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Developing mental health mHealth programs for depression management in Bolivia

Submission date
07/09/2016

Recruitment status
No longer recruiting

Registration date
14/09/2016

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
Depression is one of the most common mental disorders worldwide. The symptoms of depression can vary greatly from person to person, but generally include low mood, problems with sleeping and/or eating, and a general loss of interest in life. Depression is very common in low- and middle-income countries but is often untreated due to a shortage of mental health care resources, including trained professionals. Mobile health tools (in which healthcare is delivered via a mobile phone) may help to expand the reach of mental health care in these settings. The aim of this study is to test the feasibility of a service that uses automated cell-phone calls to monitor patients' depressive symptoms and give brief self-care advice.

Who can participate?
Depressed adults who receive care from a clinic affiliated with Universidad Catolica Boliviana and El Servicio Departmental de Salud (SEDES) in La Paz/El Alto, Bolivia.

What does the study involve?
All participants receive up to 14 weeks of automated, interactive weekly telephone calls that assess current depressive symptoms (using a questionnaire) and provide brief educational messages about how to manage their condition. Each call lasts about 10-15 minutes. At the end of the 14 week study, the amount of calls participants took is noted and participant satisfaction is measured through a telephone interview.

What are the possible benefits and risks of participating?
Participants benefit from receiving recorded advice about depression management during calls, along with feedback about any changes in their depressive symptoms. There is a small risk that talking about mental health and other personal topics may distress some participants.

Where is the study run from?
Three hospitals in La Paz (Bolivia)

When is the study starting and how long is it expected to run for?
March 2014 to November 2015

Who is funding the study?
University of Michigan School of Public Health (USA)

Who is the main contact?
Dr John Piette
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HUM00087937

Study information

Scientific Title
A pilot study: developing mental health mHealth programs for depression management in Bolivia

Study objectives
Study aim:
The aim of this study is to assess the ability to recruit eligible patients, determine patients' rates of completing the automated assessment calls, and the potential for expanding this program throughout Bolivia and to other resource-poor settings.

Hypotheses:
1. At least 75% of eligible patients will enroll in the program
2. Enrollees will complete more than 80% of their automated assessment calls
3. Patients will report information consistently during those calls
4. Patients at follow-up will report high levels of system satisfaction

Ethics approval required

Old ethics approval format

Ethics approval(s)
The University of Michigan Institutional Review Board—Health Sciences and Behavioral Sciences has determined that this study is not regulated by the IRB (HUM00087937). In Bolivia, this study was reviewed by experts on mental health within the Ministry of Health (Ministerio de Salud y Deportes del Estado Plurinacional de Bolivia) and a letter of approval of the research plan was issued on 30/06/2014. A letter of approval from the Universidad Catolica Boliviana "San Pablo" was issued on 08/07/2014.

Study design
Multi-centre non-randomised interventional trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Depression

Interventions
Upon enrollment and after informed consent, baseline surveys are administered to participants to gather data on demographics, mental and physical health and treatments, health behaviors, social support, and health care use. During enrollment, the research team explains how to use the automated phone system. At the time of recruitment, when possible, an initial automated call is sent to the patient's phone so that they can learn what to expect and have the chance to ask questions of the research associate who will be present. Participants then receive up to 14 weeks of Interactive Voice Response calls. The automated calling system makes multiple attempts to reach patients at times they indicate are convenient, with the goal of achieving one completed call per week per patient. Each call lasts about 10-15 minutes. First, the system verifies the person's identity and assesses patients' depressive symptoms with the Personal Health Questionnaire (PHQ)-8. Patients are asked about their overall health and changes since the previous week in mental and physical health. Based on patients' touch-tone responses they receive feedback about changes in their depression symptom severity along with brief pre-recorded, tailored advice for self-management. Research staff monitor call completion and contact patients who fail to complete their first week's call. Alerts based on changes in symptoms are monitored by research staff and sent to patients' primary care teams. Follow-up surveys are administered following program completion, either in-person or over the telephone.

Intervention Type
Behavioural

Primary outcome(s)
1. Call completion rate is measured using the system-tracked number of completed weekly calls out of the total number of active call-weeks
2. Participant satisfaction with program is measured at 14 weeks using both open-ended (e.g., "What did you like best about your experience?" and close-ended (e.g, Likert-scale rating of overall satisfaction with program, likelihood of recommending it to a friend) items

Key secondary outcome(s))
Depressive symptoms are measured using the Personal Health Questionnaire (PHQ-8) at baseline and during each IVR call.

Completion date
30/11/2015

Eligibility

Key inclusion criteria
1. Adults (18+ years)
2. A Patient Health Questionnaire (PHQ) score of 10 or higher
3. Receive care from a clinic affiliated with Universidad Catolica Boliviana and El Servicio Departmental de Salud (SEDES) in La Paz/El Alto, Bolivia.
4. Access to a functional telephone
5. See their primary care doctor at participating clinics

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Life-threatening health problems, such as cancer, with less than a six-month life expectancy
2. Significant memory problems
3. Severe mental illness (bipolar disorder or schizophrenia)

Date of first enrolment
30/06/2014

Date of final enrolment
31/10/2014

Locations

Countries of recruitment
Bolivia

Study participating centre
Hospital de Clínicas
Saavedra Avenue # 2245
“Miraflores” Zone
La Paz
Bolivia
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Study participating centre
Hospital Boliviano Holandés
Satelite Avenue
Corner of “Diego de Portugal” Avenue
El Alto- La Paz
Bolivia
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Study participating centre
Hospital La Paz
Corner of “Max Paredes”
“Garita de Lima” Zone
La Paz
Bolivia
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Sponsor information

Organisation
University of Michigan School of Public Health

ROR
https://ror.org/00jmfr291

Funder(s)

Funder type
University/education

Funder Name
University of Michigan School of Public Health

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/09/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes