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A collaborative care psychosocial intervention for lowering blood pressure among old adults with hypertension and depression in primary care in Guarulhos, Brazil: the PROACTIVE-H study

Submission date 30/04/2019	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 03/05/2019	**Overall study status** Stopped	
Last Edited 10/08/2022	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims

Brazil and other low and middle-income countries (LMIC) are experiencing a rapid growth of their ageing population. Hypertension and depression are common among older adults in Brazil, especially among the poor and less educated. In 2015, high systolic blood pressure (SBP) was the second leading modifiable risk factor (mostly for cardiovascular disease - CVD) for disability adjusted life years (DAYLs), whereas between 2005 and 2015 depression ranked second among the top 10 health problems that cause most years living with disability (YLDs) in Brazil. Furthermore, CVD can lead to depression and vice-versa, and individuals with depression die earlier than their age-matched counterparts, mostly due to CVD. One of the plausible reason for premature CVD mortality is the role of depression on poor adherence to treatment and unhealthy lifestyles. Health care services in most LMIC are badly prepared to meet the challenges associated with the health problems associated with population ageing. Therefore, simple, feasible and cost-effective solutions to improve the treatment of hypertension among older adults with depression, tailored to the existing primary care system, are urgently needed in Brazil. Given the lack of evidenced based solutions for poor control of blood pressure (BP) in primary care in Brazil, and the complexity of the barriers for improving the control of BP among older adults with depression, we are proposing to conduct a randomised controlled trial (RCT). We are going to test a complex intervention program, with multi-components, designed to overcome some of the barriers related to patients and the health system for the treatment of people with depression and hypertension in primary care in Brazil.

Who can participate?

Individuals aged 60 and older who are experiencing depression and high blood pressure will be invited through Family Health Units (FHUs).

What does the study involve?
Participants will be randomly placed into psychosocial intervention (intervention group) or enhanced usual care (control group). The intervention will be delivered over 17 weeks by a Community Health Worker (CHW) liaising with Family Health Teams (FHTs). We will assess participants over a period of 12 months.

What are the possible benefits and risks of participating?
Benefits of participating will be the identification of depression and hypertension situation and the report to the Family Health Unit (FHU) managers. From this point, the Family Health Teams (FHTs) will manage these participants with depression and hypertension according to usual practice. In the intervention arm, the participants will also receive the psychosocial intervention. We do not think that this trial poses any considerable risks to trial participants, as none of the components to be tested are considered harmful.

Where is the study run from?
Secretaria da Saúde de Guarulhos, Brasil.

When is the study starting and how long is it expected to run for?
May 2019 to February 2020

Who is funding the study?
1. Fundação de Amparo à Pesquisa do Estado de São Paulo (São Paulo Research Foundation), Brasil.
2. Harvard T.H. Chan School of Public Health, USA.
3. Medical Research Council, UK.

Who is the main contact?
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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MRC: MR/R006229/1; FAPESP: 17/50094-2; Harvard T. H. Chan School of Public Health (Agreement BLSCHP-1704).

Study information

Scientific Title
A collaborative care psychosocial intervention for lowering blood pressure among old adults with hypertension and depression within the Family Health Strategy in Guarulhos, Brazil: the PROACTIVE-H cluster randomised controlled trial

Acronym
PROACTIVE-H

Study objectives
The main objective of this study is to test whether a complex intervention program will improve the control of blood pressure (BP) among older adults with comorbid hypertension and depression registered with the Family Health Strategy (FHS) in Guarulhos, Brazil. We hypothesize that the intervention arm could decrease at least 7 mmHg in mean systolic blood pressure (SBP) compared to the control arm.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/08/2018, Ethics Committee of the Faculty of Medicine of the University of Sao Paulo (Av. Dr. Arnaldo, 715 - Cerqueira César, São Paulo - SP, 01246-904, Brazil; +55 11 3893 4401; cep.fm@usp.br), ref: 2.836.569

Study design
Two-arm cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Screening

Participant information sheet
Not available in internet format, please use contact details to request a participation information sheet.

Health condition(s) or problem(s) studied
Hypertension and depression in older adults.

