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A collaborative care psychosocial intervention to improve late life depression in socioeconomically deprived areas of Guarulhos, Brazil: the PROACTIVE Study

Submission date
24/04/2019

Recruitment status
No longer recruiting

Registration date
25/04/2019

Overall study status
Completed

Last Edited
25/11/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
Depression is a common chronic condition in older adults and is a leading cause of disability. Brazil is facing a rapid growth of its ageing population as most low-middle-income countries (LMIC) are. Health care systems in LMIC are badly prepared to meet the mental health challenges associated with these population changes, with late life depression being often unrecognized and left untreated. Effective treatments for late life depression have used collaborative, stepped-care models developed in high-income countries. However, generalizing from evidence gathered in high-income countries to LMIC is problematic given socio-cultural and health system differences. The aim of this study is to evaluate the effectiveness and cost-effectiveness of a psychosocial intervention developed to improve well-being and reduce depression in older adults living in Guarulhos, Brazil.

Who can participate?
Individuals aged 60 and older who are experiencing depression will be invited through Family Health Units (FHUs) which are primary care units.

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?
As we are going to deliver a psychosocial intervention designed to reduce symptoms of depression and therefore to improve people's mental health and well-being, participants might strongly benefit from taking part in this study. This intervention is expected to improve

participants' general well being and mental health. Additionally, participants may also benefit from being assessed for mental health problems (depression and anxiety) which may raise awareness of their mental health needs, i.e. their need to receive appropriate treatment.

The main risks to the participant are related to the questions we are going to ask on their mental health, particularly to assess their symptoms of depression, anxiety, and whether they have been suicidal. In the course of these assessments, participants might experience some distress related to the content of the questionnaires/interviews. The psychosocial intervention we want to undertake with participants will also tackle sources of emotional distress in our participants. However, because the intervention is designed to reduce the symtpoms of depression and improve mental health/well-being, we anticipate that such risk will be minimal.

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. Medical Research Council, UK.
2. Fundação de Amparo à Pesquisa do Estado de São Paulo (São Paulo Research Foundation), Brasil.

Who is the main contact?
Dr Marcia Scazufca, scazufca@usp.br

Contact information

Type(s)
Public

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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

Study information

Scientific Title
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.

Acronym
PROACTIVE

Study objectives
This study aims to evaluate the effectiveness and cost-effectiveness of a psychosocial intervention to improve the clinical management of depression among elderly people in poor neighbourhoods in Guarulhos, Brazil. We hypothesize that we will detect a 15 percent point difference (25% to 40%) in recovery between the control and intervention groups at 8 months after inclusion in the study, based on the PHQ-9 scores.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. 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
2. Approval pending King's College London Ethics Committee.

Study design
Interventional 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
https://drive.google.com/open?id=1rqxfeGkzHuvu8343ui8HgkEBGUrk69De

Health condition(s) or problem(s) studied
Depression in older adults.

Interventions
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 family health units (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, community health worker (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 the 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. A standard operating procedure (SOP) was developed for planning, managing and conducting the intervention.

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 1,440 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. Only those aged at least 60 years and with a 9-item Patient Health Questionnaire (PHQ-9) score of 10 or above, a threshold for depression, will be included in the study.
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).

Intervention Type
Behavioural

Primary outcome measure
Proportion of depression recovery (PHQ-9<10) at 8 months follow-up in the intervention compared to the control group.

Secondary outcome measures
1. Proportion with depression recovery (PHQ-9<10) at 12 months will assess the maintenance of any earlier clinical gains.
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
31/05/2022

Eligibility

Key inclusion criteria
1. Individuals 60 years or older registered with the selected FHTs will be screened following a randomly ordered list of names
2. Only those with a 9-item Patient Health Questionnaire (PHQ-9) score 10 or above, a threshold for depression, will be eligible for inclusion in the study

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
1440

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
30/09/2020

Locations

Countries of recruitment
Brazil

Study participating centre
Secretaria da Saúde de Guarulhos
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Sponsor information

Organisation
Universidade de Sao Paulo

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Sponsor type
University/education

ROR

https://ror.org/036rp1748

Funder(s)

Funder type
Government

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

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/11/2020	09/11/2020	Yes	No
Results article	Primary outcome data	03/10/2022	25/11/2022	Yes	No