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

Submission date	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li><li>Protocol</li></ul>		
20/02/2020				
Registration date	Overall study status	Statistical analysis plan		
02/03/2020	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
06/03/2020	Mental and Behavioural Disorders			

#### 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

# Contact information

#### Type(s)

Scientific

#### Contact name

Dr McClain Sampson

#### **ORCID ID**

https://orcid.org/0000-0003-3497-8878

#### Contact details

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# Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

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

#### Study type(s)

Treatment

#### 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(s)

- 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.

## Key secondary outcome(s))

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.

#### 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

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

Female

#### 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

#### **ROR**

https://ror.org/048sx0r50

# Funder(s)

#### Funder type

Charity

#### Funder Name

W.K. Kellogg Foundation

#### Alternative Name(s)

Kellogg Foundation, W. K. Kellogg Child Welfare Foundation, Wk Kellogg Foundation, La Fundación W.K. Kellogg, Fundación W.K. Kellogg, 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**

#### 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes