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An evaluation of the effectiveness of a psychological treatment for moderate to severe depression and harmful or dependent drinking in rural communities in Nepal

Submission date
20/01/2014

Recruitment status
No longer recruiting

Registration date
12/02/2014

Overall study status
Completed

Last Edited
16/06/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
We will carry out a study to assess the effect of having a community counsellor provide a psychosocial intervention for people with depression or alcohol problems. The goal of the study is to see whether adding a community counsellor to a mental health care package that is provided within primary health care results in better outcomes among patients.

Who can participate?
Men and women, aged 16 years and older, who attend health care centers in rural Nepal and have been diagnosed with depression or alcohol use disorder.

What does the study involve?
Participants will be randomly allocated to one of two groups: one group that receives treatment from trained health care workers (this may involve provision of medicine or psychosocial support), and a second group who receives the same treatment and additionally will be seeing a counsellor outside the health facility. The counsellor will provide psychotherapeutic support that aims to increase activation among depressed people and increase motivation to change among people who consume too much alcohol. Participants in both groups will be asked about their level of problems and reduction in daily functioning before the start of the treatment, and again after 3 and 12 months. Finally, we will compare both groups to see whether there are differences in improvement over time.

What are the possible benefits and risks of participating?
The participants to the study may see improvements in their depression or alcohol complaints after receiving treatment. Treatment in both groups may temporarily lead to increased levels of anxiety as part of the treatment process.

Where is the study run from?
All treatment in this study will be provided in or around primary health care centers in Chitwan

district in Nepal, India. All services are coordinated and supervised by TPO Nepal, a Nepali non-governmental organization, together with the Nepali Ministry of Health.

When is the study starting and how long is it expected to run for?
The study will start in May 2014 and will continue until January 2016.

Who is funding the study?
Department for International Development (DFID), UK.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Evaluating the effectiveness of community counsellor-delivered psychological treatment in reducing moderate to severe depression and harmful or dependent drinking compared to enhanced usual care in primary health facilities in Nepal: A pragmatic randomised controlled trial

Study objectives
The primary hypotheses are that the community counselling intervention in addition to enhanced usual care (EUC a Mental Health Care Package integrated in primary health care) will

be superior to EUC alone in reducing the severity of symptoms and in increasing remission rates in participants with depression and alcohol use disorder at 3 months post-enrolment.

The aim of the trial is to evaluate a psychological treatment, delivered by community counselors, for moderate or severe depression and for alcohol use disorder attached to primary care in Chitwan, Nepal. Specifically, the study aims to evaluate the impact of adding a community counselling component to a facility-based mental health care package.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nepal Health Research Council (NHRC), 18/05/2014, reg. no. 36/2014

Study design
Multi-centre single-blind pragmatic randomized controlled 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
Depression disorder, alcohol use disorder

Interventions
The study has the following two arms:
1. Enhanced Usual Care (EUC) (PRIME MHCP) = control arm
2. EUC + Psychological Treatment (PT) = treatment arm

Patients are individually randomized. The sample size calculations are based on an estimated 80% power, and a 10% loss to follow-up.

The psychological treatment (PT): The PT was developed in a systematic process which built upon the experiences of the investigators in adapting mental health interventions for use in under-resourced and socio-culturally diverse contexts. The key principles of this approach were to dismantle evidence-based PTs and combine them with strategies identified as being useful in the local context. Evidence-based PTs were identified based on the Mental Health Gap Action Programme (mhGAP) guidelines (WHO) for use in primary care. Contextually appropriate strategies were identified through a review of explanatory models, PT studies and qualitative

studies with persons with the target disorders, their care-givers and health care providers (including alternative and religious healers) about key outcomes and coping strategies. The strategies were collated and the list reduced by merging those that were similar. Strategies which were rated by local mental health providers and community health workers as being acceptable, safe and feasible for delivery in primary care were taken to the next stage of synthesis into a formal PT in intervention development workshops. The primary outcome at this stage was the identification of behavioural activation (BA) and Motivational Enhancement Therapy (MET) as the theoretical framework for the emerging PT for depression and alcohol use disorder, respectively. The next phase of treatment development involved the development and adaptation of PT manuals based on manuals available from other trials (e.g., a BA manual and a MET manual) and by testing the delivery of the PT to patients with the target disorders both by specialists and lay counsellors. The PT were finally subjected to a pilot study in which lay counsellors delivered the PT to patients in PHCs; modifications were made at this stage to enhance acceptability, feasibility and scalability, notably through the inclusion of home-based delivery where needed, extensive use of pictorial patient resource materials, encouraging the involvement of a significant other in the treatment and task-sharing the supervision of lay counsellors to peer-groups.

The resulting PT for depression is the Healthy Activity Program (HAP). HAP comprises of up to 8 sessions delivered in 3 flexible phases delivered over 2-3 months with each session lasting between 30 and 45 minutes. The core strategies of HAP are psycho-education, behavioural activation, problem solving, relaxation training, and communication strategies. The Counselling for Alcohol Problems (CAP) is delivered using a Motivational Interviewing style. CAP has three phases, and is delivered flexibly over 1-4 sessions (30 to 45 minutes each) over 6-8 weeks. The core strategies of CAP are detailed assessment, personalised feedback, evoking commitment to change and development of a change plan, drink refusal skills, managing drinking urges, management of emotions, problem solving skills and relapse prevention.

The manuals were translated into Nepali with some changes (contextualized) and over a period of 6 months a small group of counsellors was trained and supervised to deliver the treatments. The trainer received was trained by the group in India that developed the original manuals. Adaptations from the original were minor. Additional attention was paid to how both modules could be implemented by the same community counsellors.

