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Protocol

The effectiveness of video feedback intervention on mother-infant interactional quality for women with perinatal mental health illnesses: protocol for a pilot randomised control trial

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ABSTRACT

Background: The literature strongly suggests that early parent-child relational interventions for at-risk dyads can support healthy infant development and attachment security. Video Feedback (VF) is a widely used attachment-based intervention, but evidence for its effectiveness with mother-baby dyads where there is maternal psychopathology remains limited.
Methods: This study constitutes a two-armed pilot randomised controlled trial aimed at evaluating the feasibility, acceptability, and preliminary benefits of Video Interaction Guidance (VIG), a type of VF, on mother-child dyadic interactional quality for postpartum women and their infants in Malta. Participants must be mothers with a baby aged 0-12 months who meet criteria for one or more mental health disorders on diagnostic interview. Exclusions are severe maternal mental illness, active drug dependence, being in receipt of in-patient care or therapy, or inability to speak English or Maltese. Consenting, eligible mothers are randomly allocated (minimised by infant age, relationship and employment status, and number of children at home), to either 3 cycles of one-to-one VIG intervention and treatment-as-usual (TAU), or to TAU only. Outcome assessors are blind to study arm allocation. The primary outcomes are parental sensitivity and dyadic synchrony coded using the CARE-index. Secondary outcomes are maternal depression and anxiety, bonding experience, capacity for reflective functioning, and well-being.
Conclusions: This is the first study on the preliminary effectiveness of VIG within perinatal services in Malta. Findings should guide future larger scale, definitive RCTs and subsequently inform health policy and management decisions in perinatal and infant mental health care.
Trial registration: Registered 16th March 2023 in ISRCTN registry (Trial ID: ISRCTN26320951).

Keywords: VF, Perinatal mental health, Mother-baby relationship, Dyadic synchrony, Parental sensitivity

INTRODUCTION

Perinatal mental health disorders (PMHDs) are highly prevalent conditions, ranging from the common depressive and anxiety disorders to the less prevalent but more serious bipolar affective disorder or puerperal psychosis.[1,2] These illnesses may have their first onset in pregnancy or postnatally, but they may also predate the perinatal period and be exacerbated during this specific life stage.

The importance of identifying and treating PMHDs in a timely manner is widely documented in the literature. Untreated maternal mental illness may impact negatively on the woman's well-being and the rest of the family unit, including the parent-child relationship.[3-5] The

parent-child relationship quality is a key determinant of the child's development and his/her future mental health.[6-8] Parents with psychological and/or psychiatric difficulties may be less appreciative and responsive to the child's needs, and/or exhibit lower engagement and stimulation with their children, whilst others may be too intrusive or over-stimulating in their interactions.[4,5,9,10] These suboptimal parenting behaviours may result in 'mismatched' parental responses to the child's needs, or lower parental sensitivity, a significant determinant of infant attachment security.[4,11,12] Mis-coordinated interactions will also affect the synchronicity of the parent-child interaction, or the reciprocal 'intricate dance' with shared affect which is commonly observed within a healthy mother-child dyad.

Considering the above, a substantial body of evidence supports the importance of managing parental psychiatric disorders but also offering concomitant evidence-based parenting interventions to mitigate risks to the child. It is known that the sole treatment of maternal or paternal mental health symptoms, for example with psychotherapy and medications, may not necessarily minimize risks to the mother-child relationship. It is thus essential that the dyadic relationship is specifically targeted through early intervention. By integrating attachment-based interventions alongside traditional perinatal models of care, parenting and parental sensitivity can be supported to offer protection to the child.[4,9,13,14]

