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

Submission date 04/10/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [X] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/10/2013	**Overall study status** Completed	
Last Edited 13/09/2017	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Alcohol Use Disorders (AUD) are the leading cause of the global burden of mental disorders affecting men. Most patients with AUD seek their GP's help. The WHO recommends the use of Brief Interventions (BI) for harmful drinking (HD) and psychosocial treatment methods in combination with drugs for alcohol dependence syndrome (ADS). A major barrier to the implementation of these methods in 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 Counselling for Alcohol Problems (CAP), a psychological treatment for HD and ADS.

Who can participate?
Men with HD and ADS

What does the study involve?
Participants are randomly allocated to receive enhanced usual care (EUC) or EUC plus CAP. The EUC comprises of providing doctors with the WHO guidelines, contextualised for the study setting, and the screening result for ADS. The EUC also includes referral to psychiatric services for detoxification. Participants in the CAP group receive, in addition to EUC, up to four sessions of the psychological treatment delivered by trained and supervised lay counsellors over a maximum period of two months. This has been systematically developed to incorporate strategies based on global and contextual evidence.

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 are made available.

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

When is the study starting and how long is it expected to run for?
October 2013 to September 2016

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A randomised controlled trial of the effectiveness and cost effectiveness of Counselling for Alcohol Problems (CAP), a lay counsellor-delivered psychological treatment for harmful and dependent drinking in primary care in India

Acronym
PREMIUM

Study objectives
Primary hypotheses:
The CAP intervention in combination with enhanced usual care (EUC) will be superior to EUC

alone in:
1. Reducing alcohol consumption
2. Increasing remission rates
3. Reducing the physical, social, intrapersonal, impulsive and interpersonal consequences of alcohol in men with harmful drinking (HD) at 3 months after recruitment

The secondary hypotheses:
The CAP intervention in combination with EUC will be superior to EUC alone in men with both HD and alcohol dependence syndrome (ADS) in the following respects:
2. Reducing alcohol consumption, reducing the physical, social, intrapersonal, impulsive and interpersonal consequences of alcohol and increasing remission rates at 12 months
3. Reducing depressive caseness, severity of depressive symptoms and suicidal behaviour at 3 and 12 months
4. Reducing disability levels at 3 and 12 months
5. Reducing costs of illness over 12 months (thus, being 'dominant' in economic terms)

The CAP intervention in combination with EUC will be superior to EUC alone in men with ADS in the following respects:
1. Reducing alcohol consumption, reducing the physical, social, intrapersonal, impulsive and interpersonal consequences of alcohol, and increasing remission rates at 3 months
2. Increasing uptake of detoxification services at 3 and 12 months

Ethics approval required
Old ethics approval format

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

Study design
Parallel-arm individually randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
1. Harmful drinking
2. Alcohol dependence syndrome

Interventions
Patients are randomised to receive either CAP or EUC.

1. Counselling for Alcohol Problems (CAP):
CAP 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 areas. 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 mhGAP guidelines for use in primary care e.g.

Motivational Interviewing (MI). Contextually appropriate strategies were identified through a review of explanatory models and PT studies; and qualitative studies with men with AUD, 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 by lay counsellors 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 MI as the theoretical framework for the emerging PT.
The next phase of treatment development involved the adaptation of a manual for Motivational Enhancement Therapy (MET), in two key ways: adding or emphasizing contextually appropriate strategies (e.g. problem solving, managing difficult emotions) and modifying techniques to enhance their acceptability and feasibility. This process was done by testing the delivery of the PT to patients with harmful drinking both by specialists and lay counsellors. The resulting PT, 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. In Phase 1 of CAP the patient is helped to understand whether his drinking may be causing problems and may need to change. This is done through detailed assessment, personalised feedback, commitment to change and development of a change plan. In Phase 2 the patient is helped to make those changes using strategies like drink refusal skills, management of emotions and problem-solving skills. In Phase 3 the patient is helped to plan dealing with any potential or actual lapses or relapses. CAP has an inbuilt flexibility which allows the counsellor to tailor the treatment based on the patients needs and the stage of change. Based on these two criteria the patient may get a minimum of one, an optimal two and a maximum of four sessions. Any patient receiving four sessions of CAP or completing treatment in fewer sessions will be discharged. In addition to CAP, patients with ADS will also receive a referral to specialist (psychiatric) services. Patients with both AUD and depressive disorder will be first treated with CAP. On completion of the treatment they will be rescreened with PHQ9 and if they continue to have a score of 10 or above (moderate to severe depression) they 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.

