Clinical Study Protocol

Title:	**Social Media Intervention for Women with Postpartum Depression**
Short Title	PPD Social Media Intervention
Regulatory Sponsor:	
eIRB Number:	14-011491 v 12
Protocol Date:	9/11/2015

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ABBREVIATIONS AND DEFINITIONS OF TERMS

PPD	Postpartum Depression
PIWI	Parents Interacting with Infants
EPDS	Edinburgh Postnatal Depression Scale
BDI-II	Beck Depression Inventory-II
PSOC	Parenting Sense of Competency
PICCOLO	Parenting Interactions with Children: Checklist of Observations Linked to Outcomes
REDCap	Research Electronic Data Capture
DOT	Developmental Observation Topic
TFI8	Therapeutic Factors Inventory-8

ABSTRACT

Context: (Background)

Postpartum depressive symptoms are common among women following the birth of a child and can adversely impact a mother's ability to care for her child. Evidence-based parent coaching programs have been developed to guide mothers with caring for their infants but do not address the effects of depression on parenting, can be expensive to administer, and are not available in a format that facilitates participation by women with depressive symptoms.

Objectives: (primary and important secondary objectives)

1) To develop a parent coaching program for women with postpartum depressive symptoms utilizing a social media format to enhance participation.
2) To assess the feasibility and acceptability of the social media program compared to a traditional group format.
3) To explore outcomes related to each format.
4) To understand the mothers' perceptions of the relationship between postpartum depression and breastfeeding.

Study Design:

Pilot randomized controlled trial will be conducted comparing two versions of the parent coaching program: social media and traditional in-person group formats. Additionally, up to 20 mothers will be interviewed about their infant feeding experiences

Setting/Participants:

We will recruit participants who are at least 15 years old, the mother of a child 1-3 months old, have internet access on a smart phone or computer, and are attending their child's 2-month well child visit and screen positive for depressive symptoms.

We will be recruiting from three urban sites affiliated with the Children's Hospital of Philadelphia (CHOP Care Network Karabots, South Philadelphia, and Cobb's Creek). The combined total enrollment number of participants will be 180, or 90 dyads (90 mothers and 90 infants).

Study Interventions and Measures:

The intervention will consist of an eight session parent coaching program based on The Parents Interacting with Infants (PIWI) program. Each session will cover a different topic related to parenting. The topics are: Stress and Depression, Sleeping, Feeding, Books and Reading, Laughter, Safety, Temperament and Personality, and Playtime.

Feasibility (% who attend each group session or like each electronic session) and Acceptability (% who report they agree or strongly agree with statements concerning program effects-Satisfaction Questionnaire) are the main outcomes.

BDI-II, TFI8, PSOC collected via REDCap, PICCOLO will be secondary outcomes.

1 BACKGROUND INFORMATION AND RATIONALE

1.1 Introduction

Postpartum depression (PPD) is common following the birth of a child, occurring in up to 15% of women (Pearlstein, Howard, Salisbury, & Zlotnick 2009; Horowitz & Goodman 2005; Marcus 2009; Vesga-Lopez, Blanco et al. 2008). PPD is especially common among poor women, where environmental stressors such as poverty and homelessness contribute additional risk to the development of depression following childbirth (Heneghan, Johnson et al. 2000; Heneghan, Silver et al. 1998). PPD adversely impacts a new mother's ability to nurture and care for her children (Field 1995; Field 2002; Hart, Field et al. 1998; Jones, Field et al. 1997). Depressed mothers are less likely to endorse positive parenting behaviors such as playing and interacting with children than non-depressed mothers and more likely to endorse negative parenting behaviors, including yelling, spanking, and displaying annoyance (Lyons-Ruth, Wolfe, & Lyubchik 2000). Depression may affect the mother-child relationship and contribute to disorganized infant attachment (Lyons-Ruth, Lyubchik et al. 2002). While breastfeeding can improve mother-child attachment as well as mothers' mood, mothers with depression are less likely to breastfeed (Gagliardi, Petrozzi, & Rusconi 2012; Mezzacappa & Katkin, 2002). As a result of these maladaptive parenting behaviors, many young children experience inadequate growth and developmental delays beginning by age 1 and cognitive and socio-emotional delays by age 4 (Hay 1997; Field 1998). These delays contribute to behavioral and developmental disorders and result in poor school readiness (Field 1995; Field 1998; Goodman, Rouse et al. 2011). The longer, chronic, and more severe the depression, the greater the behavioral impairment in children (Yates & McCollum 2011).

Given the increasing recognition of parenting dysfunction among depressed mothers following childbirth, parent coaching programs, which typically consist of a brief series of sessions delivered in individual or group formats, have been developed to improve a mother's parenting skills. These programs have a strong evidence base for improving maternal-child relationships, but it isn't clear whether such programs are effective among depressed mothers (Webster-Stratton 1994; Webster-Stratton 1981; Webster-Stratton 1983; Webster-Stratton & Hammond 1997; Webster-Stratton & Hammond 1998; Webster-Stratton, Reid, & Hammond 2004; Taylor, Webster-Stratton, et al. 2008; McCollum 2000; McCollum, Gooler, et al. 2001; McCollum, Yates, et al. 2007). In a previous study of 61 women with depressive symptoms, we sought to adapt a group parent coaching intervention for depressed parents and assess its effects. We randomized women to receive the parenting program immediately or after a four-month delay. Those in the immediate group reported better parenting competence with similar depressive symptoms as women in the delayed intervention group. However, few (47%) women in either arm attended any parenting sessions. These results suggest that parent coaching programs may help improve the parenting skills of depressed women but need an alternative format to better engage their participation.

1.2 Name and Description of Investigational Product or Intervention

The study intervention will be an adapted version of the Parents Interacting with Infants (PIWI) program, a validated public domain parent coaching intervention that seeks to

promote the social and emotional development of infants. It will be adapted for use with depressed parents by inclusion of educational material based on Beardslee's cognitive psycho-educational family model. A social media-based format of the adapted intervention will be developed using a Facebook platform.

1.3 Findings from Non-Clinical and Clinical Studies

N/A

1.4 Selection of Drugs and Dosages

N/A

1.5 Relevant Literature and Data

Depression adversely impacts a caregiver's ability to nurture and care for children. In a nationally representative survey, depressed parents were less likely to endorse positive parenting behaviors, including establishing daily routines, regular reading to a child, or daily playing with a child than non-depressed parents.(Lyons-Ruth, Wolfe et al. 2000) They were also more likely to endorse negative parenting behaviors, including yelling, spanking, and becoming annoyed with their children. After controlling for depressive symptoms, socioeconomic factors contributed little to explaining the variance in parenting behaviors. Whether depression is a causal mechanism in dysfunctional parenting or a correlate is not clear. Parenting practices of adults in some studies have been more closely associated with parenting practices they received as children than current depressive symptoms suggesting learned dysfunctional behaviors.(Cox, Owen et al. 1985; Belsky, Hertzog et al. 1986)

As such, depression has been associated with two dysfunctional parenting styles: withdrawn and intrusive.(Field 2002) Depressed parents who adopt a withdrawn style may become absorbed in their own thoughts, turn away from their children, and exhibit a restricted range of emotions.(Field 1995) These parents disengage from their children and only respond when children exhibit distress. Depressed parents who adopt an intrusive style tend to overstimulate, over-react, and exhibit easy irritability toward their children.(Jones, Field et al. 1997; Hart, Field et al. 1998) Intrusive parents are more likely to demonstrate anger and handle their children in a rough manner. In both situations, depressed parents may ineffectively model emotional expression and contribute to maladaptive emotional regulation and higher stress levels in children.(Field 1998; Ashman and Dawson 2002) In addition, depression may contribute to disorganized infant attachment strategies, particularly among groups of clinically depressed mothers.(Lyons-Ruth, Lyubchik et al. 2002)

Parental depression and its associated dysfunctional parenting behaviors is considered by Bright Futures Health Supervision Guidelines as "one of the greatest risk factors for child behavioral and mental health problems".(Hagan, Shaw et al. 2008) The impact of depression may differ depending on the developmental age of children.(Gladstone and Beardslee 2002)

In studies of mother-infant interactions, infants of depressed caregivers may appear withdrawn, vocalize little, have lower activity levels, and display less positive and more negative affect compared to infants of non-depressed caregivers.(Cohn, Mataias et al. 1986; Field 1995) In studies of toddlers, children of depressed caregivers may experience growth retardation and developmental delays beginning by age 1 and cognitive and socio-emotional delays by age 4.(Hay 1997; Field 1998) Among older children, children of depressed caregivers may develop behavioral problems at greater rates than children of non-depressed caregivers.(Field 1995; Field 1998) These behavioral problems encompass not only internalizing disorders such as anxiety and depression but also externalizing disorders including oppositional-defiant disorder and conduct disorder. The longer, chronic, and more severe the parental depression, the greater the behavioral impairment in children.(Keller, Beardslee et al. 1986)

