Children's Hospital of Philadelphia

Informed Consent and HIPAA Authorization Form

Study Title: The Social Media-Based Parenting Program for Women with Postpartum Depressive Symptoms

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Principal Investigator: James Guevara MD, MPH Telephone: (215) 590-1130

Study Overview

You and your child are being asked to take part in this research study because you screened positive for postpartum depression symptoms.

This is a research study to learn more about how a social media-based parenting program can improve responsive parenting, or how you behave and interact with your child while playing, among mothers with postpartum depression symptoms.

Your participation will include 4 study visits (which may be completed from home) over 3-6 months that should each last less than one hour. If you take part, you will be asked to:

- Complete questionnaires;
- Engage with an online depression treatment program.
- Participate in a social media parenting program.

The main risks of this study are from the study measures. These include breach of confidentiality and embarrassment.

You may benefit directly from inclusion in this study if your depressive symptoms and parenting are improved as a result of the parenting intervention. In addition, participating infants may benefit directly from the study if their interactions with their mothers are improved as a result of the intervention. However, these benefits cannot be guaranteed.

Participation in this study is voluntary. If you do not choose to take part in this study, you can discuss other options with your doctor.

If you are interested in learning more about the study, please continue to read below.

In the sections that follow, the word "we" means the study doctor and other research staff.

How many people will take part?

About 75 families will take part in this study.

What is involved in the study?

The study involves answering questions about yourself and about parenting. You will answer questions about yourself, your social support, depressive symtpoms, parenting

competence, and parenting stress. You will be randomly assigned to the Parenting Program + MoodGym group or the MoodGym Alone group. If you are in the Parenting Program + MoodGym group, you will participate in a parenting program of 8 weekly sessions on Facebook about depression psychoeducation and behavioral activation, infant temperament, play, feeding, safety, sleep, parent-child interactions, and shared book reading. In either group, you will use MoodGym, an online program.

What are the study procedures?

Some of the procedures in this study will be repeated several times. Tests that are part of your regular, routine medical care will continue to be performed. Additional tests may be performed if any of your initial test results are not normal. The study involves the following tests and procedures.

Medical Record Review: We will review your child's medical records throughout the study to collect information about your medical history, current health, diagnosis, treatments, medications, and results of clinical tests.

Questionnaires/Surveys: You will be asked to complete questionnaires about demographics, income, social support, depressive symptoms, parenting competence, parenting stress, and use of mental health services. Any suspection of child maltreatment will be immediately reported.

Phone contact: If you screen positive for suicidality or severe depression when completing follow-up surveys, study psychologists will be immediately contacted and appropriate assessment and referrals will be made. The research team will be in touch on a weekly basis to monitor suicidality and severe depression symptoms and treatment.

Follow-up Reminders: We will send you study-related reminders throughout the study. These may be by phone call, letters, text message, and/or email. We will contact you by your preferred method.

Videotape Assessment: At the beginning and end of the study, you will be videotaped while free-playing with your child. If Study Visits 1 and/or 4 cannot be conducted in person, you may be asked to videotape yourself free-playing with your child at home on a smart phone or tablet. We may then ask you to upload the video to a secure cloud-based service called BOX, that is available through a free mobile application and used by CHOP to securely store files. Instructions for recording home videos will be provided if necessary. If you do not complete the videotape assessment of you and your child playing together at Study Visit 1, you will no longer be able to participate in the study.

Randomization: You will be randomly assigned (like the flip of a coin or drawing lots) to one of two groups: the Parenting Program + MoodGym group or the MoodGym Alone group. You will have a 50% chance of being assigned to either group.

You may be randomized to the MoodGym Group or the Social Media-Based Parenting Program Group.

MoodGym: If you are assigned to this group, you will be asked to use an online behavioral treatment program that includes interactive exercises, workbooks, anxiety and depression quizzes, and downloadable relaxation audio files. We will

also provide a contact person to check-in by text or email and encourage use of MoodGym. Additionally, at the completion of the study, you will be asked to complete a MoodGym Acceptability Survey that will address satisfaction and your overall feelings towards the content and quality of the program.

