

Strengths-based Video-feedback to improve maternal sensitivity in mother-infant dyads with maternal depressive symptoms: Study protocol for a randomized controlled feasibility trial

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Abstract

Introduction

Maternal sensitivity and mentalization are fundamental for children’s mental health development. These skills have been negatively associated with maternal postpartum depressive symptomatology. Moreover, its prevalence increases in low socioeconomic and psychosocial risk contexts, where the access to treatment is scarce. Even though Attachment Based Interventions, such as Video-Feedback has been internationally recognized as an effective intervention. Its cost, as well as the need for language translation and cultural adaptation makes it difficult to implement in Latinamerican countries.

Aim

The present study aims to assess the feasibility and acceptability of an online Video-Feedback intervention informed n mentalization aimed at mother-infant dyads with depressive symptomatology who attend Chilean public health centers.

Methods

This is a pilot randomized clinical trial with two groups of 60 mother-infant dyads between 4 and 12 months of age. Participants will be randomly assigned to control and experimental groups in a 1:1 ratio. Even though both groups will receive usual treatment, the experimental group will also receive the present video-intervention. At the end of the study, feasibility will be assessed based on focus groups aimed at interveners and quantitative outcomes such as recruitment rate, questionnaire completion rate and intervention completeness. Acceptability will be assessed from in-depth interviews with participants. In addition, effect sizes of primary and secondary outcomes will be calculated.

Expected results

Results are expected to generate parameters to design a larger-scale clinical trial and to preliminary assess the effect of the reported mentalization-informed intervention on maternal sensitivity. Additionally, it seeks to contribute with a mental health intervention for low-income mother-infant dyads, which can be implemented remotely, at a low cost, and that would be suitable for implementation at a mental health care system policy.

The protocol of this trial's design was registered at Clinical Trials (NCT04748731).

MAIN MESSAGES

- ◆ Depression in the perinatal period is highly prevalent disease and negatively affects maternal and infant mental health.
- ◆ Video-feedback interventions aimed at promoting attachment and mentalization are cost-effective worldwide. However, training is costly and needs cultural adaptations.
- ◆ The design of protocols that evaluate the implementation of brief and culturally sensitive interventions is required.

INTRODUCTION

Peripartum depressive symptomatology is a public health priority due to its high prevalence [1] and impact on maternal negative consequences and child development [2]. The challenges of early parenting have been shown to increase the risk of mental health problems, especially in women. In a meta-analysis, Shorey et al. (2018) describe an incidence and prevalence of postpartum depression of 12 and 17%, respectively. In Chile, it is estimated that between 16 and 20% of women are at risk of postpartum depression within the first six months after childbirth [3]. In children, a greater risk of suffering depression throughout life has been described [4], as well as negative consequences in affective, cognitive, and behavioral development [5,6]. The care response for this population, especially in contexts of psychosocial risk, is a cost-effective [7] and effective [8–14] public health measure at the international level. In this context, attachment-based interventions using video feedback are a good example of a brief and cost-effective tool to reduce depressive symptomatology, improve maternal sensitivity, and increase the security of infant attachment [13,15–17]. However, Chile does not have guidelines to implement such evidence-based practices at the public health level [18,19].

Local barriers to achieving this objective include the difficulty of translation, cultural adaptation, copyright, and training costs [20]. In this sense, local interventions have been developed to respond to public mental health care's specific needs, vulnerabilities, and cultural characteristics. This video intervention focused on resources (VI-FR) is an attachment-based intervention developed in 2012 to reduce depression and promote maternal responsiveness. This method has been applied for ten years by mental health professionals trained in a university diploma program and used in clinical practice in a perinatal

mental health program at the same university four years ago. Preliminary studies have shown to improve parental sensitivity, decrease postpartum depressive symptomatology, and improve infant socio-emotional development [21–23].