Depressed caregivers are less likely to have positive relationships and good communication with their children as well as less likely to engage in appropriate disciplining strategies (Riley, Cioro et al. 2009). They are also less likely to establish daily routines or read and play regularly with their child. A national survey showed that depressed caregivers were more likely to endorse parenting behaviors such as yelling, spanking and becoming annoyed with their children (Cox, Owen et al. 1985; Belsky, Hertzog et al 1986). Despite availability of effective adult mental health services, depressed caregivers rarely seek treatment for themselves but will seek medical treatment for their children (Olson, Kemper et al. 2002). As the healthcare professionals who are in frequent contact with women of childbearing age, pediatricians are uniquely poised to assess depression among caregivers of young children and ensure successful treatment of the child (Olson, Kemper et al. 2002).

Thus, it is important to recognize depression among young parents. Unfortunately, depression in this population may not be readily apparent. Depression is poorly recognized during health care encounters by providers.(Heneghan, Johnson Silver et al. 2000) This may be, because only 57% of pediatricians feel responsible for recognizing depression in the parents of their patients.(Olson, Kemper et al. 2002) Furthermore, those who do feel responsible for recognizing depression rely mainly on clinical acumen which has been shown to under-identify depression compared to standardized screening tests.(Olson, Kemper et al. 2002) Providers are more likely to recognize depression among certain groups of high risk parents, e.g. parents who are impoverished, non-white, single parents, have children with chronic health conditions, or have children with reported fair/poor health status.(Heneghan, Johnson Silver et al. 2000; Casey, Goolsby et al. 2004; Heneghan, Chaudron et al. 2007)

Identifying depression in caregivers is only half the battle. Once parents are recognized as depressed in primary care settings, they need to be referred for mental health services where effective treatment can be implemented to reduce depressive symptoms and improve child

outcomes.(Weissman, Pilowsky et al. 2006) However, few parents complete referrals for psychiatric assistance.(Grupp-Phelan, Delgado et al. 2007) There are several reasons for this including stigma associated with attending mental health facilities, perception that depression does not impact parenting, the need for child care in order to access services, lack of social support, and lack of payment or insurance for mental health services.(Anderson, Robins et al. 2006; Dennis and Chung-Lee 2006)

1.6 Compliance Statement

This study will be conducted in full accordance all applicable Children's Hospital of Philadelphia Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46, 21 CFR Parts 50, 54, 56, 312, 314 and 812 and the Good Clinical Practice: Consolidated Guideline approved by the International Conference on Harmonisation (ICH). All episodes of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consent and assent, and will report unanticipated problems involving risks to subjects or others in accordance with The Children's Hospital of Philadelphia IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

2 STUDY OBJECTIVES

The primary objective of the study is to develop a parent coaching program for women with postpartum depressive symptoms utilizing a social media format to enhance participation.

Specific Aim 1: To determine the feasibility and acceptability of the social media-based format compared to the traditional group format.

Specific Aim 2: To explore the outcomes related to each format.

Specific Aim 3: To explore mothers' perceptions of the relationship between PPD and breastfeeding

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

This is a three-phase randomized controlled study with approximately 90 women participants and their infants who screen positive for postpartum depressive symptoms at well child visits. In phase I, the first two groups will be non-randomized pilot assessing the feasibility and acceptability of a social-media based parent coaching program for mothers with postpartum depressive symptoms, phase II will consist of a revision of the intervention based on the pilot in phase I, and phase III will consist of four groups that will be randomized to compare the social-media based platform to traditional platforms and will examine differences in outcomes. Recruitment for phases I and III will be conducted at three urban practices affiliated with The Children's Hospital of Philadelphia (CHOP). These

participating practices routinely screen mothers for depressive symptoms using the Edinburgh Postnatal Depression Scale (EPDS) at their child's 2-month well child visit. To be eligible to participate in the study, women must be at least 15 years old, the mother of a child 1-3 months old, have internet access on a computer or a smart phone, and screen positive (EPDS $\geq$9) for depressive symptoms. If an eligible participant screens positive for depressive symptoms at their child's 2-month well visit, they will be asked to consent to be contacted by research staff. Eligible women will complete informed consent.

Women in phases I and III will be enrolled in parenting interventions consisting of either 8 group sessions or membership in a Facebook secret user group over the course of 8 weeks. Women in phase I will be assigned to either the in-person group or the Facebook group by the investigators. Women in phase III will be assigned by randomization to one format or the other.

Women in phase I will complete measures of feasibility and acceptability only. Women in phase III will complete measures of feasibility and acceptability and measures of depressive symptoms (Beck Depression Inventory-II [BDI-II – Appendix 2] Scale) and parenting competence (Parenting Sense of Competency [PSOC – Appendix 3] scales) prior to and after the intervention. In addition, mothers will complete the Therapeutic Factors Inventory-8 (TFI8 – Appendix 11) to measure social cohesion of the group, and mothers and infants in phase III will be videotaped during a 16-minute free play using a standardized measure of parenting interaction (PICCOLO) following completion of the intervention. The measures will provide important information on the effects of parent coaching formats on a new mother's depressive symptoms, her sense of parenting confidence, and her parenting interactions with her infant.

Women who report ever breastfeeding in the demographic questionnaire will be contacted and asked if they are willing to be interviewed about their experiences with breastfeeding (Phase IV). If they agree, they will be consented separately for this phase and participate in an in-depth qualitative interview. Interviews will be conducted in person . Following consent and before the interview participants will be asked to complete a short questionnaire (Appendix 9) with questions regarding child's demographics and birth history. Following the questionnaire, participants will participate in a 30-60 minute interview that will be audio-recorded and later. An interview guide will be used to facilitate the interviews. Questions will focus primarily on their experiences with breastfeeding and specifically how feeding practices may or may not be influenced by mood and feelings. The interview guide is attached (Appendix 10).

Screening Phase

Mothers are eligible to participate in the study if they meet the following entry requirements:

- 15 years of age or older at the start of the study
- English speaking
- Mother of a child 1-3 months old
- EPDS score of 9 or higher
- Have internet access on a smart phone or computer.

Subjects will be screened as part of routine care for depressive symptoms. Those who screen positive and agree to be contacted will be referred to research staff. If research staff is present in the clinic at the time of the screening, they will obtain written informed consent from participants in private after their appointment. If they are not present, research staff will contact the participants by phone to schedule an in-person visit and obtain consent after verifying eligibility. Research staff will visit the participant either at their home or at a public place of their choosing. Participants will either be enrolled in the traditional or the social-media based parent coaching program platforms.

Informed consent will be obtained prior to any study related procedures being performed in person. Consent will include a discussion of study aims, procedures, measures, benefits, risks, and alternatives to participation. After consent, subjects will either be assigned to the traditional format or the social media format. In phase III, 60 subjects will be randomized to either the group format or the Facebook format. Regardless of their assignment, once they have consented to participate, they will be emailed a link to a Redcap survey containing a demographic questionnaire (Appendix 1) prior to the intervention and a satisfaction questionnaire (Appendix 5) following each week of the intervention. The phase III participants will complete the BDI-II and the PSOC scales previous to commencement of the parent coaching program. If they prefer, they can complete these measures in-person or by phone with the research staff.

3.1.1 Phase 1

In Phase 1 of the study, 15 women will be assigned to the traditional format followed by 15 women assigned to the social media-based platform. The traditional format group will attend 8 weekly group sessions scheduled at their convenience in the evening hours. They will receive a meal, childcare, and transportation tokens for attending. The women assigned to the social media format will be invited to join a Facebook secret user group. (Information about Facebook groups can be found in Appendix 7.) Facebook secret user group capabilities restrict membership to those invited by the group administrators, allow presentation of educational materials in video or text format, permit individual user comments and posts to be viewed only by user group members, and allow private and confidential questions to instructors. (Information about Facebook privacy can be found in Appendix 8.) Research staff will post materials from each weekly session over the course of the week and invite subjects to like or not like posted materials, post comments, and send brief video clips of their weekly parenting activity to research staff. Research staff will moderate the Facebook user group daily, respond to comments and questions, review and provided feedback on parent-child video clips to individual parents through Facebook's messaging feature, and screen all material from participants for any inappropriate or concerning language prior to posting. Women in each group will complete the demographic measure and measures of feasibility (attendance at or liking weekly meetings) and acceptability (satisfaction questionnaire) during each weekly session. This first phase of the study is to test out the respective formats in order to assure feasibility for phase III of the study.

3.1.2 Phase II

During phase II, we will revise the group and social media-based versions of the intervention based on results of phase I. Specifically, we will examine the satisfaction and attendance measures to determine whether and how to revise the content for each session and the number of sessions. After we have revised both formats, we will then be prepared to begin phase III.