Social Media-Based Parenting Program & MoodGym: If you are assigned to this group, you will be asked to use an online behavioral treatment program (MoodGym, described above) and you will be asked to participate in a parenting program of 8 weekly sessions on Facebook about depression psychoeducation and behavioral activation, infant temperament, play, feeding, safety, sleep, parent-child interactions, and shared book reading. Additionally, at the completion of the parenting program, you will be asked to complete an Acceptability Survey and a MoodGym Acceptability Survey that will address satisfaction and your overall feelings towards the content and quality of the programs.

It is not known which group improves responsive parenting among mothers with PPD. The group you are assigned to may prove less effective.

Visit Schedule

The table below provides a brief description of the purpose and duration of each study visit.

Visit	Purpose	Main Procedures	Duration	Location
Visit 1 *Enrollment + First Study Visit*	Informed consent, screening, randomization, surveys, videotaped free play with cihld	We will ask you questions and give you forms to fill out. You will also free play with your child for a video recording.	1 hour	In person at a CHOP Primary Care center or other location. Surveys may be completed in person, by email or by telephone. If the visit cannot be completed in person, videos may be recorded offsite and sent securely to the study team.

Visit 2 *1 month after Visit 1*	Surveys about depression symptoms and service use	We will ask you questions and give you forms to fill out. Participate in MoodGym (and Parenting Program if in the MoodGym + Parenting Program)	10 minutes	In person, by email, or by telephone
Visit 3 *2 months after Visit 1*	Surveys about depression symptoms and service use	We will ask you questions and give you forms to fill out. Participate in MoodGym (and Parenting Program if in the MoodGym + Parenting Program)	10 minutes	In person, by email, or by telephone
Visit 4 *3 months after Visit 1*	Surveys about depression symptoms, service use, and parenting.	We will ask you questions and give you forms to fill out. You will also free play with your child for a video recording.	1 hour	In person at a CHOP Primary Care center or other location. Surveys may be completed in person, by email or by telephone. If the visit cannot be completed in person, videos may be recorded offsite and sent securely to the study team.

Will I receive any results from the tests done as part of this study?

Results that could be important for your clinical care will be shared with you. We will not share other results with you.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to your study doctor or your regular doctor.

While in this study, you are at risk for the following side effects:

Risks associated with Breach of Confidentiality: As with any study that collects data, there is the possibility of breach of confidentiality. Every precaution will be taken to protect your personal information to ensure confidentiality.

When you enroll, you will be assigned a study identification number. This number will be used on data collection forms and in the database. We will maintain a separate list that links your name to this number for future reference and communication.

Risks associated with completing questionnaires/surveys: You may feel uneasy about answering some questions that may seem personal. You do not need to answer questions that make you feel uncomfortable. You may stop at any time.

Risks associated with randomization: You will be randomly assigned (like the flip of a coin or drawing lots) to one of two groups: the Parenting Program + MoodGym group or the MoodGym Alone group. You will have a 50% chance of being assigned to either group.

It is not known which treatment works best. The treatment group you are assigned to may prove less effective than the other study group or other available treatments.

There are no risks from randomization per se. The risks are all attributable to the risks of various treatment assignments.

Risks associated with videotaping: At Visit 1 and Visit 4, you will be video-recorded so that we can review your behavior and interactions with your child during free-play.

There is the possibility that your video might be seen by someone outside of the study team. To prevent this, the recordings will be kept on password-protected computers. Any hard copies will be kept in locked cabinets.

Risks associated with MoodGym and Parenting Program: You may feel uneasy while participating in MoodGym and/or the Parenting Program. You do not need to participate in modules that make you feel uncomfortable. You may stop at any time.

Are there any benefits to taking part in this study?

You might benefit if your depressive symptoms and parenting are improved as a result of the parenting intervention. In addition, your child may benefit directly from the study if their interactions with you are improved as a result of the intervention. However, we cannot guarantee or promise that you will receive any direct benefit by participating in

this study. The knowledge gained from this research may help doctors determine ways to help mothers with postpartum depressive symptoms.

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

Please also note that if you do not complete the videotape assessment of you and your child playing together at Study Visit 1, you will no longer be able to participate in the study.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You do not have to take part in order to receive care at CHOP.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you and your child will be collected. This will include information from medical records, procedures, interviews, and surveys. Information related to your child's medical care at CHOP will go in their medical record. Medical records are available to CHOP staff. Staff will view your child's records only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP;
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.

