ISRCTN91657311 https://doi.org/10.1186/ISRCTN91657311

Study of the Motivational Enhancement Treatment to improve treatment engagement and outcomes in Mexican patients seeking treatment for substance abuse

Submission date
23/08/2013

Recruitment status
No longer recruiting

Registration date
25/09/2013

Overall study status
Completed

Last Edited
24/06/2015

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
The harmful use of alcohol and illicit drugs has increased within the Mexican population. This has been associated to several risks and issues that affect public health. Only a small percentage of the population using harmful substances receives adequate treatment, mainly due to treatment neglect, delay of first treatment, or lack of access to primary care services. This stresses the need for easily accessible treatment methods or strategies to improve treatment retention in Mexican patients. The motivational enhancement treatment is a method for enhancing motivation to change. The purpose of this study is to find out if the motivational enhancement treatment can be used as a component to treatment, to improve participation and recovery in patients seeking treatment for substance use disorders.

Who can participate?
People between 18 and 65 years old, male and female, who request outpatient treatment for substance abuse, reporting consumption at least within 28 days before treatment and who are available in the area, at least during the four months of treatment, can participate in this study.

What does the study involve?
All eligible patients will be asked for their informed consent and then will be part of an initial screening for inclusion or exclusion. Once they are assigned randomly to one of the two intervention groups, they will receive either three sessions of the Motivational Enhancement Treatment or three sessions of treatment as usual. They will complete the initial assessment, three weekly assessments while they are receiving treatment, an assessment 28 days after the treatment has started, and two follow-up assessments at 2 months and 4 months after starting the treatment. On every visit, they will also be asked for urine and breath samples.

What are the possible benefits and risks of participating?
The benefits of participating in the study are receiving the treatment that is normally given in the centers, which could mean a possible improvement in their substance use and mental health.

The information obtained from their participation in this study will possibly help improve future treatment of other patients. As a compensation for the time and effort spent in the study, at the end of each assessment patients will receive electronic payment cards, which are exchangeable at supermarkets and restaurants, as an incentive for study participation and to cover for transportation costs. There are few risks beyond those associated with psychological treatment or substance use disorders. However, it is possible that, as in any specialized treatment, substance use disorder symptoms or related problems may not improve or get worse. During the assessments, the evaluator will ask the participants questions about substance use, personal and family life, legal status and sexual activity. Answering these questions, as well as the repeated sampling, could be uncomfortable. There is also the possibility of being recognized as a study participant by other patients, other study participants or employees at the treatment center, although this possibility is not greater than that of the regular patient who could be identified as part of routine treatment.

Where is the study run from?
The three centers that took part in this study were:
1. Addictive Disorders Clinic at the Ramón de la Fuente Muñiz National Institute of Psychiatry, México City, Mexico.
2. Primary Care Center for Addictions, South Unit, of the Puebla State Council Against Addiction, Puebla, Mexico.
3. Azcapotzalco Outpatient Unit of the Youth Integration Centers, Mexico City, Mexico.

When is the study starting and how long is it expected to run for?
The study started in April 2012 and lasted for about 12 months. The study recruited participants for 10 months.

Who is funding the study?
This project was funded by the US Department of State, USA.

Who is the main contact?
Dr Rodrigo Marín-Navarrete
rmarin@inprf.gob.mx

Contact information

Type(s)
Scientific

Contact name
Dr Rodrigo Marín-Navarrete

Contact details
Clz. México-Xochimilco #101
col. San Lorenzo Huipulco
CP. 14370, delg. Tlalpan
Mexico City
Mexico
14370
+52 (0)55 4160-5480
rmarin@inprf.gob.mx

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
REC-INPRFM: 001 (internal number)/Grant No. SINLEC11GR0015 (sponsor number)

Study information

Scientific Title
A two-arm, randomized controlled study of the Motivational Enhancement Treatment to improve treatment engagement and outcomes in Mexican patients seeking treatment for substance abuse

Acronym
IIM (Intervención de Incremento Motivacional)

Study objectives
The Motivational Enhancement Treatment intervention (IIM for its initials in Spanish), when applied as an inductive component of treatment, will improve treatment retention and reduce substance use in Mexican patients seeking treatment for substance use disorders vs. treatment-as-usual intervention.

