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Program for effective mental health interventions in under-resourced health systems

Submission date
02/10/2013

Recruitment status
No longer recruiting

Registration date
07/10/2013

Overall study status
Completed

Last Edited
13/09/2017

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered

[X] Protocol

[X] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Depression accounts for the highest burden of disease of any mental disorder. Most patients with depression seek healthcare through their GP surgeries. The WHO recommends the use of psychoeducation for mild depression and antidepressant drugs or psychological treatments (PT) for moderate to severe depression. Antidepressants are useful only for a third to half of patients with depression. People do not adhere to this treatment, it has high relapse rates, and is not routinely available in GP surgeries. A major hurdle to the implementation of PT in GP practices of developing countries is the lack of skilled human resources. The aim of this study is to find out the effectiveness and cost-effectiveness of the Healthy Activity Program (HAP).

Who can participate?
Adults with moderate/severe depression

What does the study involve?
Participants with moderate to severe depression will be identified by screening. Eligible participants are randomly allocated to receive either enhanced usual care (EUC) or EUC plus HAP. The EUC comprises providing PHC doctors with the contextualised WHO guidelines and the results of the patient health questionnaire. Participants in the HAP group receive, in addition to EUC, an eight-session PT delivered by trained and supervised lay counsellors, over a maximum period of 3 months. This PT has been systematically developed based on evidence and includes psychoeducation, problem-solving, behavioural activation (BA) and relaxation training.

What are the possible benefits and risks of participating?
Participants receive the counselling sessions from a trained counsellor along with doctors treatment at no extra cost. If the study finds that adding counselling makes treatment more effective, this will help the researchers to work with the government to make counselling available in clinics across Goa and India. No risks are expected from taking part, apart from the fact that patients may find discussing their health and personal problems to be distressing. Patients are however assured that the counsellors and researchers have been trained to handle such situations and if required, services of other health experts will be made available.

Where is the study run from?
Eight primary health centres (PHCs) in the North district of Goa, India

When is study starting and how long is it expected to run for?
October 2013 to October 2015

Who is funding the study?
The Wellcome Trust (UK)

Who is the main contact?
Prof. Vikram Patel
vikram.patel@lshtm.ac.uk

Study website
http://www.sangath.com/details.php?nav_id=123

Contact information

Type(s)
Scientific

Contact name
Prof Vikram Patel

ORCID ID
http://orcid.org/0000-0003-1066-8584

Contact details
Faculty of Epidemiology and Population Health
Department of Population Health
Keppel Street
London
United Kingdom
WC1E 7HT
+91 (0)9822132038
vikram.patel@lshtm.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial of the effectiveness and cost-effectiveness of the Healthy Activity Program (HAP), a lay counsellor-delivered psychological treatment for moderate to severe depression in primary care in India

Acronym
PREMIUM

Study objectives
Primary hypotheses:
1. The HAP intervention in addition to enhanced usual care (EUC) will be superior to EUC alone in reducing the symptoms of depression.
2. The HAP intervention in addition to EUC will be superior to EUC alone in increasing remission rates, at 3 months post-enrolment.

Secondary hypotheses:
The HAP intervention in addition to EUC will be superior to EUC alone in the following respects:
1. Reducing depression scores and increasing remission rates at 12 months post enrolment
2. Reducing disability levels at 3 months and at 12 months post enrolment
3. Reducing costs of illness over 12 months (thus, being 'dominant' in economic terms)
4. Reducing suicidal behaviour over 12 months

The rationale for the 12-month review is to evaluate the longer-term impact of the intervention, in the context of the high relapse rates of depression, particularly in patients who receive only antidepressant medication.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Interventions Research Ethics Committee - London School of Hygiene and Tropical Medicine (6507)
2. Sangath Institutional Review Board - Sangath, India

Study design
Parallel-arm individually randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
General adult depression

Interventions
Patients are randomised to receive either HAP or EUC.