- The National Institutes of Health (NIH) who is sponsoring this research;
- Public health authorities that are required by law to receive information for the prevention child abuse.

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

The identifiable information from this study will be destroyed six years after the study is completed.

Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Certificate of Confidentiality (CoC)

A Certificate of Confidentiality (CoC) covers this research. A CoC helps protect your identifiable information and biological samples.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable information for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The National Institutes of Health (NIH) may need information to assess this project.
- You can still share information about yourself. You can also freely discuss your involvement in this research.
- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. James Guevara
The Children's Hospital of Philadelphia
Department of General Pediatrics

34th Street and Civic Center Blvd.
Philadelphia, PA 19104

Telephone: (215) 590-1130

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Additional Information

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study.

You will be informed if changes to the study are needed to protect your health. You will be told about any new information that could affect your willingness to stay in the study, such as new risks, benefits or alternative treatments.

Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

Will there be any additional costs?

If you use the parenting portal on a mobile device, data rates may apply.

Will you be paid for taking part in this study? You will be compensated $50 to offset the costs of cellular data charges for the duration of the study.

- You will be paid $50 after completing Study Visit 1
- You will be paid $5 after completing Study Visits 2 and 3
- You will be paid $50 after completing Study Visit 4

If you receive payment using a bankcard, the bank will have access to identifiable information. The bank will not have access to any medical information.

You will be offered the option of arranged transportation to Study Visits 1 and 4, or travel reimbursement:

- If you have a car seat, we may be able to arrange transportation for you and your child. If your travel to CHOP (e.g. car ride) is arranged and paid for by the study team, the agency making the reservations and their representatives will have access to identifiable information.
- If you do not have a car seat, or would like to arrange your own transportation, we can reimburse you for your travel expenses based on mileage. The reimbursement will be given on your pre-paid CHOP-issued debit card. The study team will also be able to provide a courtesy parking pass that will be given to you at the time of the visit.

Who is funding this research study?

The National Institutes of Health is providing funding for this study.

What if you have questions about the study?

If you have questions about this study or how your samples/data are going to be used, call the study doctor, Dr. James Guevara at 215-590-1130. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Sharing Data with the National Institutes of Health (NIH)

Why will my data be shared with the National Institutes of Health (NIH)?

The NIH is funding this study. The NIH's goal is to maximize the benefits that come from the research.

The National Institutes of Mental Health (NIMH) requires a data transfer every six months as part of the NIH grant to the NIMH Data Archive (NDA). During the course of the study and after its completion, we will send the information about you and the other participants to the NDA repository at the NIH, where the data is stored and managed. The NIH then shares that information with researchers. The information will be de-identified (no names or other direct information about you will be included). The NIH will not be able to re-identify you or any other individual.

The NIH intends to share the collected information with other researchers for future research. The researchers who receive data must promise to keep the data confidential and to use it only for the purpose approved by NIH. They must also promise to not try to re-identify anyone.

Risks Associated with Sharing Data with the NIH

There are risks associated with sharing your data with the NIH but they are very unlikely to occur. There is only a very small chance that someone could find out that the data came from you.

Benefits Associated with Sharing Data with the NIH

Sharing your information for future research will not directly benefit you. It is hoped that it will lead to a greater understanding of mental health. This knowledge could help others in the future.

Controlled or Unrestricted Access

The data about you will either be made available by the NIH through controlled access or unrestricted. Controlled access means the data are made available for other research only after investigators have obtained approval from NIH to use the requested data for a particular project. Data for unrestricted access are publicly available to anyone.

What will be done with my data when this study is over?

We will use and may share data for future research. They may be shared with researchers/institutions outside of CHOP. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your data.

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part and to allow your child to take part in this research study, and you are legally authorized to consent to your child's participation. You are also agreeing to let CHOP use and share the health information that will be collected for this study, as explained above. If you don't agree to the collection, use, and sharing of health information, you and your child cannot participate in this study.
NOTE: *A foster parent is not legally authorized to consent for a foster child's participation.*

Consent for Child's Participation

Name of Subject	
Name of Authorized Representative	Relation to subject: ☐ Parent ☐ Legal Guardian
Signature of Authorized Representative	Date

Consent for Mother's participation

Name of Mother	
Signature of Mother	Date