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PST4PPD: Problem Solving Therapy for Postpartum Depression, a home visit intervention for low-income Latina mothers

Submission date
20/02/2020

Recruitment status
No longer recruiting

Registration date
02/03/2020

Overall study status
Completed

Last Edited
06/03/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Postpartum depression (PPD) is a type of depression that many parents experience after having a baby. Latina immigrants who experience isolation, language barriers and limited health care access have been identified to be at a higher risk of developing PPD. This study aims to provide an effective program to reduce PPD in this community.

The study used community health workers (CHWs) to carry out home visits to low-income Latina mothers with mild to moderate postpartum depression in the hope of reducing this depression and improving their self-belief in caring for their infant. The home visit program was designed to solely focus on mothers' mental health by teaching techniques of PST and coaching through a 7-step process in problem definition and action. In a previous pilot, PST has been shown to be an effective, affordable and accessible treatment for postpartum depression, and might be relevant for low-income, culturally diverse mothers.

The aim of the study is to provide evidence that the home visit intervention will decrease postpartum depression and increase the self-belief in parenting ability among low-income Latina mothers.

Who can participate?
Latina mothers up to 12 months postpartum

What does the study involve?
The study will involve a Community Health Worker (CHW) visiting participants in their home for an hour-long session, once-a-week for five weeks. During these sessions, the CHW will deliver Problem Solving Therapy (PST) where participants will be asked to identify an issue causing them stress to work on each week. Together with the CHW, participants will work out how to manage this problem. They will also be given a workbook that explains how thoughts affect how people approach problems. Participants will also be asked to answer a number of questions about depression symptoms and beliefs about their parenting ability at the start and the end of this program.

What are the possible benefits and risks of participating?
Direct risks & discomforts
There is always a possibility of feeling stress or discomfort when talking about difficult feelings and moods. If the intervention brings up negative feelings that you would like to discuss with a mental health professional, a referral will be made. The Lay health worker (LHW) will have a list of local mental health workers who can offer counseling services for low cost. All information you share with your LHW will be confidential. The only time your LHW may discuss your situation is if you tell us you have a desire to harm yourself or your child. The LHW and you can talk further and assess severity by consulting with onsite supervisor and possibly the PI. State law may require your LHW to report harm to self or others. Harm to self or others is the only time the LHW would need to break confidentiality and she will inform you that she needs to report to her supervisor.

You will have the option to withdraw from participation at any time if you feel uncomfortable answering questions. Withdrawal from this study will not affect the services you receive at the agency.

Direct benefits
While you will not directly benefit from participation, your participation may help researchers better understand how to reduce risk or prevent postpartum depression. Also, there may be a benefit to you by talking with the lay health worker about your problems related to depression. You may choose to not participate in this study. Withdrawal from this study will not affect the services you receive at the agency.

Incentives/Remuneration
You will not be asked to pay any costs related to this research.

Participants will be compensated for their time with a $20 Wal-Mart gift care at intake, $20 Wal-Mart gift card at the last PST session and $10 Walmart gift card for each follow up phone call they participate in. If you participate in all 5 sessions and the 2 follow up phone calls the total compensation over time is $60 in Wal-Mart gift cards.

Where is the study run from?
Urban strategies, Arlington partners:
1. Creciendo Unidos (Growing together) (USA)
2. Nuestra Señora de Guadalupe (USA)
3. Neighborhood Ministries (USA)
4. ProSalud (USA)
5. enFamilia (USA)

When is the study starting and how long is it expected to run for?
July 2017 to November 2018

Who is funding the study?
W.K. Kellogg Foundation (USA)

Who is the main contact?
Dr McClain Sampson
mmsampson@uh.edu

Study website

N/A

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
N/A

Study information

Scientific Title
The PST4PPD Home Visiting Postpartum Depression Intervention: Results Among Low-Income Latina Mothers

Acronym
PST4PPD

Study objectives
The PST4PPD home visit intervention will decrease the depression scores and increase the self-efficacy scores among low-income Latina mothers

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/12/2016, University of Houston Institutional Review Board (Office of Research Policies, Compliance and Committees (ORPCC), University of Houston, Division of Research; +1 713 743 9204; cphs@central.uh.edu), ref: 14444001-7079

Study design
Single-cohort, non-randomized, pre-post intervention comparison study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format. Please use contact details to request a pariticipant information sheet.

