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Evaluation of an online help program for the treatment of depression and drug abuse in Mexico

Submission date
04/04/2014

Recruitment status
No longer recruiting

Registration date
12/05/2014

Overall study status
Completed

Last Edited
03/10/2016

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Many people who abuse drugs also experience depression. However, most available treatments approach these problems separately. And although both problems are common, few people seek treatment. Because of a shortage of quality specialized care, there is a gap between these serious problems and available health services. In some countries, health care providers are looking to new information technologies in their search for more efficient treatments that can serve more people at less cost. There is much evidence that online interventions are effective in the treatment of psychological problems. In Mexico, there are few treatment options for drug abusers, and there are no interventions that treat drug abuse and depression as related problems. The aim of this study is to evaluate the Online Help Program for Drug Abuse and Depression (OHPDAD) which addresses the two problems together and to see whether OHPDDA reduces drug consumption in adult patients who seek help in treatment centers, in comparison with the usual treatment and in comparison with the usual treatment plus printed guide.

Who can participate?
Adult women and men who rank high on substance abuse detection tests, have access to the internet, have not received substance abuse treatment in the past 12 months and seek help in the treatment centers selected for the study

What does the study involve?
The process begins with an introduction to the study for all patients seeking treatment at participating centers. Eligible participants are randomly allocated to one of three groups:
Group 1 OHPDAD (Online Help Program for Drug Abuse and Depression) online treatment and counsellor.
Group 2 BI-ASSIST+Treatment As Usual - A brief behavioral intervention developed by the World Health Organization (WHO), which includes a face to face session with an addiction therapist to improve motivation and to show how to use the ASSIST Guide to Self-Help Strategies which has techniques for reducing or eliminating drug use.
Group 3 Treatment As Usual - treatment ordinarily offered to patients in the participating

Treatment Centers.
Participants must complete three evaluation interviews: before the beginning of the treatment, eight weeks after the initial evaluation, one month after the final evaluation.

What are the possible benefits and risks of participating?
The risks and benefits are similar to those of any psychological treatment for substance abuse: there may or may not be an improvement in drug use or mental health. If there are no improvements, we will suggest a different type of treatment that will respond better to the participants needs and his/her participation in the study will end there. There is no cost for participation. The information obtained from participants may help to improve treatment for others in the future. As compensation for the time and effort contributed to the study, participants will receive a department store gift card after the completion of each of the three evaluation interviews.

Where is the study run from?
The study is conducted at two treatment centers: Centro de Prevención de las Adicciones Dr. Héctor Ayala Velázquez, Facultad de Psicología, Universidad Nacional Autónoma de México, Mexico City and Instituto Mexiquense contra las Adicciones (Anti-Addiction Institute in the State of Mexico), with three satellites (Centro de Atención Primaria a las Adicciones (CAPA) Estado de México, Centro de Atención Primaria a las Adicciones (CAPA) Pirules, Centro de Atención Primaria a las Adicciones (CAPA) Manantiales Estado de México)

When is the study starting and how long is it expected to run for?
The study started in April 2013 and will end in June 2014, with a 10-month recruitment period.

Who is funding the study?
United States Department of State.

Who is the main contact?
Dr Marcela Tiburcio
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number

REC-INPRF-002, Clinical Trial Network, National Institute of Psychiatry EP12 4229.0, Department of Epidemiological and Psychosocial Research

Study information

Scientific Title
Comparison of three methods of delivering cognitive behavioral brief interventions for substance abuse and depression in Mexico: a pilot controlled trial

Acronym
OHPDAD (Online Help Program for Drug Abuse and Depression)

Study objectives
Participants receiving online treatment will show a greater reduction in drug consumption than those who receive treatment as usual or those who receive the ASSIST Brief Intervention plus treatment as usual.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Institutional Review Board of the Instituto Nacional de Psiquiatría Ramón de la Fuente (Ramón de la Fuente National Institute of Psychiatry), 15/04/2013, ref: CEI/C/004/2013