Interventions
The study is a two-arm, cluster randomised controlled trial with Family Health Unit as the clusters and a 1:1 allocation ratio. This trial will be conducted in the city of Guarulhos, situated in the metropolitan region of São Paulo city, Brazil. Participants will be recruited from Family Health Units (FHU) which are primary healthcare units, where the Family Health Teams (FHT) provide healthcare assistance to the registered population. In this study, we will recruit 20 Family Health Units (FHU) with at least four FHT. Within each of these 20 FHU, four FHT will be randomly sampled, making a total of 80 FHT participating in our study. We will also recruit an additional 4 FHU as reserve, which will include a total of 16 FHU randomly sampled. For stratification, we will use the educational level information (percentage of individuals with no education or who had completed a literacy program for adults) collected through the electronic database (eSUS) of the 60 years or older individuals registered with each selected FHUs. Stratification will be into two sets of FHU (according to whether they are above or below the median on this educational variable). Thus, ten FHU will be allocated in each arm (five from each stratum).

We aim to recruit 880 individuals 60 years or older registered with the selected FHTs. A list with all names and contact information of the individuals aged 59 years or over for each randomly selected FHT will be provided by the primary care administration of Guarulhos. Each participant will receive a random number when entering into the PROACTIVE database. Thus, a new list will be defined and the independent research assistant (RA) will contact the individuals according to this new order.

Complete blinding of participants to trial allocation is impossible given the nature of this intervention. To decrease the risk of observer bias at follow-up, the two assessments will be made by RAs who are not involved in the initial recruitment or in delivering the intervention. We will rotate these RAs so that unless it is unavoidable the same researcher does not conduct any interview with the same participant more than once. We will also ensure that the data analysis is completed blind to trial allocation (i.e. unblinding will occur only after the analysis of endpoints has been completed). This study is nested in the “A collaborative care psychosocial intervention to improve late life depression according to PHQ-9 in depressed elderly people living in socioeconomically deprived areas of Guarulhos, Brazil: the PROACTIVE cluster randomised controlled trial.” (ISRCTN registry - ISRCTN57805470)

Interventions will include a psychosocial intervention (intervention group) and enhanced usual care (control group).

“Enhanced” usual care
This comprises improved recognition of depression by the research team (screening with the PHQ-9 to identify depression) and usual care. Soon after participants are included in the study,

the research group will send information about participants' levels of depression (based on PHQ-9) to the FHUs participating in the control and in the intervention arms. The research team will not interfere with usual care (care continues as usual in both arms of the study), such as, prescription of medications, CHW usual monthly home visits, or access to family doctors or specialists.

Psychosocial intervention

The psychosocial intervention was designed to provide care to depressed older adults registered with FHUs within the Family Health Strategy (FHS) framework in Brazil. The intervention is planned to last 17 weeks. Core principles of the intervention are task shifting, collaborative care and stepped care.

• Task shifting: the FHT's CHWs visit homes regularly, are involved in the care of chronic conditions, and for this reason they have been chosen to deliver the psychosocial intervention;
• Collaborative care: the CHW will work collaboratively with all other members from their FHT to deliver the intervention;
• Stepped care: the intensity of care management is tailored according to needs. Those who need more receive more and vice versa.

The FHT will decide if the participant needs further support. The participant will continue receiving the psychosocial intervention in situations where he/she is referred to see the family doctor or mental health specialist.

The intervention is based on:
(a) measurement-based care – depression symptoms are measured in all home sessions with the use of the PHQ-9;
(b) psychoeducation – education about depression, relapse prevention strategies, and simple ways to cope with depression symptoms and associated problems;
(c) behavioural activation technique – educate about the importance of engaging in pleasant activities thus increasing positive interactions with their environment;
(d) use of technology – the CHWs will deliver the intervention with the support of an application installed on tablets.