One type of attachment-based intervention which has gained popularity in recent years is Video Feedback (VF). Many different types of this method exist, each with similar designs and which make use of video techniques to target parenting, in particular parental emotional availability. One type is Video Interaction Guidance or VIG for short. At the heart of this intervention which is focused on the adult-child relationship is the notion of inter-related connectedness, or 'shared moments of attunement'. The latter has been shown to be fundamental for a child's healthy development and functionality.[15-19] This intervention, like other VF methods, works by primarily targeting the behavioral level by means of video-recorded micro-moments of attuned parent-child interaction. Parents are engaged in a possible journey of change. The practitioner guides the caregiver to develop questions about aspects of their relationship with child which could be improved. The parent is then filmed interacting with the child for up to 10 minutes, with the aim of capturing "better than usual" moments of interaction. A few short clips and/or stills of positive interaction linked to the caregiver's targets for change are identified and then reviewed with the parent. The selected micro-moments are studied intensely by the practitioner and the parent, and together they work to identify aspects of the parent's behaviour which is contributing to the attuned relationship, to eventually reach the desired goal. In other words, VF is used to highlight, reinforce and to guide attuned and sensitive interactions. By observing these moments, parents can appreciate better the importance of these experiences for their own children and subsequently build on them.[20] The intervention empowers the parent and enhances his/he self-efficacy, whilst increasing parental sensitivity and attunement to the child, hence promoting the child's attachment security.[19]

VIG has been studied in a variety of populations of vulnerable children, such as with children with autism, hearing impairments and premature babies, and with parents or caregivers at risk.[21-23] The 2019 Cochrane review on the use of VF in children under five years stated that this treatment "can be provided to parents with wide-range challenges and in almost any setting".[24] This review was wide-focused and targeted a variety of clinical contexts, such as children with different forms of difficulties (e.g., prematurity) and parents who were facing challenges themselves (e.g., parental depression). However, very few of the included studies focused on parental mental health, meaning that no definite conclusions were drawn about the implications of VF with at-risk dyads where the parent has postnatal mental health difficulties. This proposed small-scale study is an important first step in bridging this gap in knowledge. In other words, by means of this methodologically rigorous pilot randomized control trial (RCT) focused on mothers with perinatal mental health problems, preliminary efficacy data for this intervention when applied to this population can be drawn and suggestions for further larger scale studies can be made.

Objectives

The primary goal of this pilot RCT is to: (1) assess the feasibility of a future RCT based on recruitment (consent and eligibility rates), withdrawals, drop-outs, and retention rates, and evaluate acceptability of the intervention in terms of uptake and completion rates. The secondary objective is to (2) provide preliminary evidence of efficacy for VIG in improving the mother-infant relational quality, for dyads where the mother is experiencing postpartum mental health difficulties. The two study arms include a control group (TAU) and an experimental group (VIG and TAU). Initial treatment effectiveness will be taken to include higher 'maternal sensitivity' and/or 'dyadic synchrony' scores from baseline to post-intervention.

Trial design

This study comprises a single-centre, two-armed, community-based, parallel group, individually randomised pilot trial with pre- and post-test quantitative assessments in which eligible mother-infant dyads are allocated (minimised by infant age, maternal employment status, maternal relationship status, and number of children residing at home) to one of two arms: i) TAU consisting of an initial assessment and regular follow-up

reviews by psychiatrists, and prescription of medications if indicated ii) three cycles of one-to-one VIG delivered over 12 to 16 weeks alongside standard care as delineated in (i).

METHODS

Study setting

This study will be conducted in Malta, the largest of the three Maltese Islands. Notwithstanding its small geographical size, the Maltese Archipelago is quite populous with a total of 514,564 inhabitants and an annual birth rate of approximately 4000 births.[25]

For pregnant and postpartum women in Malta, most of the maternity physical healthcare is provided from Mater Dei Hospital, the only hospital in the public health system in Malta. Less commonly, such services are also offered from governmental-run primary health care services, or health centres located across the island. Additionally, a minority of women living in Malta opt for private healthcare, rather than the freely available state healthcare mentioned above. However, these women represent a very small proportion of the perinatal population in Malta. In fact, the national obstetric information system (NOIS) reported that only 0.8% and 0.5% of deliveries in 2018 and 2019 respectively, occurred in private institutions.[26] For perinatal mental health, the service is community-based and freely available to all women during pregnancy and postnatally. To date, there exists no specialised in-patient mother-baby unit, where mothers can be admitted during pregnancy, or after childbirth with/out their baby for treatment and stabilisation. The perinatal mental health multi-disciplinary service receives approximately 400 referrals each year, the majority of which are self-referrals.