The resource-focused video intervention is a brief intervention, flexibly structured to be tailored to each mother-baby dyad. Specifically, the intervention seeks to:

- 1) Increase "shared pleasure" in the dyad, activating reward circuits that reinforces mother and infant to repeat this experience.
- 2) Improve the maternal sensitive response using mentalization as a mechanism.
- 3) Reduce maternal hostility, reinforcing positive interactions observed in videos and reflecting on complex or dysfunctional aspects.

The aim is to observe the positive interactional patterns and talk about challenging aspects by quoting the mother herself in functional episodes, observed in order to rethink complicated interactions and discover new ways of dealing with them. According to local experience [23], these objectives can be accomplished in four sessions to complement existing maternal and infant mental health services.

The resource-focused video intervention considers the therapist's attitude as a key factor: he/she is positioned not as an expert but as a collaborator with curiosity and doubts. Therapists are trained in trauma and its intergenerational transmission, capable of recognizing and validating the experience of the other, and regularly participating in reflective supervision groups.

At the same time, the COVID-19 health crisis highlighted the overload of the health system and the need for remote mental health care during the postpartum period aimed at public

service users with clinical symptomatology [1,24]. The resource-focused video intervention seeks to respond to these needs straightforwardly and remotely, using a strategy that has shown promising results in this population [25].

Considering the above, the study presents a brief, online intervention based on attachment theory and using video feedback to improve parental sensitivity in depressed, low-income mother-baby dyads and users of Chilean public health services. This model is expected to:

- 1) Provide a remote postpartum mental health intervention for low-income dyads with restricted access to face-to-face care [26].
- 2) Low-cost, evidence-based, and suitable for scale-up to public mental health care.

OBJECTIVE

To assess the feasibility and acceptability of a resource-focused video-feedback intervention for mothers with depressive symptoms and their children to design a larger-scale randomized clinical trial. As a secondary objective, we seek to evaluate the intervention's effect on maternal sensitivity preliminarily.

MAIN RESULTS (TRIAL FEASIBILITY)

- 1) Recruitment rates for participation and randomization.
- 2) Retention and follow-up rates as participants progress through the trial.
- 3) Rates of adherence to study procedures, intervention attendance, and engagement.
- 4) Effect size in maternal sensitivity (calculating sample size in randomized clinical trials).
- 5) Progression criteria for a definitive trial.

METHODS

This study has the full ethical approval of the local Ethics Committee (Comité de Ética Científico de Medicina, Pontificia Universidad Católica de Chile, ID 201201009, date 17-12-20). Written informed consent will be obtained from the participants. This trial was registered in February 2021 in Clinical Trials, registration number NCT04748731 (<https://clinicaltrials.gov/ct2/show/NCT04748731>).

DESIGN

Pilot randomized clinical trial with two parallel groups of mothers with depressive symptomatology and their infants. Both groups will receive the usual treatment plus psychoeducational material. Only the experimental group will receive the intervention with the proposed resource-focused video-intervention model. Details on the chronology of the study are presented below in Figure 1.

SETTING

As shown in Figure 1, the recruitment, intervention, and data collection will be conducted entirely online. Participants will be referred to the study from five primary care centers in Santiago, Valparaíso, and Puerto Varas. The Chilean public health system provides free care to the two poorest segments of the population [27]. The virtual platform will be Zoom – a videoconferencing service identified as a valuable and secure tool for conducting research interviews and has demonstrated acceptability [28].

SAMPLE SIZE

It was estimated considering its usefulness in providing information to assess feasibility. Guidelines for developing pilot randomized clinical trials consider 30 participants per group as a reasonable number to reliably estimate the variation among participants' outcomes [29] and estimate the standard deviation of outcome variables and the correlation coefficient between baseline and follow-up scores [30]. Considering the above, we expect to invite 570 mothers to recruit 72 in the trial and end up with 60 participants at follow-up (30 for each arm).

ELIGIBILITY CRITERIA

Regarding eligibility criteria, this study include women aged 18 years or older who are:

- 1) Mothers of infants between 4 and 12 months of age.
- 2) Users of public health care.
- 3) Scoring five or more points on the Edinburgh Postnatal Depression Scale during routine assessments in their care centers.
- 4) Fluent in Spanish.

Patients will be excluded with the presence of:

- 1) Maternal severe intellectual deficit and/or psychotic symptoms.
- 2) Severe developmental disorders in infants.
- 3) Identification of current family violence and legal proceedings for violation of rights.

The participants' referral medical centers will evaluate eligibility criteria.

INSTRUMENTS

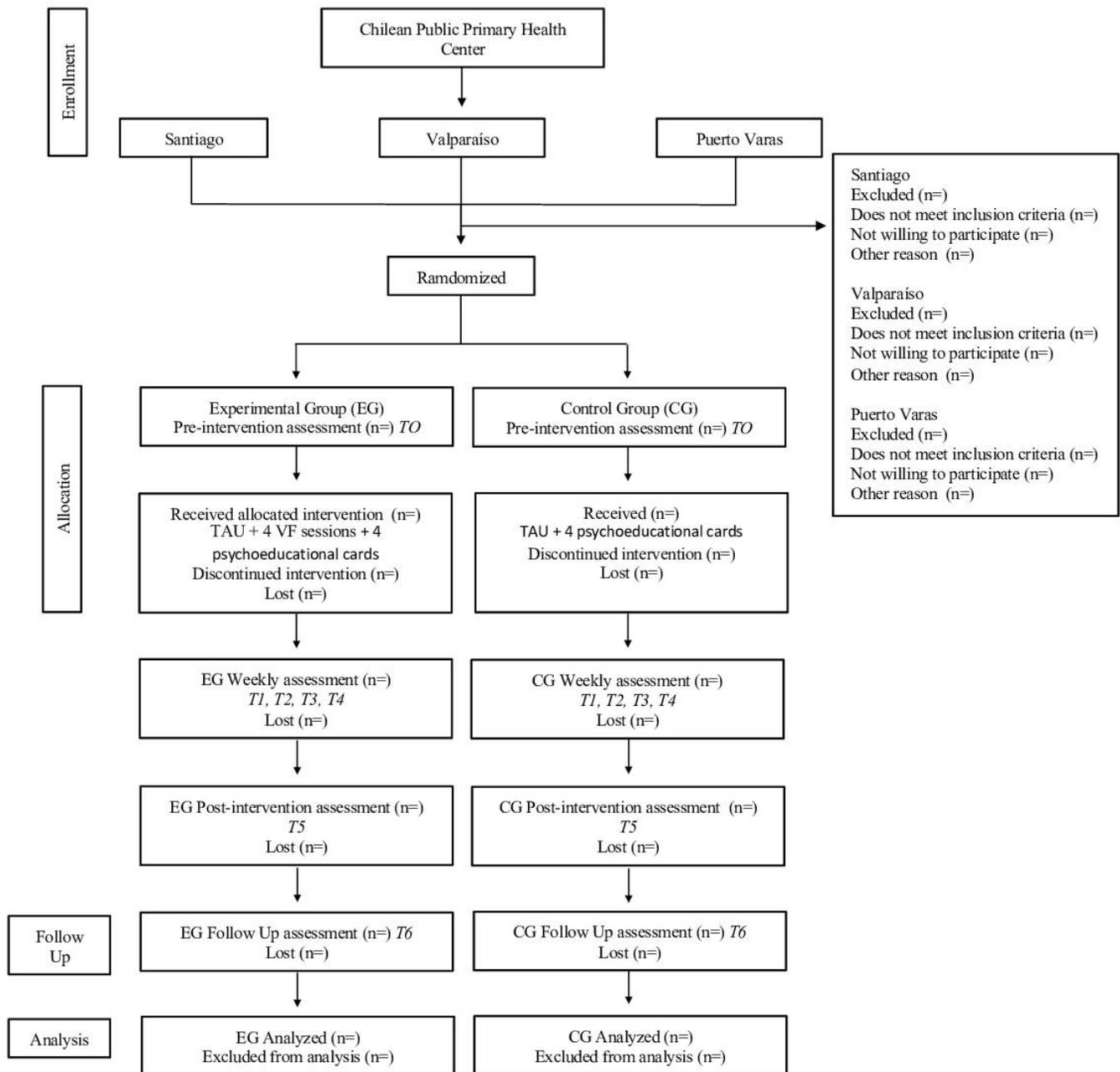
Table 1 summarizes all of the study's assessment instruments.