Health condition(s) or problem(s) studied
Postpartum Depression

Interventions
Community Health Workers (CHWs) delivered the intervention in participants' homes once a week for five weeks. The intake session began with the CHW describing the project, obtaining consent, and administering a battery of psychosocial instruments measuring demographic characteristics, depression, knowledge of PPD, and self-efficacy. The intake session concluded with a motivational interviewing (MI) module. Using of MI skills and a script, CHWs assessed participants’ readiness and perception of receiving treatment for depression, delivered the PPD fact sheet, and described what Problem Solving Therapy (PST) is. Lastly, the CHW scheduled a second home visit within two weeks in which the PST content would be covered.

After the intake session, the CHWs conducted four PST sessions, once weekly, over a period of four weeks. Each session, the CHW used a workbook to help the participant develop a plan to solve one manageable problem. A guiding premise of PST is to focus on everyday stressors, choosing a manageable problem to work on each week. The workbook also explained how thoughts affect approaches to problems. Participants encouraged to focus on manageable everyday stressors rather than “depression” as the problem to solve. Each session took approximately one hour.

On completing the four PST sessions the participants were all assessed using the same psychosocial instruments as the intake session.

Intervention Type
Behavioural

Primary outcome measure
1. Depressive symptoms measured using the Edinburgh Postnatal Depression Scale (EPDS) and the Patient Health Questionnaire (PHQ-9) at baseline and 5 weeks
2. Self-belief in infant care capabilities measured using the nine-item Maternal Efficacy Questionnaire (MEQ) at baseline and 5 weeks. Each item was rated on a 4-point Likert-type scale from 1 (not good at all) to 4 (very good), with potential total scores from 9 to 36.

Secondary outcome measures
PPD knowledge (knowledge of facts and belief in myths about PPD) was measured at baseline and 5 weeks using a non-standardized measure created by the PI (available on request from mmsampson@uh.edu). Nine questions were on the measure and were generated from information posted on the NIMH website and common beliefs the PI had heard from her previous work. Examples include, “Please answer True or False to the following question: Having postpartum depression means you are a bad mom” and “Please answer True or False to the following question: Postpartum depression is just a medical term in America and does not happen in other countries.” Higher scores (scored between 0 and 9) represent higher levels of PPD knowledge.

Overall study start date
01/03/2016

Completion date
01/11/2018

Eligibility

Key inclusion criteria
1. Latina
2. ≤12 months postpartum
3. Aged ≥18 years
4. Scoring at least 10 on the Edinburgh Postnatal Depression Scale (EPDS)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
100

Total final enrolment
96

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/07/2017

Date of final enrolment
28/02/2018

Locations

Countries of recruitment
United States of America

Study participating centre
Urban strategies
2341 9th St S
Arlington
United States of America
22204

Study participating centre
Creciendo Unidos (Growing together)
2801 N 31st Street
Phoenix
United States of America
85008

Study participating centre
Nuestra Señora de Guadalupe
2415 North Butrick Street
Waukegan
United States of America
60087

Study participating centre
Neighborhood Ministries
1918 W. Van Buren Street

Phoenix
United States of America
85009

Study participating centre
ProSalud
6500 Rookin Street
Houston
United States of America
88074

Study participating centre
enFamilia
16090 SW 293 Drive
Homestead
United States of America
33033

Sponsor information

Organisation
University of Houston

Sponsor details
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Sponsor type
University/education

Website
http://www.uh.edu/

ROR
https://ror.org/048sx0r50

Funder(s)

Funder type
Charity

Funder Name
W.K. Kellogg Foundation

Alternative Name(s)
Kellogg Foundation, La Fundación W.K. Kellogg, Fundación W.K. Kellogg, W. K. Kellogg Child Welfare Foundation, Fondasyon W.K. Kellogg, WKKF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication of a results paper by the end of 2020

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		27/02/2020	06/03/2020	No	No