The null hypothesis is that the IIM intervention has no significant effect on treatment retention or substance use in the patient population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Ramón de la Fuente Muñiz National Institute of Psychiatry (Mexico) - Project Number: IC112033.0., approved 10/10/2011

Study design
Randomized two-arm multisite controlled clinical 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
Any substance use disorder according to DSM-IV criteria

Interventions
Study Intervention:
Three individual behavioral therapy sesisons of Motivational Enhancement Treatment delivered weekly during the first 28 days of treatment + regular concurrent interventions for substance abuse treatment

Control:
Three individual behavioral therapy sessions of Treatment as Usual delivered at the participating center during the first 28 days of treatment + regular concurrent interventions for substance abuse treatment

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. For Substance Use: Days of substance use reported using a scheduled self-report assessment (Time Line Follow-Back) and drug or alcohol presence measured using qualitative measures for urine and breath samples. These will be measured at baseline, three times during treatment and at follow-up.
2. For Treatment Retention: Self-report of treatment utilization and involvement during the treatment phase and at follow-up.

We contemplated three follow-up assessments: one post-treatment assessment at the end of the 28-day treatment phase, a first follow-up assessment at 8 weeks after randomization (Follow-Up 1) and a second follow-up (Follow-up 2) 16 weeks after randomization.

Secondary outcome measures
1. Participant individual characteristics such as motivation for change, HIV risk behavior, therapeutic alliance, substance use-related problems and treatment expectations and satisfaction is measured at baseline, at the end of the 28 day treatment phase, and at two follow-ups on 8 and 16 weeks after randomization
2. For therapeutic process, treatment discriminability assessment and fidelity to the MET intervention, audio-recordings of all treatment sessions delivered during the 28-day treatment phase are listened and evaluated by an independent rater who is blinded to their treatment condition at no specific time-point

Overall study start date
16/04/2012

Completion date
01/04/2013

Eligibility

Key inclusion criteria
1. Male and female between 18 and 65 years old
2. Requesting ambulatory treatment for substance abuse
3. Reporting any substance use at least within 28 days before treatment
4. Willing to be assigned randomly to one of the intervention groups
5. Being available in the area where the study would be held, at least, during the four months of study duration
6. Having a stable home address where they can be contacted within the duration of the study
7. Reporting to have understood the conditions of the study and give their informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Presenting medical conditions and psychiatric instability that excludes the possibility of receiving ambulatory treatment. Therefore, those who present cognitive deterioration or other organic-brain damage, uncontrolled psychotic symptoms, suicidal ideation or suicidal or homicidal behaviors when starting treatment, is not considered eligible to participate in the study.
2. Being in a legal situation that involves the possibility of imprisonment or visits to an entity of the judicial system during the four months following admission to treatment
3. Women in the eighth month of pregnancy or past the eighth month, whose state of birth and /or postpartum period may interfere with their participation in the study
4. Requesting only detoxification treatment
5. Requesting opiate substitution treatment with methadone or buprenorphine
6. Having a couple, husband or significant other (e. g. family with those who share housing) who is participating in this research protocol

Date of first enrolment
16/04/2012

Date of final enrolment
01/04/2013

Locations

Countries of recruitment
Mexico

Study participating centre
Clz. México-Xochimilco #101
Mexico City
Mexico
14370

Sponsor information

Organisation
U.S. Department of State (USA)

Sponsor details
Navy Hill South
2430 E St. NW, Washington DC 20037
Washington DC
United States of America
20037

Sponsor type
Government

Website
http://www.state.gov

ROR
https://ror.org/02rcrvv70

Funder(s)

Funder type
Government

Funder Name
U.S. Department of State (USA) - Merida Initiative program, Grant No. SINLEC11GR0015

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2014		Yes	No