Study design
Randomized three-arm multisite controlled pilot trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Use of psychoactive substances (except alcohol, tobacco and opiates) and depressive symptomatology

Interventions
Participants will be randomly assigned to one of following three groups:

1. OHPDAD. The Online Help Program for Drug Abuse and Depression (OHPDAD) is an alternative internet treatment program for those persons who wish to reduce their use of drugs and who present depressive symptomatology. The structural design of the OHPDAD is based on the transtheoretical model of change and incorporates elements of the cognitive-behavioral psychotherapeutic approach, including self-control techniques, functional analysis of drug use, exercises for the identification of risk situations, and plans for confronting those situations. In addition, it includes cognitive-behavioral strategies to identify and transform negative thoughts that are associated with depressive symptomatology. It includes online applications that allow

the user to keep a daily register of drug use, establish a goal, and various exercises to help reach it. Completing the entire program requires approximately 8 weeks. There is online follow-up by a counselor from the treatment center.

2. BI-ASSIST + Treatment As Usual. These participants receive the ordinary treatment provided by the treatment center, plus the ASSIST Brief Intervention (WHO, 2011). The latter modality includes an in-person session and use of the ASSIST Guide to Self-Help Strategies (WHO, 2011b), which provides various exercises that help the user to reduce drug use or arrive at abstinence, including maintenance of a daily registry of drug use, establishment of goals, and others. The exercises provided can be completed in approximately 2 weeks, at which time participants will receive treatment as usual.

3. Treatment As Usual. These participants will receive the treatment ordinarily offered at the participating treatment centers.

Participants must complete three evaluations:
1. Initial, before beginning treatment
2. Final, 8 weeks after the initial evaluation
3. Follow-up, 1 month after the final evaluation

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Number of days of substance use, assessed with the Timeline follow back at baseline, 8 weeks later, and follow-up
2. Severity of substance use measured with the Drug Abuse Screening Test-20 (DAST-20) (0 = N/A, 1-5 = low, 6-10 = intermediate, 11-15 = substantial, 16-20 = severe) at baseline, 8 weeks later, and follow-up
3. Depressive symptoms with the Patient Health Questionnaire (PHQ-9) (0-9 = mild, 10-14 = moderate, 15-19 = severe, 20-27 = major depression) at baseline, 8 weeks later, and follow-up

Key secondary outcome(s))
1. Readiness to change measured with the Readiness to Change Questionnaire (RCQ), at baseline, 8 weeks after starting treatment, and at follow-up
2. Consequences of substance use and thoughts associated with substance use through self-report check list at baseline, 8 weeks later, and follow-up

Completion date
30/05/2013

Eligibility

Key inclusion criteria
1. Man or woman 17 years of age or older
2. Consumer of psychoactive substances: marijuana, inhalants, cocaine, sedatives and other drugs (except alcohol, tobacco and opiates)
3. Can read and write

4. Risk score on the ASSIST substance abuse detection test ranging from low (0-3) to moderate (4-27)
5. Regular internet user
6. Has not had substance abuse treatment in the previous 12 months
7. Seeking treatment in the participating treatment centers

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Younger than 17 years of age
2. User principally of alcohol, tobacco or opiates
3. Present a risk of high level of drug abuse
4. Present suicide attempt or suicidal ideation in the previous 3 months
5. Lack basic ability to use the internet

Date of first enrolment
15/05/2013

Date of final enrolment
30/05/2013

Locations

Countries of recruitment
Mexico

Study participating centre
Calz. Mexico-Xochimilco 101
Mexico
Mexico
14370

Sponsor information

Organisation

U.S. Department of State (USA)

ROR
https://ror.org/02rcrvv70

Funder(s)

Funder type
Government

Funder Name
U.S. Department of State (Grant No. SINLEC11GR0015)

Alternative Name(s)
United States Department of State, Department of State, State Department, U.S. State Department, Committee of Foreign Affairs, Department of Foreign Affairs, DOS, USDOS

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/09/2016		Yes	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