Study participants and eligibility criteria

Eligible women are mothers aged 18 years or above, resident in Malta, of any parity, who have a baby/infant aged between 0 to 12 months, and who meet one or more diagnostic criteria for a mental health disorder. The timing or onset of the mental health symptoms will not be relevant to participation unless it is a specified diagnostic criterion. Additionally, mothers have to have the capacity to provide informed consent and have a good understanding and command of either the English or Maltese language. Exclusions are mothers with acute and severe mental health pathology (such as psychotic mental illness, active suicidal thoughts, or thoughts of harming baby/others), and/or active drug or alcohol dependence, and/or receiving in-patient psychiatric care, and/or are in therapy, and/or with multiple babies, and/or have an infant with significant health-related complications and/or are involved in any other trial.

Interventions

Two study arms are included:

Control group

Every participant in both treatment groups will receive TAU. This includes an initial 60-90-minute assessment by a perinatal psychiatrist (EA or EF) whereby a detailed full psychiatric history will be undertaken, followed by 30-minute reviews every few weeks, as deemed necessary by the treating clinician. Depending on the woman's symptom severity, level of risk, and treatment preferences, medications may be offered. The prescription of drug therapy will be recorded for each participant. The control group will receive TAU only.

Intervention group

Mother-infant dyads in the intervention group will receive three cycles of one-to-one VIG intervention, alongside the TAU. The three VIG cycles will be delivered over a period of three to four months, starting soon after treatment allocation, with each cycle lasting around 60 minutes in total. Each cycle will consist of (1) video-recording the parent interacting with the child during play or any other everyday caregiving activity for around 8-10minutes, (2) the editing of the recording by the practitioner, and (3) a shared review of around 30 minutes whereby the parent and practitioner jointly review and discuss the recordings. These sessions will be provided by a psychiatrist who is also an accredited VIG practitioner, and the main author of this project (RB). This same person will not be involved in the recruitment, assessment and randomisation procedures. The possibility of conducting the intervention within the participant's own home environment will be offered to all participants. Alternatively, sessions will be carried out in clinics.

Research tools and outcome measures

A combination of self-report and clinician-rated instruments will be used in the screening and assessment procedures, and as primary and secondary outcome measures. These include the following:

Demographic sheet

A demographic and clinical characteristics sheet will be compiled by the main researcher and completed by participants at recruitment stage. It will include self reports of the woman's age, nationality, location of residence, relationship and employment statuses, educational level, parity and number of children living with her, whether pregnancy was planned or not, mode of delivery, delivery date, prematurity and birth weight, gender of baby, and any prescribed psychiatric medications.

Diagnostic interview

A clinician-administered semi-structured diagnostic interview for mental health disorders, the Structured Clinical Interview for DSM-5 (SCID-5), specifically the research version (SCID-RV) and the borderline disorder module from the personlity disorders version (SCID-PD), will be used to confirm or refute the presence of PMHDs.[27,28] The diagnostic assessment will be offered only to those participants who score 11 or higher in the EPDS and/or 9 or higher in the GAD-7 during the first-stage screening for eligibility. It will be performed within two weeks of completion of the questionnaires by a trained mental health professional with experience in psychiatric clinical practice.

Amongst others, the SCID assesses for mood disorders, psychotic disorders, obsessive-compulsive disorders, anxiety disorders, and trauma-and stressor-related disorders. This tool was selected to ensure systematic evaluation of some of major mental health diagnoses and to ensure that study population have current symptoms that meet DSM-5 diagnoses criteria. Whilst SCID-RV has not been assessed for its psychometric properties, clinician version of this same instrument has been found to have excellent reliability as well as the high specificity.[29]

Primary outcome measure

The well-established Infant Child-Adult Relationship Experimental Index (CARE-Index) (ICI) will be used to provide an objective assessment of the mother-infant interaction based on a 3-to-5-minute videorecording of a free-play session.[30] It evaluates the quality of the interaction and the maternal sensitivity within a relational context.[30] Whilst the ICI does not directly assess attachment patterns, it evaluates dyadic features which are associated with attachment, and therefore helps to identify infants at risk of attachment problems.[31] In the ICI, the adult is evaluated for parental sensitivity, control, and unresponsiveness, whilst the baby/infant is assessed for passiveness, compliance and/or cooperation. These scale descriptors are based on seven aspects of interaction behaviour related to assessment of affect (facial and verbal expression, position, body contact, affection) and temporal contingencies (turn-taking, control, and activity) within the dyad. The ICI also identifies false positive affect in mothers and their babies (compulsive patterns), which are often mis-identified as sensitive/cooperative dyads, but which are presumed to indicate high risk.[30] The outcome in the ICI includes a separate individual score for each of these different maternal and infant patterns and an overall rating of dyadic synchrony and relational risk. The total ICI score ranges from 0-14 with a high score reflecting high sensitivity, and vice versa.[30] Only the toddler CARE-Index has been assessed for its psychometric properties with evidence of good reliability and validity data.

Secondary outcome measures

Self-report scales for depressive and anxiety symptoms, the Edinburgh Postnatal Depression Scale (EPDS) and the Generalised Anxiety Disorder Scale-7 item (GAD-7) will be used. The EPDS is a well-validated 10-item scale for maternal depression, with each item having four possible reponses and a score ranging from 0 to 3.[32,33] A cut off value of 11 or higher was identified to have the maximised combined sensitivity and specificity (0.85 to 0.91).[34] In addition to EPDS which includes 3 items for anxiety symptoms, the GAD-7 questionnaire will be included as an anxiety screening measure. Its use was found to help differentiate clinically significant anxiety from normal perinatal-related worries.[35] Whilst its reliability and validation has been confirmed amongst the general population,[36] this has not been the case for perinatal women. Nonetheless, the combined use of the EPDS and the GAD-7 will decrease the chance of perinatal women with anxiety symptoms to remain undetected.

Maternal-infant bonding will be measured using the Postpartum Bonding Questionnaire (PBQ).[37] This 25-item self-report measure is rated on a 6-point Likert scale, and includes 4 sub-scales: ‘imparied bonding’, ‘rejection and anger’, ‘anxiety about care’, and ‘risk of abuse’. Scale 1 (impaired bonding) has a sensitivity of 0.93, meaning that it identifies over 90% of women with such difficulties.[37] This bonding instrument has acceptable reliability[38,39] and overall reasonable validity, with evidence of strong psychometric properties when compared to other parent-infant relationship and bonding measures.[40] There is also supporting evidence for the combined use of the PBQ and the EPDS to achieve an early diagnosis of bonding disorders and to provide insight into maternal feelings and attitudes towards the child.[38,39]

Maternal reflective functioning, or mothers’ ability for mentalisation, will be assessed using the Parental Reflective Functioning Questionnaire (PRFQ).[41] This self-report 18-item, multi-dimensional questionnaire explores the parent’s interest and curiosity in the child’s internal mental states and how these impact on the child’s behaviour.[42] There is evidence for the convergent validity of the PRFQ when analysed against the gold standard interview-based Reflective Functioning Scale, and also the preliminary evidence for its sensitivity to change.[41,43]

The extent of mothers’ level of psychological distress will also be assessed using the Clinical Outcomes in Routine Evaluation Outcome Measure (CORE-OM). The CORE-OM is a self-report 34-item questionnaire, consisting of 4 domains (subjective well-being, difficulties or symptoms, function, and risk) which are graded using a 5-point Likert scale.[44] Total scores vary between 0-136, with high scores representing poorer overall functionality. A score of 10 or above is recommended for determining clinical

significance.[45] The CORE-OM has good internal and test-retest reliability (0.75-0.95), as well as the convergent validity.

Timings of assessment and outcome measures

The demographic sheet and the EPDS and GAD-7 questionnaires will be completed at baseline or recruitment stage, followed by the SCID if threshold is met (Table 1). The remaining questionnaires (PBQ, PRFQ, CORE-OM) and the 3-minute mother-baby CARE-Index filming will be conducted only for mothers meeting full eligibility criteria and after their randomisation to one of the two treatment groups. These latter four assessments will be completed at two points, pre-intervention (immediately after randomisation), and post-intervention (at the end of study duration, that is within 2 weeks following the final (third) VF session for intervention group participants, and 4 months after date of treatment allocation for control group participants). The EPDS and GAD-7 will also repeated post-intervention (Table 1).

Table 1: Timing of assessment measures and data collection for participants.

Variables	Details and timing of data collection		
Instrument	**Baseline**	**Pre-intervention**	**Immediate post-intervention**
Edinburgh Postnatal Depression Scale (EPDS)	X		X
Generalised Anxiety Disorder-7 item (GAD-7)	X		X
Structured Clinical Interview for DSM-5 (SCID-5)	X		
Demographics	X		
Postpartum Bonding Questionnaire (PBQ)		X	X
Parental Reflective Functioning Questionnaire (PRFQ)		X	X
Parental Reflective Functioning Questionnaire (PRFQ)		X	X
Infant CARE-Index (ICI)		X	X

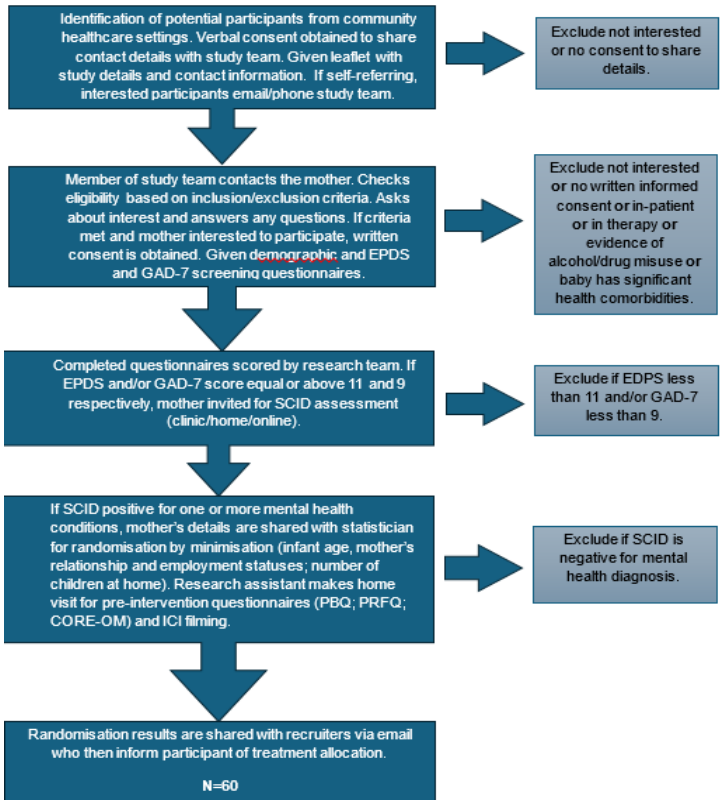

Figure 1: Participant timeline from time of referral to randomisation process.

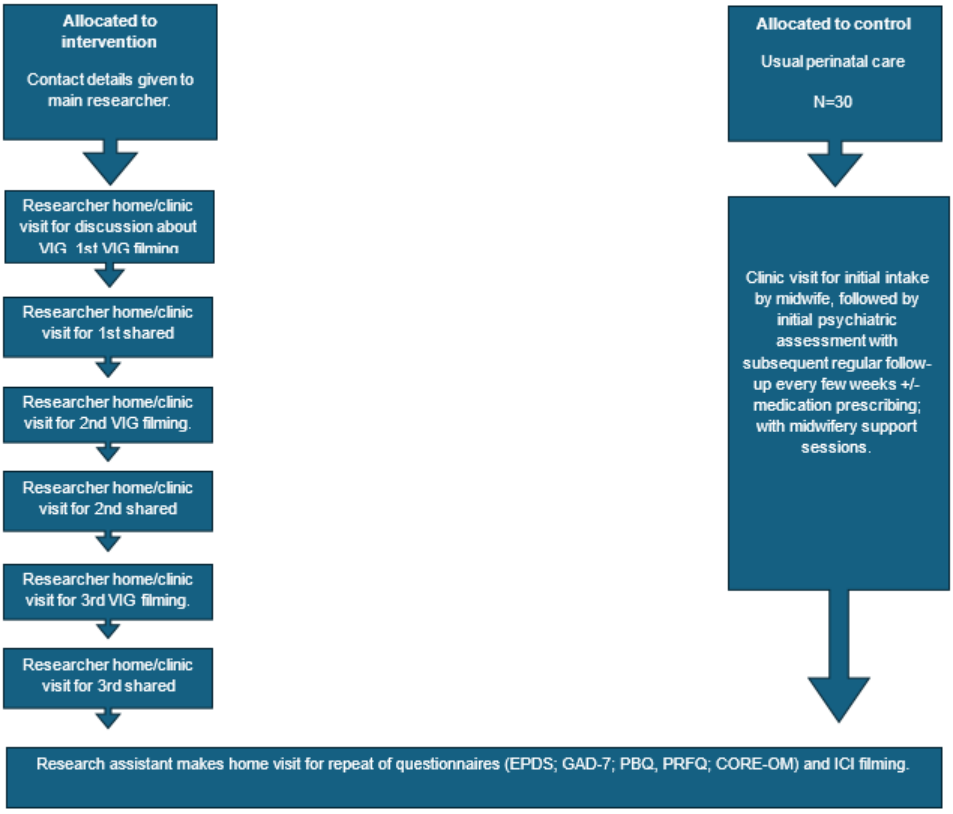

Figure 2: Participant timeline from treatment group allocation by randomisation to end of participation.

Participant timeline

The trial start date was September 2022 and it is anticipated that the study will be completed by August 2024. Recuitment commenced in March 2023. Figure 1 and Figure 2 display details of participant timeline from the time of referral through to the end of the study. Both the control and intervention arms will receive their respective treatment for a total duration of approximately 4 months.

Sample size

The sample size for the pilot trial was calculated based on the standardised effect size reported by O'Hara and colleagues for our main outcome of interest, parental sensitivity.[24] A small to medium effect size of 0.44 was identified for parental sensitivity for VF interventions for parent-child dyads under the age of 5 years. For such an effect size, sample sizes of 25 to 15 per study arm for pilot studies is recommended.[46] Each treatment arm in this study will include 30 mother-baby dyads, hence the total study population will be of 60 dyads.

Recruitment

Recruitment of potential eligible participants will take place through healthcare professionals (psychiatric nurses, perinatal midwives, psychiatry trainees etc) within community general adult mental health clinics. Referrals from other non-psychiatric healthcare settings (such as family practices or breastfeeding clinics) will also be considered. The referring healthcare professional will obtain the verbal consent of interested mothers to be contacted by the research team. The study will also be promoted on social media using posters. Interested participants will be asked to email or call the research team.

Referred mothers will then be contacted by a research assistant to share all details about the study and participation, and send them a copy of the information and consent sheets. Participants will be given the time and space to ask and clarify any questions. Also, eligibility will be confirmed against the inclusion and exclusion criteria by the research assistant.

As a next step, participants will be asked for their written consent and to complete the EPDS, GAD-7, and the demographic information sheet. Participants will return these documents to the research team by post or email. The reserch assistants will score the received questionnaires. Depending on the total EPDS and/or GAD-7 scores, participants may be invited for the SCID diagnostic interview, which will take place in person or remotely, depending on the person's preference. This assessment will be conducted by a qualified mental health professional. Women will be included in the study if diagnostic criteria for at least one psychiatric disorder, including BPD, is met.

Randomisation and allocation

A random deterministic minimisation program will be used to produce two study groups balanced for infant age, number of children living at home, maternal relationship and employment statuses. Randomisation will be done by an independent statistician with no other involvement in the trial. The minimisation procedure will ensure balanced groups for the above-mentioned prognostic factors. Allocation to one of the two study arms is computer generated and delivered by email to the research assistant who then contacts the respective mother to inform her of the group allocation.

Blinding

Given the nature of the intervention, participants and the researchers cannot be truly blinded to treatment. However, clinicians providing perinatal psychiatric reviews to women in both study groups will not provided with any information about assigned treatment groups to protect against detection bias.[47] The same blinding procedures will be followed with the coders scoring the dyadic films, and with outcome assessors collecting and scoring the self-report questionnaires. Data collectors will also be masked to clinical information about the dyad and assigned treatment group.

Data collection and data management

Basic demograpic information about the woman, the pregnancy and birth, and the baby or infant's general health will be gathered from all participants in both study arms. Also, quantitative data from self-report outcome measures will be collected at time points specified above, and then scored by independent research assistants. None of this data will be collected by phone. Data collection will also include the 3 minute ICI mother-baby filming which will be recorded either at the participants' home or in clinics by the research assistants. The coding of these video-recorded observations will be performed independently by two qualified ICI coders with research level reliability. Any disagreement in scoring will be discussed and resolved between the two coders. All data will be inputted in a password protected excel scheet in a pseudoanonymised format, removing all identifiable participant details. Access to this data sheet will be restricted to the research assistants, main researcher and supervisors only.

Statistical methods

All descriptive analyses and measures of preliminary treatment effects will be conducted using the IBM SPSS statistics program. Baseline characteristics and demographic variables for both groups will collated in descriptive analyses and presented as numbers and percentagesin a table format. Narrative reporting with raw counts (numbers, percentages) will also be provided for all feasibility outcomes. These will include recruitment rates (number of eligible participants recruited each month), retention rate (proportion of randomised participants remaining in the study and evaluated using primary outcome measures), attrition rate (proportion of participants dropping out during recruitment, after confirmation of full eligibility, and during delivery of treatment) and uptake rate of the studied intervention (the ratio of participants who attend at least 2 out of the 3 VIG cycles).

Preliminary descriptive statistics on primary and secondary clinical outcomes will be provided to determine initial intervention effects.. The mean, standard devation (SD), and 95% confidence intervals (CIs) will be calculated for all continuous outcomes, that is dyadic synchrony and maternal sensitivity, depressive and anxiety symptoms, bonding, reflective functioning, and well-being. Change over time in outcome measures from baseline to post-test will be determined at both individual and group level for any clinically significant changes, and results of both groups will be compared to assess for intervention effects. Of note, since the trial sample size is small and underpowered, statistical testing will not be possible.

All outcome analyses will be completed according to intention-to-treat principle. Whenever possible, all eligible participants consenting to participation will be followed from pre- to post-intervention, even in the case of drop out during the course of the intervention. Effort will be made to collect outcome measures even for participants who drop out early from the study. If this is not possible, the principle of last value carried forward will be applied whereby the last available measure at the point prior to withdrawal from the study will be retained for subsequent analysis purposes. This process of considering all randomised participants in the final analysis, irrelevant of drop out or not, maintains sample size and minimises bias secondary to attrition of participants.[47] As a secondary, a pre-protocol analysis will also be included to assess whether any preliminary treatment effects of the studied intervention changes with complete adherence to study protocol. This will correct for any underestimation of treatment efficacy from the last value carried forward dataset.[48] The pre-protocol analysis will be completed using outcome data of participants completing their assigned intervention.

The number and points of drop-outs, as well as details/reasons for the attrition, especially if related to outcome of interest, will be documented, explored and analysed for their effect size to determine whether they had a clinically relevant effect or impacted on the final study results. Additionally, characteristics of these participants will be contrasted to those who completed their treatment course.

DISCUSSION

This is the first study to evaluate initial treatment effects of VF intervention within the perinatal population in Malta, and its success is dependent on the support of

healthcare professionals working with young families to identify potential eligible mothers. Given the lack of previous feasibility work in this field, as well as the potential difficulty to recruit to target as a result of the nature of population and type of intervention (filming technique etc.), the following progression criteria for a RCT are being recommended: (1) achieving target sample size on time, that is within 12 months from the start of recruitment (2) at least 50% of participants eligible for diagnostic interview consenting to this assessment (3) at least 75% of participants in intervention group completing all 3 cycles of VIG and (4) preliminary evidence of at least a small-to-medium size improvement estimate in dyadic synchrony and maternal sensitivity as measured on ICI for participants in the intervention group when compared to control participants. These feasibility and acceptability outcomes, and preliminary efficacy data, can provide guidance as to whether any amendments to present protocol are needed before a definitive RCT is considered. In other words, failure to achieve on or more of these criteria will not necessarily indicate that a future definitive RCT is unfeasible. Also, treatment effect estimates from pilot studies might be imprecise and therefore, decisions to progress to a main trial should not be based primarily on this result only.

CONCLUSION

We believe that results of this pilot RCT will be key in informing the feasibility of conducting a larger scale, powered RCT to later guide decision-making by policy-makers with regards to VF implementation within NHS family-focused services.

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