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Co-design of group psychosocial health intervention for indigenous women in Guatemala

Submission date
20/06/2018

Recruitment status
No longer recruiting

Registration date
26/06/2018

Overall study status
Completed

Last Edited
11/07/2019

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
Improvement in the mental health of mothers may have the added benefit of improving early infant growth and development. Indeed, the first 1,000 days of life (starting at conception) are the critical window of time for infant growth and development. Improving the mental health of vulnerable women of childbearing age could open a new path toward improving maternal and infant health but also that of their families and communities over the long run. The aim of this study is to test an intervention (Women's Circles for vulnerable women, led by trained community leaders) to empower marginalized communities to look after and promote the health and wellbeing of their own mothers and young infants.

Who can participate?
Women who are pregnant or have given birth in the last two years, with at least one of the following conditions: socioeconomic disadvantage, domestic violence, difficult interpersonal relationships, poor social support, psychological distress

What does the study involve?
Participants are interviewed about their living situation, their health, and how they have felt lately, and are measured to assess their nutritional status. They are then randomly allocated into two groups. The first group are invited to participate in 11 sessions of Women's Circles started weeks after the first evaluation, while the other group are invited several months later after the second evaluation. The objective of Women´s Circles sessions is that women have a safe place to discuss their concerns, express their views, and learn more about their and their baby´s health and development. These sessions are conducted over a period of several months, with about 2 sessions per month, in the place that the group decides. One woman in each community is selected to ask her opinion about the Women´s Circles, what she thinks about the sessions, and if they are helpful to her or not, to learn how to improve the intervention.

What are the possible benefits and risks of participating?
The benefit gained from this study is that participants will be evaluated by a health worker and also participate in the Women´s Circles where they will be able to talk about their difficulties,

ask for help and learn new ways of taking care of themselves, their babies, and their families. They will also receive written information on the nutritional status of their child and will be referred for help if a problem is found. All risks related to the assessment and Women´s Circles are minimal. Sometimes it happens that a person feels uncomfortable with a question or activity. If this happens, they are free not to answer the question or participate and can ask the interviewer to go to the next question. Also, if for some reason they don´t want to be measured, there is no problem, they can say “no”. Participation in this study is voluntary. Participants are therefore free to refuse to participate and can withdraw from the study at any moment. A decision not to participate in the study or to withdraw from it will not have any impact on the quality of care and services or their relationship with the research team. All information collected will remain strictly confidential. The data will be stored for a period of 5 years and then destroyed. The study and does not involve any monetary compensation for participation.

Where is the study run from?
1. 5 communities of San Juan Ostuncalco (Espumpuja, Los Romero, La Union, Los Lopez, Los Escobares) (Guatemala)
2. 3 communities in periurban Quetzaltenango (Choqui, Chiquilaja, San Jose la Vina) (Guatemala)

When is the study starting and how long is it expected to run for?
November 2013 to September 2015

Who is funding the study?
Grand Challenges Canada

Who is the main contact?
Dr Anne Marie Chomat

Contact information

Type(s)
Scientific

Contact name
Dr Anne Marie Chomat

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GCC0333-04

Study information

Scientific Title
Tackling maternal psychosocial distress among marginalized women in Guatemala: a community-based approach

Study objectives
1. The Women's Circles are a locally feasible and culturally acceptable space for vulnerable women in these areas
2. Participation in the Women's Circles as a significant impact on mother’s wellbeing and positive functioning

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Douglas Mental Health Institute (McGill University affiliate), approved 28/04/2014, addendum approved 19/02/2015, Protocol 14/00
2. Institute of Nutrition of Central America and Panama (INCAP), approved 06/05/2014, addendum approved 11/02/2015, Protocol MI-CIE-14-010

Study design
Pilot randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Maternal psychosocial health and wellbeing

Interventions

Women leaders known to the PI requested a group intervention that could help women in their communities. Local leaders steered group processes. The participatory research approach involved initial needs assessment and co-design, co-development, and co-implementation of the intervention with the 16 circle leaders. This enabled optimizing community-level engagement with the intervention and ensured that the research and intervention were culturally safe, locally relevant, and respectful of local values.

Ten one-day workshops scheduled monthly enabled the circle leaders to co-design the intervention. They collectively chose a project name and logo; developed a theory of change; mapped community needs, resources, and stakeholders; and pilot-tested group methodologies. Individual and group activities drew from a broad range of evidence-based and local approaches including cognitive behavioural therapy (CBT) (emotional self-management, problem-solving, cognitive reframing), interpersonal therapy (IPT) (learning-through-play, communication strengthening, role plays, art-based methods), educational (popular education, sharing among women), and mindfulness-based (rituals, breathing and relaxation exercises, guided meditation). Methods included both psychological and mental health promotion approaches. All were adapted by the women to be used locally. Local resources and practices complemented these activities. Finally, women's interest in developing livelihood-sustaining skills prompted us to also incorporate productive activities (i.e. doll making, crochet, cooking) as a form of vocational therapy and potential small-scale income generation.

The intervention was transdiagnostic, addressing a range of mental health issues, and was intended to foster reflection and dialogue.

The 10 sessions of the group psychosocial intervention followed a fixed format. Pre-sessions involved toy-making of dolls, books or rattles mothers could use to stimulate and play with their infants. Sessions started with a participant-led prayer (often accompanied by the lighting of a candle), followed by a prior session recap. A group dynamic (dinámica) served as an icebreaker. Activities that enabled personal and group reflection (drawing, painting, dramatization) led to sharing lessons-learned, aspirations and personal experiences. A closing dinámica released tensions or promoted relaxation. Sessions concluded with a collective embrace. Sessions took place every fortnight in settings of participant's choosing (i.e. house, community center), and lasted on average two hours.