INTERVENTION

Control group: usual treatment plus psychoeducational cards

In addition to usual primary public healthcare, the dyads in the control group will receive four psychoeducational parenting cards via weekly text messages.

Figure 1. Recruitment, randomization, follow-up, and analysis flowchart.



Source: Prepared by the authors of this study.

Intervention group: usual treatment plus video feedback and psychoeducational cards

The intervention is delivered online by trained clinical psychologists (30 hours of training). The implementation considers a pre-assessment session and four one-hour intervention sessions with the same structure (Figure 2). All sessions are recorded for supervision.

As shown in Figure 2, the elements of the intervention process are as follows:

- 1) Pre-assessment: 90 minutes. It considers the application of instruments to the mother, the infant, and the dyad. We intend to explore the mother’s concerns about the child, their relationship and maternal role, the reason for the consultation, and the objectives of the intervention.
- 2) Autonomous work of the therapist: 60 minutes, weekly frequency. This activity aims to review the case’s clinical background, analyze the interaction observed in the video and its possible association with maternal concern and infant distress.

Table 1. Instruments and their characteristics.

Authors	Year	Instrument	Variable	Type of instrument
Prepared by the research team	2020	Socio-demographic background sheet	Socio-demographic characteristics, clinical and family history	Self-administered questionnaire
Biringen, Z., Derscheid, D., Vliegen, N., Closson, L., & Ann Easterbrooks, M.	2014	Emotional availability scale	In the adult: (a) sensitivity, (b) structure, (c) non-intrusiveness, and (d) non-hostility; in the child: (a) receptivity and (b) involvement	Mother-infant interaction video coding grid
Ensink, K., Borelli, J. L., Roy, J., Normandin, L., Slade, A., & Fonagy, P.	2019	Parental reflective functioning interview	Reflective parental functioning, using the Slade et al. coding system (2005)	Post-video mother-infant interaction interview
Squires J, Bricker D, & Twombly E.	2002	Ages and stages questionnaires: Social-emotional	Difficulties in socioemotional development from 3 to 60 months: self-regulation, compliance, communication, adaptive behaviors, autonomy, affect, and interaction with people.	Self-administered questionnaire
Saldivia, S., Aslan, J., Cova, F., Vicente, B., Inostroza, C., & Rincón, P.	2019	Patient health questionnaire	Depressive symptomatology	Self-applied questionnaire of 9 items with a Likert-type scale from 0 to 3
Jadresic E, Araya R, Jara C.	2001	Escala de depresión postnatal Edimburgo	Depressive symptomatology	Self-applied questionnaire
Trujillo, A., Feixas, G., Bados, A.,... & Evans, C.	2016	Evaluación de resultados clínicos CORE Outcome Measure	Therapeutic outcomes: subjective well-being, problems/symptoms, functioning, and risk	Self-applied questionnaire of 18 and 5 items with a Likert-type scale from 0 to 4
Spencer, R., Guzmán, M., Fresno, A., & Ramos, N.	2013	Experience in close relationships	Two dimensions of adult attachment, anxiety (of relationships) and avoidance (of intimacy)	Self-administered questionnaire of 18 items with a Likert-type scale from 0 to 7
Behn, A., Vöhringer, P. A., Martínez, P., Domínguez, A. P., González, A., Carrasco, M. I., & Gloger, S.	2020	Childhood trauma questionnaire – short form	Presence of adverse childhood experiences in adults: emotional abuse, physical abuse, sexual abuse, emotional neglect, and physical neglect	Self-administered questionnaire of 28 items with a Likert-type scale from 0 to 4
Deville & Borkovec	2000	Credibility/expectancy questionnaire	Acceptability of online intervention: credibility and expectation	Self-administered questionnaire of 6 items with a Likert-type scale from 0 to 9
Prepared by the research team	2020	Semi-structured interviews for the qualitative study	Subjective experience of participants in terms of their perception of the intervention, feasibility of the intervention with associated health center workers, and therapists' perspective on the modality of the intervention, its difficulties, and benefits	Three semi-structured interview scripts

Source: Prepared by the authors of this study.

