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Promoting healthy beginnings using video interaction guidance for infants of mothers with mental health illnesses the first year following the birth of a child

Submission date
25/02/2023

Recruitment status
No longer recruiting

Registration date
16/03/2023

Overall study status
Completed

Last Edited
02/07/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Perinatal mental health disorders are significant complications of pregnancy and the postpartum period. They are known to affect up to 20% of expectant and new women within the first year after having a baby. These problems cover a wide range of conditions, including depression, anxiety, obsessive-compulsive disorder, and post-traumatic stress disorders, amongst others. Left untreated, these disorders can have a significant and long-lasting negative effect on the woman, the relationship with the child and his/her development, and the rest of the family unit. Additionally, we understand that the COVID-19 pandemic has created a challenging climate and brought about additional stressors for new mothers, which may in turn have a toll on their mental health. Without the right support, mental health issues can make it more challenging for parents to care for and connect with their baby.

If these relationship difficulties are not addressed early on after birth, they may have devastating consequences for the developing young child, which may well persist into adolescence and adulthood. In fact, the first three years of a baby's life are described as 'fundamental' for his development and necessitate the input of a reliable and consistent caregiver at all times.

This study seeks to gain an in-depth understanding of whether the developing relationship between mothers with mental health needs and their baby can be supported through a specific relationship-based intervention, named Video Interaction Guidance, or VIG in short. Results from this study can provide policy makers with evidence-based information on how this first and early life relationship can be safeguarded, whilst minimising the risk of negative developmental sequelae for the child.

Who can participate?
Women who are at least 18 years of age, resident in Malta, of any nationality, have a baby/infant aged 0-11months (inclusive) old, and are experiencing some form of ill-mental health (e.g feeling

depressed or anxious) will be considered for assessment of eligibility into this trial. The woman should not be receiving any form of talking therapy at study entry, and her baby must have been delivered at full term (37 weeks or beyond) and weighed at least 2000grams at birth.

What does the study involve?
In this study, interested participants will first have an introductory session with the main researcher to discuss the trial and what participation involves. Participants will be provided with a research pack consisting of a welcome letter, information leaflet about the study, and a consent form. Once consent is obtained, the woman will be given two questionnaires, the Edinburgh Postnatal Depression Scale (EPDS) and the Generalised Anxiety Disorder-7 item (GAD-7) scale to complete which will screen for possible depressive and/or anxiety symptoms in this postnatal period, respectively. These questionnaires will take around 5-10minutes to fill in. Participants who score positively in any of these two measures will be asked to attend for an interview with a qualified mental health practitioner to confirm or refute the present of mental health disorders, and hence eligibility for inclusion into the trial. This assessment of around 30-45minutes' duration, will be conducted remotely or face to face (depending on participant's preference) within one week of receiving the completed EPDS and GAD-7 questionnaires.

Following this assessment and upon confirmation of the participant's eligibility for inclusion in the trial, the woman will be asked to self-complete another three brief questionnaires about her bonding experience, her ability to understand her own and her baby's behaviour in terms mental states, and her psychological well-being. Also, a three minute video clip of the woman and her baby playing together will be taken as part of the assessment measures. All these questionnaires will be scored by an independent person with no other involvement in the trial. Subsequently, the participant will be randomly assigned using a computer-generated sequence to one of two study groups, intervention or control group. All participants in both groups will receive treatment-as-usual, consisting of an initial assessment by a qualified perinatal psychiatrist with follow-up sessions every few weeks, for a period of around 6 months during which a treatment plan will be collaboratively formulated to address the woman's needs. One group will also receive three sessions of VIG intervention, in addition to the above reviews. Each session or cycle of VIG will consist of the following: (1) A filming session of around 8-10minutes of the mother and her baby playing or interacting together in an everyday activity and (2) A follow up session where the woman and the practitioner meet together to review short clips or images selected from the original filming. These clips and images will display positive moments of interaction between the dyad. During this discussion, the mother will learn more about her baby as the practitioner guides the mother to reflect on what she would be seeing, on how she and her baby might be feeling, and how to continue building a positive relationship with her child. These cycles, each lasting around 45minutes in duration, will be repeated three times, every 2-3 weeks.

At the end of treatment, the woman will be asked again to fill in the same questionnaires completed at pre-intervention stage and another 3-minute filming of mother-baby interaction will again be taken.

What are the possible benefits and risks of participating?
There are no reasonably foreseeable risks or harms for participants in this study.

Naturally, some of these questions of the questionnaire and interview might be sensitive in nature (i.e. questions about anxiety, depressed mood etc.) and might elicit emotional changes in you. Participants will not be obliged to answers questions that make them feel uncomfortable. If they feel distressed due to participation in this study, the service of the perinatal mental health team at Mater Dei Hospital in Malta will be available at no financial cost on your part. This team

may be contacted on +356 25457410 or by sending an email to perinatalmentalhealth.mdh@gov.mt.

By agreeing to participate in the study, the woman will benefit by having your mental health needs addressed by expert professionals in the perinatal mental health field. Furthermore, she may also be selected to receive the VIG intervention to build on your relationship with her baby. Additionally, if the VIG intervention proves to be be beneficial and efficacious for mothers and infants receiving this intervention, it will also be offered to participating mothers in the other study groups.

Where is the study run from?
The study will take place from community general adult and perinatal mental health clinics as part of National Health Services in Malta, an island with an annual birth rate of around 4500 births, located in the centre of the Mediterranean.

When is the study starting and how long is it expected to run for?
September 2020 to September 2024

Who is funding the study?
This project has been funded through the Voluntary Organisations Project Scheme managed by the Malta Council for the Voluntary Sector supported by the Ministry for Inclusion, Voluntary Organisations and Consumer Rights (MIVC) and the Tertiary Education Scholarship Scheme financed by the Ministry for Education, Sport, Youth, Research and Innovation in Malta.

Who is the main contact?
Dr Rachel Buhagiar, rachel.buhagiar.07@um.edu.mt

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil Known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The effectiveness of video interaction guidance on maternal-infant interactional quality in postpartum mothers with perinatal mental health illnesses: a pilot randomised controlled trial

Acronym
VIGinPMH

Study objectives
1. Perinatal mental health disorders are associated with less sensitive and less synchronous parent-child interactions.
2. Participation in Video Interaction Guidance (VIG) intervention is associated with better maternal-infant interactional quality, that is more sensitive-cooperative mother-child patterns, higher dyadic synchrony, and lower relational risk, when compared to the dyadic mother-baby relationships who do not receive this intervention.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/05/2022, Faculty Research Ethics Committee (Faculty for Social Wellbeing, Room 113, Humanities A Building, University of Malta, Msida, -, Malta; +356 23402237; research-ethics.fsw@um.edu.mt), ref: 9798_30092021

Study design
Single-centre interventional two-arm individually pilot randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
The mother-infant interactional quality in women with postpartum mental health disorders and their infants

Interventions
Current interventions as of 02/07/2024:
A total of around 50-60 mother-infant dyads, where the child is aged 0-12months (inclusive), and the mother is identified to be suffering from one or more mild-moderate mental health illnesses will be recruited from community-based general adult and perinatal psychiatry services. Self-referrals or referrals from any other healthcare professionals will also be considered.

Eligibility for inclusion into the trial will involve a two-stage procedure. Interested participants will first be screened for possible mental health illnesses using two self-report measures, the Edinburgh Postnatal Depression Scale (EPDS) and the Generalised Anxiety Disorder-7 item (GAD-7) scale. If the total score in any of these two symptom scales is equal to or above the selected cut-off values (9 or above in the GAD-7; 11 or above in the EPDS), the Structured Clinical Interview for DSM-5 (SCID-5) diagnostic assessment will be administered to confirm or refute the presence of a psychiatric disorder, and therefore eligibility for the trial. This assessment will be performed by a trained mental health practitioner with no other involvement in the trial.

Upon confirmation of eligibility for inclusion into the study, participants will be allocated to one of the two study groups, intervention or control, through randomisation by minimisation using a computer program. The randomisation procedures will be completed by an independent third party. Each participant in both groups will receive treatment-as-usual (TAU), consisting of an initial 60-minute assessment by one of two qualified and experienced perinatal psychiatrists (EF /EA) with subsequent regular 30-minute follow-up sessions, every few weeks, as per clinical need. Medications may be offered if indicated with the woman's informed consent. The control group will only receive TAU.
Participants in the intervention group will receive three sessions or cycles of one-to-one Video Interaction Guidance (VIG) intervention, in addition to the TAU. These three cycles will be delivered every 2-3 weeks over a period of 3 months, starting soon after treatment allocation. Each cycle or session will consist of (1) a video recording of the parent-child interaction during play or any other everyday caregiving activity for around 8- 10 minutes, (2) editing of the original recording by the practitioner, and (3) a shared review of around 30 minutes whereby the parent and practitioner will jointly review and discussed the recordings. This intervention will be provided by the main researcher (RB) who is an accredited VIG practitioner. It will be delivered within clinics or participant's homes. The total duration of participation in the trial, starting from recruitment to the end of treatment administration, will be approximately 6 months for both groups.

A combination of self-report and clinician-rated instruments will be used for assessment and as outcome measures. The collection, scoring and analysis of these scales will be performed by independent persons with no other involvement in the study. These will be completed pre-intervention and immediately post-intervention.

Previous interventions:
A total of around 60-70 mother-infant dyads, where the child is aged 0-11 months (inclusive), and the mother is identified to be suffering from one or more mild-moderate mental health

illnesses will be recruited from community-based general adult and perinatal psychiatry services. Self-referrals or referrals from any other healthcare professionals will also be considered.

Eligibility for inclusion into the trial will involve a two-stage procedure. Interested participants will first be screened for possible mental health illnesses using two self-report measures, the Edinburgh Postnatal Depression Scale (EPDS) and the Generalised-Anxiety Disorder-7 item (GAD-7) scale. If the total score in any of these two symptom scales is equal or above the selected cut off values (9 or above in the GAD-7; 11 or above in the EPDS) , the Structured Clinical Interview for DSM-5 (SCID-5) diagnostic assessment will be administered to confirm or refute the presence of a psychiatric disorder, and therefore eligibility for the trial. This assessment will be performed by a trained mental health practitioner with no other involvement in the trial.

Upon confirmation of eligibility for inclusion into the study, participants will be allocated to one of the two study groups, intervention or control, through randomisation by minimisation using a computer program. The randomisation procedures will be completed by an independent third party. Each participant in both groups will receive treatment-as-usual (TAU), consisting of an initial 60-minute assessment by one of two qualified and experienced perinatal psychiatrists (EF /EA) with subsequent regular 30-minute follow-up sessions, every few weeks, as per clinical need. Medications may be offered if indicated with the woman's informed consent. The control group will only receive TAU.
Participants in the intervention group will receive three sessions or cycles of one-to-one Video Interaction Guidance (VIG) intervention, in addition to the TAU. These three cycles will be delivered every 2-3 weeks over a period of 3 months, starting soon after treatment allocation. Each cycle or session will consist of (1) video-recording of the parent-child interaction during play or any other everyday caregiving activity for around 8- 10minutes, (2) editing of the original recording by the practitioner, and (3) a shared review of around 30 minutes whereby the parent and practitioner will jointly reviewed and discussed the recordings. This intervention will be provided by the main researcher (RB) who is an accredited VIG practitioner. It will be delivered within clinics or participant's home. Total duration of participation in the trial, starting from recruitment to the end of treatment administration, will be of approximately 6 months for both groups.

A combination of self-report and clinician-rated instruments will be used for assessment and as outcome measures. The collection, scoring and analysis of these scales will be performed by independent persons with no other involvement in the study. These will be completed pre-intervention and immediately post-intervention.

Intervention Type
Behavioural

Primary outcome measure
Mother-infant interactional quality is measured in terms of maternal sensitivity, mother-infant dyadic synchrony, and relational risk, using the Infant Child-Adult Relationship Experimental Index (Infant CARE-Index) at baseline and immediately post-intervention (approximately 3 months). Each mother-baby film will be coded independently by two international coders with a research-level reliability qualification in this tool. Both coders will not be given any information about the trial, its hypothesis/aims, or participants.

Secondary outcome measures
1. Mother-infant bonding measured using the Postpartum Bonding Questionnaire (PBQ) at baseline and post-intervention (approximately 3 months).

2. Maternal depressive and anxiety symptoms measured using the EPDS and the GAD-7 at baseline and post-intervention.
3. Maternal reflective functioning measured using the Parent Reflective Functioning Questionnaire (PRFQ) at baseline and post-intervention.
4. Global psychological distress measured using the Clinical Outcomes in Routine Evaluation Outcome Measure (CORE-OM) at baseline and post-intervention.

Overall study start date
20/09/2020

Completion date
30/09/2024

Eligibility

Key inclusion criteria
Inclusion criteria include mother-infant dyads where the:
1. Women is 18 years or older AND
2. Resident in Malta AND
3. Not receiving any counselling support or any form of psychological interventions AND
4. Baby is aged between 0-11months (inclusive) AND
5. Baby was born at full term (37 weeks or beyond) AND
6. Baby's birth weight was at least 2000 grams.

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Women with acute and severe mental mental health pathology (such as psychosis, mania, or active suicidal thoughts or thoughts of harming the baby or others).
2. Women with active drug or alcohol dependence.
3. Women who are unable to consent to participation.
4. Women who are unable to read or converse in the English or Maltese language.

Date of first enrolment
15/03/2023

Date of final enrolment

30/06/2024

Locations

Countries of recruitment
Malta

Study participating centre
Mental Health Services, Malta (Community general adult and perinatal mental health services)
Notabile Road
Attard
Malta
ATD 9033

Sponsor information

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ROR
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Funder(s)

Funder type
Government

Funder Name

Voluntary Organisations Project Scheme, Malta

Funder Name
Tertiary Education Scholarship Scheme, Malta

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/02/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the main researcher (Dr Rachel Buhagiar: rachel.buhagiar.07@um.edu.mt)

IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			01/03/2023	No	Yes