publication and a publication on the overall study outcomes. The involved countries are recommended to publish further study outcome papers based on their data in their respective languages.

**Intention to publish date**

28/02/2020

**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?
<a href="#">Protocol article</a>	protocol	01/02/2018	19/09/2019	Yes	No
<a href="#">Results article</a>		27/08/2021	31/08/2021	Yes	No
<a href="#">Abstract results</a>		26/09/2019	30/11/2022	No	No
<a href="#">Abstract results</a>		29/06/2022	30/11/2022	No	No