- From this information, the therapist elaborates the script for the feedback and observation of the video with the mother.
- 3) Intervention sessions with video feedback: 60 minutes, weekly frequency. The main objective is observing the interaction videos and their analysis, seeking to promote reflection in the mother about the internal states in her and the child, the underlying needs, the mutual influence, and the elements of

- her childhood history that relate to elements of the observed interaction. The session is conducted online by the same therapist who conducted the initial assessment. From the second session onwards, changes observed from the tasks defined in the previous session are reviewed with the mother.
- 4) Videorecording: each session considers the video recording of an interaction from a new task (e.g., playing, feeding, singing).

- 5) Post-video interview: after each video recording, a semi-structured interview addresses the mother’s subjective experience during the interaction and the experience she imagines her child had.
- 6) Definition of tasks or practices between sessions: at the end of each session, possible activities to be carried out during the week are defined together, taking into account the mother’s discoveries or new learning.
- 7) Supervision: the team of therapists meets weekly for two hours to supervise the intervention processes. The objective is to address challenges that arise in the intervention, evaluate progress and ensure fidelity to the model. A reflective methodology [31] is used during supervision, which considers each participant’s experience. The supervisor and the clinical team act as support figures for the therapist.

PROCEDURE

Professionals from the collaborating healthcare centers will verify compliance with the inclusion/exclusion criteria and invite to participate in the study. Those who agree to participate will be assigned to a group (experimental or control), and will be contacted for the initial assessment, in which, after informed consent signing, the following variables will be evaluated: depressive symptoms, maternal sensitivity, socioemotional development of the child, adult attachment, adverse childhood experiences, credibility and expectations about the treatment and therapeutic progress. After the initial assessment, the same therapist who performs the assessment will begin with the interventions according to the assigned group. Once the intervention is completed, a different therapist will perform the post-assessment and the three-month follow-up. The assessments and interventions are detailed in Figure 3.

RANDOMIZATION AND BLINDING

Participants will be randomly assigned to the control or experimental group in a 1:1 ratio. A sequence of random numbers will be generated from permuted block sizes of two and four using Study Randomized®. The sequence will be administered by an external person who will contact the study coordinator each time a participant joins the study. While participants and therapists may not be blinded, outcome assessors will be blinded.

PRIMARY OUTCOME MEASURES: FEASIBILITY OF STUDY OBJECTIVES

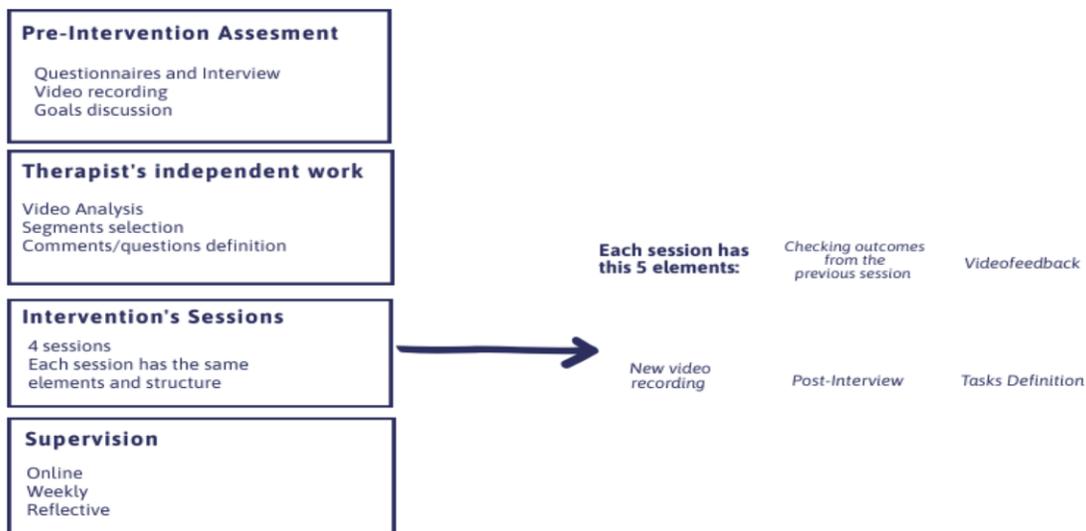
Recruitment, retention, and follow-up rates