The Health Activity Program (HAP):
The psychological treatment was named the Healthy Activity Program and consisted of up to eight sessions in three flexible phases delivered over 2-3 months with each session lasting between 30 and 45 minutes. Any patient receiving eight sessions of HAP or achieving a prior clinical recovery criteria will be considered to have completed the treatment. Patients who do not respond to HAP at the end of eight sessions will receive a referral to psychiatric services. Any patient missing two consecutive scheduled sessions will be considered as a treatment drop out. However, patients who re-engage at any point during the trial will be offered the opportunity to continue from the last session.

HAP will be delivered by lay counsellors who are members of the local community, are above 18 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. Trainee counsellors were recruited by placing advertisements in newspapers and through word of mouth. Trainees were selected based on their performance in a structured interview and role play. Post selection, the trainees underwent a three-week participatory workshop (which also covered the drinking problems treatment). Trainees who met competency standards (based on role play and multiple choice questions) progressed to the pilot study. Training was conducted by mental health professionals who were closely involved in the development of HAP. During the pilot study the trainee counsellors delivered HAP to eligible patients in PHCs. Supervision was carried out both in individual and weekly group format. Therapy quality was assessed mainly through rating of audio-taped sessions using a specially developed scale, the Quality of HAP (Q-HAP), adapted from the Counselling Skills Scale (CSS) and Quality of Behavioural Activation Scale (Q-BAS), which itself is modelled after the 'cognitive therapy scale' and modified to apply to the strategies used in BA. As the trainee counsellors gained experience in delivering the intervention the supervision format evolved from expert-led (i.e. local mental health professionals skilled in the delivery of HAP) to peer-led group supervision. Only trainees who achieved competence, as assessed by standardised role plays and therapy quality assessments, have been selected to deliver HAP in the trial. Each PHC will have one counsellor, with a pool of back-up counsellors in the event of attrition (for e.g. due to counsellors leaving for other opportunities).

Enhanced Usual Care:
Usual care for depressive disorders in India is, in effect, no care at all. This has been confirmed in the study setting during the pilot study. This is primarily because most cases are not diagnosed and, amongst those who are, most do not receive either antidepressants or psychological treatments. In PREMIUM, usual care is enhanced in the following ways:
1. Provision of the screening results for depression to the primary care physician
2. Provision of a contextualized version of the mhGAP guidelines for depression to the primary care physician, including explicit guidelines on when and where to refer patients for psychiatric care.

Intervention Type
Behavioural

Primary outcome measure
1. Mean difference in total score measured by the Beck's Depression Inventory (BDI-II), at 3 months , a 21-item questionnaire assessment of depressive symptoms; each item is scored on a Likert scale of f 0 to 3. It measures depression severity based on symptom scores
2. Remission, defined as a score of <10 measured at 3 months by the Patient Health Questionnaire (PHQ-9), a nine-item questionnaire for the detection and diagnosis of depression based on DSM-IV criteria. It is scored on a scale of 0 to 3 based on frequency of symptoms

Secondary outcome measures
1. Mean difference in total score measured by the Beck's Depression Inventory (BDI-II) at 12 months
2. Remission defined as a score of <10 on the Patient Health Questionnaire (PHQ-9) at 12 months
3. Mean difference in disability score measured by the World Health Organisation Disability Assessment Schedule (WHODAS) at 3 and 12 months, a 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
4. Costs of illness (direct and indirect) measured by the Client Service Receipt Inventory at 3 and 12 months, a questionnaire to collect data on the utilisation and costs of health care and lost productivity (including that of care-givers)
5. Suicidal thoughts or attempts: assessed with item 9 of the PHQ-9 and with an additional question on suicide attempts at 12 months, based on interviews used to assess suicidal behaviour in earlier studies in Goa
6. Experience of intimate partner violence at 3 and 12 months, based on questions used in an earlier study of women's mental health in Goa
7. Level of activation based on an adapted version of the Behavioural Activation for Depression Scale- short form (BADS-SF) assessed within the last week at 3 and 12 months
8. Other secondary outcomes: change in marital status, employment status, based on a sociodemographic questionnaire at 3 and 12 months

