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Cuidándome: a self-management intervention for depression and anxiety among Latina immigrant women

Submission date
20/12/2023

Recruitment status
No longer recruiting

Registration date
21/12/2023

Overall study status
Completed

Last Edited
09/01/2024

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
The aim of this study is to examine the feasibility and acceptability of Cuidándome delivered virtually (via Zoom) to Latina immigrant survivors of adverse childhood experiences (ACEs) with depression and anxiety symptoms. Cuidándome is a 10-week, patient-centered, culturally appropriate, trauma-informed, group intervention delivered by a trained facilitator that promotes self-management of depression/anxiety symptoms through education and problem-solving training

Who can participate?
Latina immigrant women who were at least 18 years old, had experienced at least one ACE, and had at least mild symptoms of depression or anxiety

What does the study involve?
Participants are randomly allocated to Cuidándome or a comparison group delivered by trained facilitators. The researchers assess for changes in depression and anxiety symptoms as well as social problem-solving styles at baseline, post-intervention, and 3- and 6-month follow-up. Participants are expected to join group sessions via Zoom every week for 10 weeks, and complete surveys administered by a research assistant at baseline, and 3, 6, and 9 months post-intervention.

What are the possible benefits and risks of participating?
Participants in the intervention group had the opportunity to understand how ACEs may be impacting their personal lives and gained a better understanding of mental health conditions and how they may be managed. Those who participated in the control group learned about health behavior practices that may improve their well-being.
Because the education sessions were conducted in a group format, a potential but very unlikely risk was a breach of confidentiality; in addition, the nature of some questions – particularly to those who had experienced abuse – may have caused the participants to become upset or uncomfortable. Participants were also aware that participation was voluntary and that they could stop at any time.

Where is the study run from?
This study was conducted remotely from Baltimore, with participants in the Baltimore area participating from their homes.

When is the study starting and how long is it expected to run for?
September 2019 to March 2022

Who is funding the study?
Robert Wood Johnson Foundation (USA)

Who is the main contact?
Carmen Alvarez, alcarmen@upenn.edu

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
IRB00287200

Study information

Scientific Title
Feasibility and acceptability of the cuidándome telehealth intervention for self-management of depression and anxiety among Latina immigrant women: randomized controlled trial

Study objectives
It is hypothesized that compared to the comparison group, the intervention group would report lower depression and anxiety symptoms.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 13/05/2021, Johns Hopkins School of Medicine IRB (615 N Wolfe St, Baltimore, 21205, United States of America; +1 (0)443 927 1794; jpugh17@jhmi.edu), ref: IRB00287200

Primary study design
Interventional

Study design
Randomized controlled study

Study type(s)
Other

Health condition(s) or problem(s) studied
Depression and anxiety symptoms

Interventions
1:1 randomization is completed by REDCap. Randomization is stratified based on ACE score so that one group would not have more people with higher average ACEs than the other.

Cuidándome (Intervention): a 10-week, patient-centered, culturally appropriate, trauma-informed, group intervention delivered by a trained facilitator that promotes self-management of depression/anxiety symptoms through education and problem-solving training

Health education (Attention Control): 10, 1-hour weekly sessions on general health information (nutrition, exercise, bone health, etc).

Intervention Type
Behavioural

Primary outcome(s)
Depression symptoms measured using the Patient Health Questionnaire 8 (PHQ-8) at baseline and 3, 6, and 9 months post-intervention

Key secondary outcome(s)
Anxiety symptoms measured using the Generalized Anxiety Disorder (GAD-7) at baseline and 3, 6, and 9 months post-intervention

Completion date
31/03/2022

Eligibility

Key inclusion criteria
1. Being ≥18 years
2. Foreign-born (or born on the island of Puerto Rico)
3. Self-identify as a Latina
4. Self-report of ≥1 ACE
5. Ability to understand and speak Spanish
6. Have a score of ≥5 on the Patient Health Questionnaire-8 (PHQ-8), an assessment for

depression symptoms, or ≥5 on the Generalized Anxiety Disorder-7 (GAD-7), an assessment for anxiety symptoms

Participant type(s)
Population

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Female

Total final enrolment
47

Key exclusion criteria
1. Women currently enrolled in another study about mental health (to limit potential confounding or carryover effects)
2. Women who reported being pregnant

Date of first enrolment
29/06/2021

Date of final enrolment
14/07/2021

Locations

Countries of recruitment
United States of America

Study participating centre
Centro Sol
Mason F. Lord Center Tower 4200
5200 Eastern Ave
Baltimore
United States of America
21224

Sponsor information

Organisation
Robert Wood Johnson Foundation

ROR
https://ror.org/02ymmdj85

Funder(s)

Funder type
Charity

Funder Name
Robert Wood Johnson Foundation

Alternative Name(s)
RWJ Foundation, The Robert Wood Johnson Foundation, Johnson-New Brunswick Foundation, Johnson New Brunswick Foundation, RWJF

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 data on which this study is based are not publicly available due to ethical considerations. Data are available on request for the corresponding author and with a data use agreement. All requests for participant-level data should be directed to Carmen Alvarez (alcarmen@upenn.edu). Only de-identified data will be shared after a data agreement has been established. Data will be available until 2025. The researchers do not have the participants' permission to publicly share their data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/01/2024	09/01/2024	Yes	No