Any participant receiving the maximum number of stipulated sessions of the PT or completing treatment goals in fewer sessions will be discharged. Participants receiving HAP who do not respond to the PT at the end of these sessions will receive a referral to psychiatric services. Any participants missing three consecutive scheduled sessions will be considered as a treatment drop out. However, participants who re-engage at any point during the trial will be offered the opportunity to continue from the last session.

Counsellors: The PT will be delivered by community counsellors who are members of the local community, are above 21 years of age, completed at least high school education and who do not have any professional mental health training, and have an expressed desire to help people with mental health problems. All community counsellors, before receiving the specific modules for depression and alcohol use disorder, had received a basic psychosocial counselling course (focused on generic counselling and problem solving skills) of 4-6 months (full time), provided by TPO Nepal (the implementing organization for this trial) and other organizations working in psychosocial area. This training course alternated skill-based classroom-based learning with supervised practice.

Trainee counsellors were recruited by placing advertisements in newspapers and through review of trainees that had successfully completed the 4-6 months basic training course. Trainees were selected based on their performance in a structured interview and role play.

Enhanced Usual Care (PRIME MHCP): Usual care in primary care for depression and alcohol use disorder in Nepal is, in effect, no care at all. This has been confirmed in the study setting during the pilot study. Within the program usual care is enhanced in the following ways:
1. Provision of the screening results to the health worker
2. Provision of a contextualized version of the mhGAP guidelines (WHO) for the target disorders to the health workers. This includes:
2.1. Pharmacological treatment when indicated, by trained health workers.
2.2. Basic psychosocial support (psycho-education and emotional support) by trained non-prescribing health workers.
2.3. Referral to formal mental health services when indicated.
3. Community sensitization programs targeting low mental health literacy and high levels of stigma.
This EUC represents the most intensive model of primary care for both target disorders which may be envisaged in the foreseeable future in Nepal. The care incorporates the treatment guidelines as recommended by the WHOs mhGAP, and is the most acceptable comparator arm ethically (i.e., knowing that true usual care is no care).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Depression symptoms, measured with the Patient Health Questionnaire; 9-item questionnaire assessment of depressive symptoms assessed on a scale of 0 to 3; measured at baseline, 3 months and 12 months.
2. Alcohol use disorder symptoms, measured with the Alcohol Use Disorders Identification Test; 10-item questionnaire with 3 questions on the amount and frequency of drinking, 3 questions on alcohol dependence, and 4 on problems caused by alcohol; measured at baseline, 3 months and 12 months.
3. Functional impairment, measured with the WHO Disability Assessment Scale; 12-item questionnaire for measuring functional impairment over the previous 30 days. In addition, two items assess number of days the person was unable to work in the previous 30 days; measured at baseline, 3 months and 12 months.

Secondary outcome measures
1. Alcohol consumption in past two weeks, using the Time Line Follow Back (TLFB), a calendar tool supplemented by memory aids to obtain retrospective estimates of daily drinking over a specified time period; measured at baseline, 3 and 12 months follow-up.
2. Cost of illness, using the Client Service Receipt Inventory (CSRI), a questionnaire to collect data on the utilisation and costs of health care and lost productivity (including that of care-givers); measured at baseline, 3 and 12 months follow-up.
3. Adverse consequences of alcohol consumption, using the Short Inventory of Problems (SIP), 15-item questionnaire which assesses physical, social, intrapersonal, impulsive, and interpersonal consequences of alcohol consumption; measured at baseline, 3 and 12 months follow-up.
4. Suicide plans and attempts, using the CIDI Suicidal Behaviours subscale, 8 items on suicide

attempts; measured at baseline, 3 and 12 months follow-up.
5. Perceived social support; mean total score, using the OSLO-3, 3-item social support scale; measured at baseline, 3 and 12 months follow-up.
6. Perceived stigma, using the Patient experience of stigma and discrimination (ISMI); 8-item scale on perceived stigma among mental health patients; measured at baseline, 3 and 12 months follow-up.

Overall study start date
01/05/2014

Completion date
01/01/2016

Eligibility

Key inclusion criteria
1. Primary health care attendees above the age of 16 years
2. Intending to reside at the same address in the catchment area of the health care facility for at least the forthcoming 12 months (to enable the research team to complete review assessments)
3. Screened positive for depression or alcohol use disorder.
3.1. The Patient Health Questionnaire (PHQ-9) is a 9-item questionnaire that will be used for the detection of depression.
3.2. The Alcohol Use Disorders Identification Test (AUDIT) is a 10-item screening questionnaire that will be used for the detection of alcohol use disorder.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
The estimated sample size is n = 426, with 213 respondents in each study arm

Total final enrolment
282

Key exclusion criteria
1. Pregnant women
2. Patients who need urgent medical attention (defined as needing emergency treatment and/or in-patient admission) or are unable to communicate clearly (for example due to a speech or hearing disability).

Date of first enrolment
01/05/2014

Date of final enrolment

01/01/2016

Locations

Countries of recruitment
Nepal

Netherlands

Study participating centre
Lizzy Ansinghstraat 163
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Sponsor information

Organisation
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Funder(s)

Funder type
Government

Funder Name
Department for International Development - HRPC10 Improving Mental Health Services in Low Income Countries (PRIME: http://www.prime.uct.ac.za/)

Alternative Name(s)
Department for International Development, UK, DFID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/08/2019	16/06/2020	Yes	No