Counsellors:
CAP 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 development of CAP. During the pilot study the trainee counsellors delivered CAP 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 CAP (Q-CAP), adapted from the MITS (Motivational Interviewing Target Scheme) and the Counselling Skills Scale (CSS). 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 CAP) 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 CAP 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).

Supervision:
Supervision during the trial will be primarily in a peer-led group format. The supervision groups will be held once a week in the field office or a PHC. Supervision will primarily comprise two types of activities: first, assessment of the quality of audio-recorded sessions using the Q-CAP and provision of feedback; and second, discussion of any other difficult cases. If there are any treatment-related issues that cannot be resolved in the peer group these will then be discussed with experts. In addition, individual supervision will take place once a month on-site (i.e. at the respective PHC) by an expert who will review individual patient progress and quality of documentation, assess any patient safety issues, and address any site or counsellor-specific practical difficulties or concerns.

2. Enhanced Usual Care:
Usual care for HD 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 MI. In PREMIUM, usual care will be substantially enhanced in two specific ways:
1. Providing the primary care physician the findings of the screening results for AUD; and
2. Providing a contextualized version of the mhGAP guidelines for HD and ADS, including explicit guidelines on when and where to refer patients with ADS for psychiatric care.
This EUC represents the most intensive model of primary care for AUD which may be envisaged in the foreseeable future in India or other LMIC, is the one which is recommended by the WHO, and is the most acceptable comparator arm ethically (i.e. knowing that true usual care is no care).

Intervention Type
Behavioural

Primary outcome(s)
1. Mean alcohol (gms) consumed in one week, measured 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.
2. Alcohol Use Disorder severity score and remission measured as mean AUDIT score and an AUDIT score of <8, respectively. The AUDIT is a 10-item questionnaire with three questions on the amount and frequency of drinking, three questions on alcohol dependence, and four on problems caused by alcohol.
3. Physical, social, intrapersonal, impulsive and interpersonal consequences of alcohol measured as mean score on the Short Inventory of Problems (SIP), a 15-item questionnaire which assesses physical, social, intrapersonal, impulsive and interpersonal consequences of alcohol and drug consumption. Respondents indicate whether each item occurred in the previous 3 months and how frequently it occurred on a 3-point Likert scale.

Key secondary outcome(s))
1. Mean alcohol (gms) consumed in one week, measured using the Time Line Follow Back (TLFB), at 12 months post randomisation.
2. Alcohol Use Disorder severity score and remission measured as mean AUDIT score and an AUDIT score of <8 respectively, at 12 months post randomisation.
3. Physical, social, intrapersonal, impulsive and interpersonal consequences of alcohol measured as mean score on the Short Inventory of Problems (SIP), at 12 months post randomisation.
4. Mean difference in disability score and total disability days, measured at 3 and 12 months post

randomisation, using the World Health Organisation Disability Assessment Schedule (WHODAS), 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.
5. Costs of illness (direct and indirect) and health service utilisation, measured at 12 months post randomisation, 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).
6. Uptake of detoxification services, measured at 3 and 12 months post randomisation, using an additional item on the CSRI.
7. Presence of depression and depression severity score, measured at 3 and 12 months post randomisation, using the Primary Health Questionnaire-9 (PHQ-9), a 9-item questionnaire which scores each of the DSM-IV criteria for depression on a scale of 0 to 3 based on how frequently they occur.
8. Suicidal thoughts or attempts, measured at 3 and 12 months post randomisation, assessed with item 9 of the PHQ-9 and with an additional question on suicide attempts, based on interviews used to assess suicidal behaviour in earlier studies in Goa.
9. Perpetration of intimate partner violence, measured at 3 and 12 months post randomisation, based on questions used in an earlier community survey of alcohol use in Goa.
10. Other secondary outcomes measured at 3 and 12 months post randomisation: change in marital status, employment status, based on a sociodemographic questionnaire.

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 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 for HD and ADS in the past 3 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Key exclusion criteria

1. Patients who need urgent medical attention (defined as needing emergency treatment and/or in-patient admission)
2. Patients unable to communicate clearly (for example due to a speech or hearing disability)
3. Patients already receiving the PREMIUM counselling treatment

Added 26/05/2015:
4. 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)

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust (UK) Ref: 091834/Z/10/Z

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

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?
Results article	results	14/01/2017		Yes	No

Results article	12-month follow-up results	12/09/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan	Statistical analysis plan for -month outcomes:	12/03/2017		No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes