# Promoting Healthy Beginnings for Infants of Mothers with Perinatal Mental Health Illnesses

Dr Rachel Buhagiar

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MINISTRY FOR EDUCATION AND EMPLOYMENT

# Information Sheet

## Researcher: Dr Rachel Buhagiar

If you would like more detail about something mentioned hereunder, or information which is not included here, feel free to ask. *Please take the time to read this carefully and to understand any accompanying information.* The University of Malta has approved this research study. Ethics Approval ID is the following: 9798_30092021

## Purpose of the Study

You are kindly invited to participate in a study entitled "*The Effectiveness of Video Interaction Guidance on Maternal-Infant Interactional Quality of Mothers with Perinatal Mental Health Difficulties in Malta: A Randomised Control Trial"* which is being conducted by Dr Rachel Buhagiar, researcher from the Faculty for Social Wellbeing at the University of Malta. By participating, you will be helping us better understand the effect of a specific relationship-based intervention, named 'Video Interaction Guidance' or VIG for short, on the relationship quality between a mother who is experiencing mental health difficulties and her baby.

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 the mothers with mental health needs and her baby can be supported through VIG. We hope that this project will also help provide policy makers with evidence-based recommendations on how to safeguard this first and early life relationship and therefore, minimise the risk of future negative developmental sequelae for the young child.

## What will I be asked to do?

As a voluntary participant in this study, you will have an introductory session with the main researcher or the research assistant, in a place and at a time which is convenient for you, for approximately 30 minutes. If you prefer, this initial meeting can also take place over the phone or remotely. You will be provided with a research pack consisting of a welcome letter, information leaflet about the research and consent form. You will also be given the time and space to ask any questions about the research and your participation. If you then agree to participate, you will be asked to sign a consent form, a copy of which will be given for your records.

Data about your mental health needs will be collected through two different questionnaires: the Edinburgh Postnatal Depression Scale and the Generalised Anxiety Disorder 7-item. You will be asked to fill in these questionnaires which take around 5-10 minutes to complete. If you score above the cut-off point for any of these two questionnaires, you will be asked to attend for an interview with a trained mental health professional with vast experience in the field. This assessment, which will take around 30-45 minutes, will confirm or refute whether you are experiencing any mental health difficulties and therefore, your eligibility for the study. This assessment may take place in person or remotely.

Once your eligibility is confirmed, you will be asked to complete three other questionnaires about your bonding and parenting experiences, and your overall psychological well-being. This take around 5-10 minutes to fill in. You will also be video-taped playing with your child as you would normally do in everyday life for approximately 3 minutes.

Following this, you will be randomly assigned to one of two different groups. All participants in the two groups will be reviewed and followed-up by a perinatal psychiatrist for 6 months during which a collaborative treatment plan will be drawn up with you to address your needs.

1. A group of participants will receive psychiatric review and follow-up only.

2. A group of participants will receive psychiatric review and follow up AND the VIG intervention. The VIG intervention will consist of 2 steps (one cycle):

    a. Filming session of you with your baby for around 8-10minutes. During the filming, you will be asked to interact and play with your baby as you would generally do in your everyday life.

    b. A follow up session with the practitioner where you will have the opportunity to review together selected short clips or images taken from the original filming. These clips/images will be focused solely on positive moments of interaction between you and your baby. During this discussion session, you will learn more about your child. The practitioner will help you reflect on what you are seeing, on how you and your baby might be feeling, and how to continue building a positive relationship with him/her.

This two-step process, or cycle, will be repeated again after a few weeks.

At the end of these interventions, you will again be asked to fill in the same three questionnaires (mentioned above). Additionally, another 3-minute video clip of you and your baby playing together will be taken. This will be the end of your participation.

## What type of personal information will be collected?

Your email address and phone number will be collected to communicate with you regarding the follow-up questionnaires. Basic demographic details (such as age, marital statues, educational level etc) and information pertaining to your health (such as past medical, obstetric, and psychiatric history) will be recorded. However, none of this information will be attached to your data as it is stripped of identifiers before being processed, as described in the next paragraph. Your demographic variables will be used only for analysis and descriptive purposes.

As a participant, you have the right, under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, to access, rectify and where applicable ask for the data concerning you to be erased.

## What happens to the information I provide?

There will be no deception in the data collection process. Personal data will be pseudonymised, meaning that codes will be used to replace your name and any other personally identifiable information. Personal data will be processed by assigning a code to each participant and recording these codes but not the personal identification information on the data collection forms and assessments. These codes and associated personal information will be saved on a separate document, which will be stored securely and separately from the data collection forms and assessments. Your identity and personal information will not be revealed in any research outputs. Only group information will be summarised for any presentation or publication of results. These summary findings may be presented as part of a doctoral thesis, at conferences, and in journal articles. These completely anonymous data may also be used in follow-up studies. Should you choose to withdraw from the study, all data that you would have provided up until the point of your withdrawal will be removed from the final data set.

The data may only be accessed by the researcher. The academic supervisor/s and the examiners will typically have access to coded data only. There may be exceptional circumstances which allow the supervisor and examiners to have access to personal data too, for verification purposes. The videotapes and the data files will be stored on the researcher's personal computer that is password protected and in an encrypted format. Any material in hard-copy form will be placed in a locked cupboard. The 3-minute videotapes, showing faces of the mother and her baby/infant, will be shared with an international coder for scoring purposes only, using a secure server, which will also be password protected. The international coder, however, will not have access to any of your personal data or information.

Once the study is completed and the results are published, personal (identifiable) data, including video-recordings will be deleted, whilst any subsequent anonymised data will be retained for archival purposes for a period of around 5 years. In case of any incidental findings identified through the assessment/s, such data will be shared with my clinician with my consent, so that treatment can be adjusted according to my needs.

## Are there risks or benefits if I participate?

There are no reasonably foreseeable risks or harms to you as a participant 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. You are not obliged to answers questions that make you feel uncomfortable. If you feel distressed due to participation in this study, the service of the perinatal mental health team at Mater Dei Hospital will be available at no financial cost on your part. This team may be contacted on 25457410 or by sending an email to perinatalmentalhealth.mdh@gov.mt.

By agreeing to participate in the study, you will benefit by having your mental health needs addressed by expert professionals in the perinatal mental health field. Furthermore, you may also be selected to receive the VIG intervention to build on your relationship between you and your 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.

## Am I obliged to participate?

No, you are not obliged to participate in this study. Your participation in this study is completely voluntary, and you are free to accept or refuse to take part without giving a reason. You may also end participation and/or withdraw from the study at any time without penalty or explanation.

## Questions/Concerns

If you have any further questions or want clarification regarding this research and/or your participation and/or if you have any questions concerning your rights as a possible participant in this research, please contact me Dr Rachel Buhagiar (email rachel.buhagiar.07@um.edu.mt; contact number 99796347) or my supervisor Dr Kristina Bettenzana on kristina.vella@um.edu.mt.

# Consent Form

I, the undersigned, give my consent to take part in the study conducted by Dr Rachel Buhagiar. The purpose of this document is to specify the terms of my participation in this research study.

1. I have been given written and verbal information about the purpose of the study and all questions have been answered.
2. I understand that I have been invited to participate in a study, in which the researcher will ask questions and perform tests to investigate the effectiveness of an intervention called Video Interaction Guidance in improving the interactional quality of the mother-child relationship for mothers with mental health difficulties in Malta.
3. I am aware that the total duration of participation will take approximately 6 to 9 months. I understand that these sessions will be conducted in a place and at a time that is convenient for me. Some sessions may also be offered remotely.
4. I am aware that the interview session or diagnostic assessment, which will take approximately 30 to 45 minutes, will audio-recorded by means of the Zoom video recording function. This video recording device will have end-to-end encryption security feature and be GDPR compliant.
5. I am aware that some sessions will be video-recorded as part of the assessment and intervention and data will be written on the prepared record forms. Specifically, the three-minute video clip of me and my baby will be shared with international coders for scoring purposes, using a secure server which is also password protected. I understand that these short video clips which will be shared with international coders will show my face and that of my baby.
6. I am aware that all personal data needed for this research will be collected by the researcher herself and no data will be obtained from my personal medical records. Furthermore, I understand that this data, will be coded and stored securely and separately from any codes and personal data.
7. I am aware that the researcher is the only person who has access to this data. The academic supervisor/s and examiners will typically have access to coded data only. There may be exceptional circumstances which allow the supervisor and examiners to have access to personal data too, for verification purposes.
8. I am also aware that the video-recordings and data files will be stored on the researcher`s personal computer that is password protected and in an encrypted format. Any material in hard-copy form will be placed in a locked cupboard and kept until results are published.
9. I am aware that my identity and personal information will not be revealed in any publications, reports or presentations arising from this research.
10. I also understand that I am free to accept, refuse or stop participation at any time without giving any reason. This will have no negative repercussions on myself, and that any data collected form me will be erased. Data will be stored anonymously if it is impossible to delete (e.g., if it has already been anonymised).
11. I also understand that my contribution will serve to better understand whether Video Interaction Guidance is effective in strengthening the bond and relationship quality of mothers with mental health needs and their young children. This intervention will benefit individual mothers and their babies in developing more healthy and positive relationships early on after childbirth. This is known to result in long-term positive consequences on the child's development and his/her later success in life. Furthermore, I understand that participating mothers will receive professional help and support from qualified perinatal specialists for their ill-mental health issues.
12. If I feel distressed because of participation in this study, the perinatal mental health services at Mater Dei Hospital (contact number of this service 25457410) will be available to provide a service at no financial costs on my part. Whilst there are no reasonably foreseeable risks or harm to you or your baby as participants in this study, naturally some questions of the questionnaires and interviews

might be sensitive in nature (e.g., questions about anxiety, depressed mood etc.) and might elicit emotional changes in you. I will not be obliged to answer questions that make me feel uncomfortable.

13. I understand that under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, I have the right to access, rectify, and where applicable ask for the data concerning me to be erased.
14. I also understand that once the study is completed and results are published, all personal (identifiable) data, including video-recordings will be deleted, and the rest of the data will be retained in anonymous form for archival purposes for a period of around 5 years.
15. In case of any incidental findings identified through the assessment/s, I consent for this data to be shared with my clinician so that treatment can be adjusted according to my needs.
16. I will be provided with a copy of the information letter and consent form for future reference.
17. I have read and understood the points and statements of this form. I have had all the questions answered to my satisfaction, and I agree to participate in this study.

**Participant name:** _____

**Signature:** _____

**Date:** _____


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**Dr Rachel Buhagiar**
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99796347


For office use only: Participant _____