Recruitment rates will be calculated from the number of signed consent participants. The percentage of the total number of invited and registered participants will be used. For each arm of the trial, the number of participants who withdrew or could not be contacted will be quantified. Data will be presented as a percentage of the total number of participants in each arm of the trial. The Consolidated Standards of Reporting Trials, CONSORT guidelines for pilot and feasibility studies will be followed (Annex 1 https://figshare.com/articles/preprint/Adaptaci_n_telem_tica_de_las_actividades_grupales_de_un_hospital_de_d_a_infanto-juvenil_Un_estudio_piloto_cualitativo/19375694) [32].

Sample size and effect size estimation

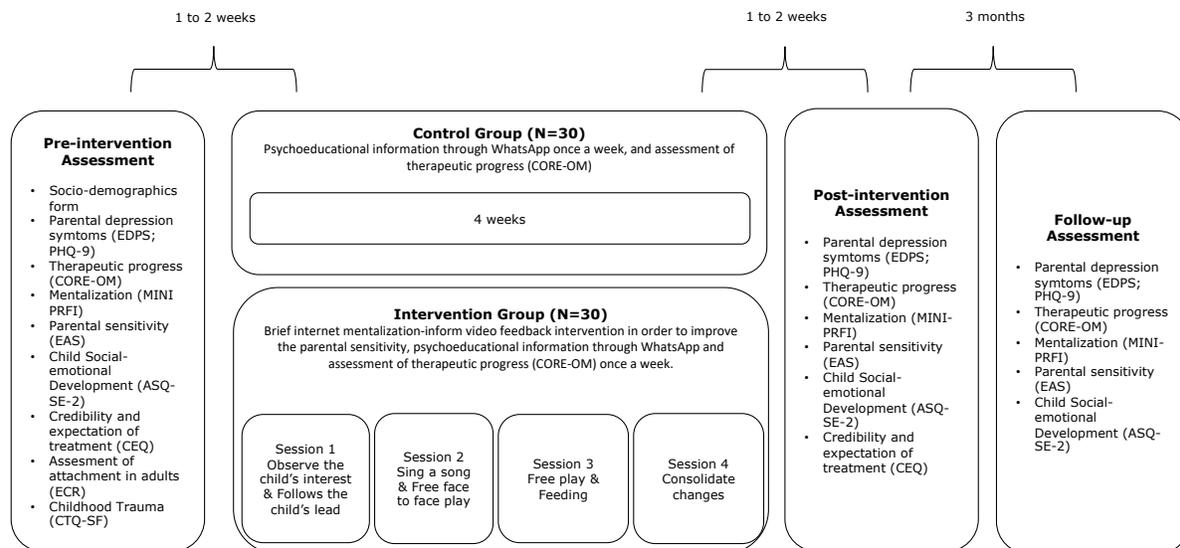
Standard deviations of continuous secondary outcomes related to maternal sensitivity will be calculated to estimate the sample size for a future trial. To estimate potential effect sizes for a primary outcome in a future trial (i.e., the change in scores on main and secondary outcomes before and after the

Figure 2. Summary of intervention elements.



Source: Prepared by the authors of this study.

Figure 3. Intervention and evaluation process flowchart.



Source: Prepared by the authors of this study.

intervention), we will calculate the difference between pre-intervention and post-intervention mean scores for the experimental trial and control groups and divide by the pooled standard deviation at baseline [33].

Success criteria

Progression to a definitive clinical trial will be decided based on the following criteria: recruitment rate over 70% of eligible consenting participants; questionnaire completion rate over 70% of participants (at time 1); and intervention completion rate over 50% of participants who attended all resource-focused video intervention sessions.

Acceptability and feasibility of the intervention

The acceptability of the intervention will be evaluated using in-depth interviews with the participants, aimed at finding out both the subjective effect of the intervention and their perception of the benefits and aspects to be modified. Feasibility will be evaluated through focus groups with therapists and health workers from the reference healthcenters to explore their assessment of the intervention. In addition, the success criteria previously mentioned will be considered for this objective.

Secondary outcomes

Secondary outcomes will be changes in maternal responsiveness, reflective functioning, depressive symptomatology, and socio-emotional development.

Table 2 below summarizes the entire schedule of activities associated with the study:

DATA ANALYSIS

Quantitative analysis

Descriptive statistics will be used to determine the clinical and socio-demographic variables of the groups, the eligibility rate, recruitment rates, dropout rates, and participation-attendance rates, and to estimate the effect size between groups post-intervention and follow-up. To determine differences between groups, repeated measures analyses will be used, controlling for a baseline for each outcome. Measures considering observation and coding will include at least two independent certified coders, and Cohen- κ will be used to estimate inter-rater reliability.

Qualitative analyses

In-depth interviews will be analyzed using content analysis [34].

DISCUSSION

Research in parenting and early childhood has demonstrated the importance of considering the mental aspects underlying

Table 2. Calendar of recruitment, evaluations, and interventions.

	Recruitment	Database	Randomization	Post-randomization						Closure
	T1	T0		Intervention				Post-intervention		
Time	T1	T0		T1	T2	T3	T4	T5	T6	
Recruitment										
Eligibility evaluation	x									
Informed consent	x									
Randomization			x							
INTERVENTION										
VF + psychoeducational primers				x	x	x	x			
TU + psychoeducational primers				x	x	x	x			
Evaluation										
Quantitative										
EDPS		x						x		x
PHQ-9		x						x		x
CORE-OM		x		x	x	x	x	x		x
MINI PRFI		x						x		x
EAS		x						x		x
ASQ-SE-2		x						x		x
CEQ		x						x		x
CTQ-SF		x						x		x
ECR		x						x		x
Socio-demographic questionnaire		x						x		x
Qualitative data from caregivers										x
Qualitative data from therapists										x

ASQ-SE, Infant Social-Emotional Development Questionnaire

. CEQ: credibility/expectation questionnaire. CORE: CORE System Group Outcome Measure. CORE-OM: CORE System Group Outcome Measure.

CTQ-SF: scale of adverse experiences during childhood and adolescence (Childhood Trauma Questionnaire Short Form). EAS: Emotional Availability Scale

(Emotional Availability Scale). ECR: Experiences in Close Relationships Questionnaire. EDPS: Edinburgh postnatal depression scale. MINI PRFI: MINI

Parental Development Interview. PHQ-9: Patient Health Questionnaire. TU: treatment as usual. VF: video feedback intervention.

Source: Prepared by the authors of this study.

behavior in understanding mother/parent-child interactions [35,36]. Parental mentalization addresses this aspect, and evidence shows that it plays a crucial role in increasing responsiveness and security of attachment [37,38]. Additionally, parental mentalization is fundamental for the development of affect and self-regulation [38–42], the intergenerational transmission of attachment [43,44], and the development of social and mentalization skills in infancy. However, video feedback interventions to enhance parental sensitivity often lack explicit consideration of mentalizing as one of the critical processes involved in maternal sensitivity.

The present study arises in response to the need to provide culturally sensitive interventions for low-income mother-infant dyads in contexts where face-to-face care is restricted. In this setting, online care offers a modality to address the need for care for postpartum depressive symptomatology [1,45].

The results of this pilot trial aim to provide evidence to adjust the intervention, define the required sample size and

subsequently develop a larger randomized clinical trial to evaluate its effectiveness. The long-term purpose of the research is to contribute with a brief and cost-effective psychotherapeutic intervention based on attachment theory and video feedback. It is also intended that the intervention developed will be adaptable to the Chilean public health system.

Notes

Contributor roles

MO, FL, SC, JM, ML, CS, AM, and CH conceived the study and participated in project management. KE, NB, and PL provided theoretical advice for the study. All authors contributed to the writing of this paper and approved the final manuscript.

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Competing interests

The authors declare that they have no conflicts of interest.

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Protocol registration

The design of this clinical trial was registered in Clinical Trials (NCT04748731).

Ethics

Full ethical approval of the study was obtained from the local Ethics Committee (Comité de Ética Científico de Medicina, Pontificia Universidad Católica de Chile, ID 201201009, date 17-12-20). The study will be conducted according to ethical principles from the Declaration of Helsinki (1996) and the principles of Good Clinical Practice (such as data storage and administrative functions). Written informed consent will be obtained from study participants (adults and children). Participants will be free to withdraw from the study at any time without giving a reason and without their health care being affected. All information collected during this trial will be kept confidential. Interviews that are transcribed will be anonymized at the time of transcription. Any third party involved in transcribing interviews will sign a confidentiality agreement and receive full instructions on anonymizing transcripts. There is no financial compensation for participating in the study.

Data sharing statement

The data set used in the current study will be made available upon request to the corresponding author.

Language of submission

Spanish.

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Video-retroalimentación Focalizado en los Recursos para mejorar la sensibilidad en díadas madre-infante con síntomas depresivos: protocolo de un ensayo clínico aleatorizado piloto

Resumen

Introducción

La sensibilidad y la mentalización materna constituyen competencias fundamentales para el desarrollo de la salud mental infantil. A su vez, dichas habilidades han sido negativamente asociadas con la presencia de sintomatología depresiva postparto, la cual aumenta su prevalencia en contextos de bajo nivel socioeconómico y riesgo psicosocial, en donde el acceso a tratamiento escasea. Paralelamente, si bien internacionalmente el video-retroalimentación constituye una herramienta efectiva en intervenciones basadas en el apego, el costo, idioma y necesidad de adaptación cultural dificultan su implementación en países latinoamericanos.

Objetivo

Evaluar la factibilidad y aceptabilidad de una video-intervención informada por la mentalización, dirigida a díadas madre-bebé con sintomatología depresiva, atendidas en centros públicos de atención en salud mental en Chile.

Métodos

Ensayo clínico aleatorio piloto con dos grupos de 60 díadas madre-bebé de entre 4 y 12 meses de edad, quienes serán asignados aleatoriamente a grupos control y experimental en una proporción de 1:1. Si bien ambos grupos recibirán el tratamiento habitual, el grupo experimental recibirá también la video-intervención. Al término del estudio se evaluará la factibilidad a partir de grupos focales dirigidos a interventores e indicadores de resultados cuantitativos tales como tasa de reclutamiento, de completación de cuestionarios y finalización de la intervención. La aceptabilidad se evaluará a partir de entrevistas en profundidad a las participantes. Adicionalmente se calculará tamaño del efecto de indicadores de resultados primarios y secundarios.

Resultados esperados

Se espera que los resultados del estudio generen parámetros para diseñar un ensayo clínico de mayor escala y evaluar preliminarmente el efecto de la intervención informada en la mentalización en la sensibilidad materna. Se busca además contribuir con una intervención en salud mental basada en la teoría del apego dirigida a díadas madre-bebé de bajos ingresos, que pueda ser implementada de manera remota, a bajo costo y apta para ser escalada a los sistemas de atención en salud mental. El diseño de este ensayo clínico fue registrado en Clinical Trials (NCT04748731).



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