Overall study start date
28/10/2013

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. Must be above the age of 18 but below the age of 65
2. Must reside within the geographic area which is selected for the PHC
3. Must plan to stay at the same address for at least 12 months
4. Must be able to speak one of the following languages: Konkani/Hindi/Marathi/English
5. Must not have been screened in the previous 3 months

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
450

Key exclusion criteria
1. Pregnant women
2. Patients with drinking problems (as the guidelines require such patients to be treated first for drinking problems and this will be handled in a companion trial)
3. Patients who need urgent medical attention (defined as needing emergency treatment and/or in-patient admission)
4. Patients unable to communicate clearly (for example due to a speech or hearing disability)
5. In receipt of PREMIUM counselling treatment

Added 26/05/2015:
6. Patient lives together in the same household with previously recruited patient or is in regular contact with previously recruited patient(s)

Date of first enrolment
28/10/2013

Date of final enrolment
31/07/2015

Locations

Countries of recruitment
India

Study participating centre
8 primary healthcare clinics in north Goa
India
-

Sponsor information

Organisation
London School of Hygiene and Tropical Medicine (UK)

Sponsor details
Keppel Street
London
England
United Kingdom
WC1E 7HT
+44 (0)20 7636 8636
michael.robinson@lshtm.ac.uk

Sponsor type
University/education

Website
http://www.lshtm.ac.uk

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust (UK) Grant Ref no: 091834/Z/10/Z

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
A multi-modal dissemination plan is envisaged. This will seek to share findings in different formats with a wide constituency of user communities. These strategies will mainly include scientific publications and policy briefs. The scientific publications will be in open-access format, and the main report of the trials is scheduled to be submitted six months after data collection is complete and the database is cleaned and locked. Dissemination strategies will also include

compilation of treatment manuals which are already available and accessible on the website (see http://sangath.com/manuals.php), workshops with health officials/staff from the Primary Health Care clinics and Health Directorate of Goa, and community meetings.

Intention to publish date
30/09/2017

Individual participant data (IPD) sharing plan
The dataset contains redacted participant level records of adult male/female PHC attendees (one patient per row) recruited in the trials site between 28/10/2013 and 30/07/2015, and followed-up for outcome assessments till 01/09/2016. The datasets encompass: enrolment, treatment process (including therapy quality), and outcome data.

Repository name:
1. London School of Hygiene and Tropical Medicine (LSHTM) Data Compass
2. Sangath project data folder (intranet)

Persistent weblink: http://datacompass.lshtm.ac.uk

In compliance with the Wellcome Trust policy on data management and sharing, and the access options supported at the London School of Hygiene and Tropical Medicine, managed access at the level of 'restricted' will be used, backed by a licence based on 'open data commons' model. This means anyone can freely access, use, modify, and share for any purpose (subject, at most, to requirements that preserve provenance and openness), but requests for data access will have to be made through completing a formal request form to the principal investigator - Professor Vikram Patel (vikram.patel@lshtm.ac.uk).

The curated raw trial data, in addition to the variable codebook will be deposited in the named repository by 31/12/2017, and will remain available to the public for the next 10 years.

Informed consent was obtained from participants. Participants were made to understand that the data collected will be used for only research purposes and persons not directly involved in the study will not have access to the data in order to uphold confidentiality. Participants were also assured that all identifying information will be removed when publishing findings of the study.

Data will be redacted to ensure both direct and indirect identifiers are not shared.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	02/04/2014		Yes	No
Results article	results	14/01/2017		Yes	No
Statistical Analysis Plan	Statistical analysis plan for -month outcomes:	12/03/2017		No	No
Results article	12-month follow-up results	12/09/2017		Yes	No