The intervention is divided into Initial (3 weeks) and Second (14 weeks) phases. All participants complete the Initial phase, which includes three weekly home meetings. The goal of the programme's initial phase is to start psychoeducation, i.e. what are the main symptoms of depression, how participants can deal with their problems associated with depression, and develop, along with the participant, simple strategies to cope with these problems that deal with depression symptoms that can help them to feel better. During the Second phase, participants can have access to either low or high intensity regimens. If the participant improves after the Initial phase (PHQ-9<10 in both Session 2 and 3), then she/he will proceed to the Second phase and receive a low intensity treatment regimen. If the participant shows improvement (PHQ-9<10 in Session 2 and Session 3) she/he will proceed to low-intensity regime which includes five additional meetings (3 every other week and 2 monthly). If the participant did not show improvement (PHQ-9≥10 in Session 2 and/or Session 3) she/he will proceed to the high-intensity regime which includes eight additional meetings (6 weekly and 2 monthly).
The intervention therefore lasts for 17 weeks in total, regardless of the regime. However, this period can be extended up to 22 weeks, if needed. The goal of the programme's Second phase is to teach participants behavioural activation and relapse prevention techniques, i.e. how participants can identify that symptoms are coming back. The choice of behavioural activation was due to the demonstrated feasibility and efficacy of this technique for the treatment of depression. It is a simple technique to apply and requires a short period of professional training.

Before the intervention starts in each FHU, the 12 CHWs participating in the study will receive training to conduct the intervention. Training will be conducted at the FHU, by a clinical supervisor and an information technology specialist, during three group sessions of six hours each. During the period of the intervention, the CHWs will also receive group supervision at the FHU by a hired psychologist. The maximum number of CHWs in each group supervision will be six. Initially the supervision will be weekly, and then fortnightly or less frequently depending on the need of CHWs.

Intervention Type
Behavioural

Primary outcome measure
Difference in systolic blood pressure (SBP), measured using sphygmomanometer, between the two study arms eight months after baseline assessment.

Secondary outcome measures
1. The maintenance of any earlier clinical gains regarding the SBP (proportion of participants that maintain the lower SBP) at 12 months.
The following additional secondary measures will be completed at 8 and 12 months and compared between the two arms:
2. European Quality of Life five-dimensional questionnaire, Five-level version (EQ-5D-5L)
3. ICEpop CAPability measure for Older people (ICECAP-O)
4. Behavioural Activation for Depression Scale (BADS)
5. Stressful life events (SLE); General Anxiety Disorder-7 (GAD-7)
6. Lubben Social Network Scale-6 (LSNS-6)
7. Alcohol Use Disorders Identification Test-Consumption (AUDIT-C)
8. Loneliness Scale (3-item UCLA)
9. We will assess the cost-effectiveness of the intervention at 12 months.

Overall study start date
01/06/2018

Completion date
31/05/2020

Reason abandoned (if study stopped)
Unfortunately, it was not possible to collect data in the homes of older adult participants due to the COVID-19 pandemic.

Eligibility

Key inclusion criteria
1. Individuals 60 years or older registered with the selected FHTs
2. 9-item Patient Health Questionnaire (PHQ-9) score 10 or above (threshold for depression)
3. Systolic blood pressure (SBP)≥140mmHg or diastolic blood pressure (DBP) ≥ 90 mmHg will be eligible for inclusion in the study.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
880 participants

Key exclusion criteria
1. Partner or another person that lives in the same household has already been included in the study
2. Acute suicidal risk in response to the PHQ-9 and the additional suicidal risk questionnaire
3. Completely deaf
4. Unable to communicate (non-native speaker, cognitive impairment and psychotic symptoms)
5. Unable to engage in the trial for the period of 12 months (terminal illness, partner with terminal illness, plans to move out to another area)

Date of first enrolment
06/05/2019

Date of final enrolment
28/02/2020

Locations

Countries of recruitment
Brazil

Study participating centre
Secretaria de Saúde de Guarulhos
Rua Íris 300
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Sponsor information

Organisation
Faculdade de Medicina da Universidade de São Paulo

Sponsor details
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Sponsor type
University/education

Website
http://www.fm.usp.br/cpesq/portal/

ROR
https://ror.org/03se9eg94

Funder(s)

Funder type
Research organisation

Funder Name
Fundação de Amparo à Pesquisa do Estado de São Paulo

Alternative Name(s)
São Paulo Research Foundation, State of São Paulo Research Foundation, Foundation for Research Support of the State of São Paulo, FAPESP

Funding Body Type
Private sector organisation

Funding Body Subtype
Local government

Location
Brazil

Funder Name
Harvard T.H. Chan School of Public Health

Alternative Name(s)
Harvard Chan, Harvard Chan School, Harvard Chan Public Health, HSPH

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United States of America

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We aim to publish at least three papers related to this study: the RCT protocol paper; two/three papers reporting data analysis and main findings.

Intention to publish date
30/11/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request