A non-computerized randomization process was used. In each of the eight communities, names of consenting women were put in a box and 12 were drawn randomly to join the intervention group. Remaining names were allocated to the control arm. Intervention status was disclosed after allocation since it was impossible to maintain blinding among participants. However, blinded researchers conducted assessments. Given the nature of the intervention, masking was not possible.

Mothers were assigned to Women's Circle groups in the intervention arm but not in the control arm. The control arm was a waitlist control, and all women assigned to this group were invited to attend the intervention later when the post-intervention assessment was complete (waitlist control). Their scores as controls, prior to their own participation, were included in the present analyses. The pilot (including follow up) was conducted within six months.

Intervention Type
Behavioural

Primary outcome measure

A questionnaire assessed the following four measures of psychosocial health and functioning (primary outcomes) at baseline and at one-month post-intervention:
1. Maternal symptoms of depression and anxiety over the last month, measured using the Hopkins Symptom Checklist-25 (HSCL-25), a symptom inventory composed of a 10-item anxiety cluster, a 13-item depression cluster, and two additional somatic symptoms. Each item scores on a scale from one (not at all) to 4 (extremely); item scores can be summed to provide an estimate of the severity of anxiety and depression symptomatologies. A higher score indicates greater distress
2. Maternal wellbeing, measured using the Mental Health Continuum Short Form (MHC-SF), comprised of 14 items representing the three dimensions of wellbeing: emotional, social and psychological. Each item scores on a scale from zero (never) to four (always), based on experiences in the previous month, allowing for continuous assessment of positive mental health. A higher score indicates greater wellbeing
3. Self-efficacy, measured using a four-item subscale measuring self-efficacy in childcare (feeding, caring and cleaning, playing and talking, helping recover from illness) and a four-item subscale measuring self-efficacy in self-care (overcoming daily problems; staying calm when worried, nervous, or afraid; finding reliable people for support; dedicating time to herself). Each item scores on a scale from zero (I can't do it) to three (I can do it), allowing for continuous assessment of childcare self-efficacy, self-care self-efficacy, and total self-efficacy. A higher score indicates greater self-efficacy
4. Mother's engagement in early infant stimulation, measured using six items from the UNICEF Multiple Indicator Cluster Survey Early Child Development module capturing adult-child interactions, assessing whether mothers engaged with her infant in six different activities (e.g., reading, singing, playing, talking) over the preceding three days. Each item scored as zero (no) or one (yes). The cumulative number of activities was used as a continuous variable for analyses. Only those women who had a child under two years old participated in this questionnaire. A higher score indicates greater involvement in early infant stimulation activities

Secondary outcome measures
1. Acceptability was assessed in post-intervention focus groups and in-depth interviews, when participants were asked whether they were satisfied with the intervention, would recommend it to other women, and would have preferred it to be any different. Participants were also asked to report on their (or other women's) barriers to participation; circle leaders were asked what strategies they used to overcome these
2. Intervention feasibility was assessed during post-intervention focus groups and in-depth interviews. Circle leaders were asked whether they felt comfortable in their ability to lead the Women's Circles, had received enough training and support, felt that implementation logistics were appropriate (i.e. session frequency, location and length, materials, compensation), and what they might change. Objective data included: rate of circle leader retention, rate of women participant retention, and number of sessions attended

Overall study start date
01/12/2013

Completion date
01/09/2015

Eligibility

Key inclusion criteria

1. Pregnant or under two years postpartum
2. At least one of the following conditions: socioeconomic disadvantage, domestic violence, difficult interpersonal relationships, poor social support, psychological distress. These criteria were based on known risk factors, circle leaders' assessment of what constituted maternal vulnerability, and prior research in nearby Mam communities

Participant type(s)
Other

Age group
Other

Sex
Female

Target number of participants
96

Total final enrolment
155

Key exclusion criteria
1. Women who were not from study communities
2. Not within the first 1,000 days (pregnancy to 2 years postpartum)
3. Failed to provide consent

Date of first enrolment
10/05/2015

Date of final enrolment
31/07/2015

Locations

Countries of recruitment
Guatemala

Study participating centre
5 communities of San Juan Ostuncalco (Espumpuja, Los Romero, La Union, Los Lopez, Los Escobares)
Municipality of San Juan Ostuncalco
Guatemala
-

Study participating centre
3 communities in periurban Quetzaltenango (Choqui, Chiquilaja, San Jose la Vina)
Municipality of Quetzaltenango

Quetzaltenango
Guatemala
-

Sponsor information

Organisation
Instituto de Nutricion de Centro America

Sponsor details
Calzada Roosevelt 6-25 zona 11, Apartado Postal 1188
Guatemala City
Guatemala
01011

Sponsor type
Research organisation

Website
http://www.incap.int/ciipec/index.php/es/

ROR
https://ror.org/03wzeak38

Funder(s)

Funder type
Government

Funder Name
Grand Challenges Canada

Alternative Name(s)
Grands Défis Canada, GCC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Publication and dissemination plan
1. Manuscript to describe acceptability, feasibility and proof-of-concept
2. Methodological paper to describe co-design of project

Intention to publish date
01/07/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Anne Marie Chomat. The type of data is: sociodemographic and psychosocial health variables for all intervention and control women. It can be made available within less than a month. It will be shared with researchers who can demonstrate a sound plan for additional analyses, and whenever such analyses can contribute significantly to knowledge that can improve vulnerable women's lives. No consent was obtained from the participants for data sharing.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/04/2019	11/07/2019	Yes	No