3.1.4 Phase III

In phase III of the study, there will be 4 groups of 15 members each assigned to each format of the program for a total of 60. Eligible women will be stratified by site and randomized using computer-generated random numbers to the group or social media format. Randomization will be done prior to enrollment with study assignments contained in sequential sealed opaque envelopes. The study will run in the same fashion as phase I of the study, with women in each group completing the demographics measure and measures of feasibility and acceptability following each session and at the conclusion of the intervention. In addition, subjects will complete the Beck Depression Inventory-II (BDI-II) and the Parenting Sense of Competence Scale (PSOC) prior to and after the 8-week intervention, as well as the Therapeutic Factors Inventory-8 (TFI8) and the Parenting Interactions with Children: Checklist of Observations Linked to Outcomes (PICCOLO), a standardized videotaped measure of parenting interaction at the end of the intervention.

If mothers from the traditional group format participate in the two study visits, they will also be offered an opportunity to participate in the Facebook sessions following their final study visit. We would like to be sure that, even if they are unable to attend many sessions in person, they are able to access the content after they've completed the study measures.

3.1.5 Phase IV

In Phase IV of the study, participants who report that they have attempted breastfeeding in the demographic questionnaire will be contacted after the start of phase I or phase III and asked if they are willing to be interviewed about their breastfeeding experience. If so, participants will be called, and arrange a time when they are able to come to a CHOP facility to be interviewed. These interviews will be scheduled at the preferences of the participants, e.g. in order to coincide with clinic visits.

3.2 Allocation to Treatment Groups and Blinding

The participants in the first phase of the study will not be randomly assigned. In the third phase of the study, participants will be stratified by site and randomized through computer generated random numbers. Blinding will not be used in this study.

3.3 Study Duration, Enrollment and Number of Sites

3.3.1 Duration of Study Participation

Study staff will 'verify eligibility' by reading inclusion/exclusion criteria to participants. The study duration per subject will be up to 12 weeks, allowing up to 1-2 weeks following screening/consenting and after completion of the intervention in order to conduct pre- and post-intervention measures.

3.3.2 Total Number of Study Sites/Total Number of Subjects Projected

The study will be conducted at three urban, CHOP-affiliated practices in Philadelphia, Pennsylvania: CHOP Care Networks Karabots, South Philadelphia, and Cobb's Creek. These sites will be individually recruited to participate (see PeRC letter of support).

Recruitment will stop when approximately 180 subjects (90 dyads of mother and infant) are enrolled or all six parenting groups have been completed.

Qualitative interviews on breastfeeding will be conducted on CHOP campus at 3535 Market St. or participating CHOP clinical practices (PCC Cobb's Creek, PCC Karabots, PCC South Philadelphia)

Study Population

3.3.3 Inclusion Criteria

1) Females
2) English speaking
3) 15 years of age or older at the start of the study
4) Access to the internet via a computer or a smartphone
5) Mother of a child 1-3 months old
6) EPDS score of 9 or higher
7) Informed consent and HIPAA authorization.

3.4.2 Exclusion Criteria

1) Have significant suicidal symptoms. Significant suicide risk is defined as current suicidal intent and a plan for suicidal behavior.

4 STUDY PROCEDURES

4.1 Screening Visit

Women attending their child's 2-month well child visit at the urban practiced affiliated with CHOP will be screened as part of routine care for depressive symptoms using the EPDS. All women who screen positive (EPDS score ≥ 9) will receive mental health resources and referrals. For phase I, 15 women and their infants will be assigned to each intervention format. For phase III, up to 60 women and their infants will be randomly divided into 4 groups, two groups for both intervention formats. Women in the first phase will complete a

demographics questionnaire, while women in the second randomized phase will complete a demographics questionnaire, and the BDI-II and the PSOC before the intervention using an email link to the surveys on REDCap.

4.2 Study Treatment Phase

4.2.1 Phase I

In phase I, the 15 women and their infants assigned to the group format will be asked to attend 8 weekly group sessions and scheduled at their convenience in the evening hours. Women assigned to the group format will meet weekly and go through a different Developmental Observation Topic (or DOT) each week on different parenting topics. These sessions will be expected to last 2 hours and cover 8 topics: depression and stress, sleep, safety, temperament, play, feeding, laughing, and reading. Each session will begin with an introduction to the topic provided by research staff, include a series of questions on predictions to an activity, a dyadic activity specific to the session involving mother and infant with guidance from research staff, and a wrap-up and discussion of homework. A meal, childcare, and transportation tokens will be provided as an incentive to participate.

The 15 women and their infants assigned to the social media format will be invited to join a Facebook secret user group. This will allow the group administrator to restrict membership to only those invited, present educational materials from the DOTs in video or text format, allow users to comment and allow posts to be only viewed by group members. They will be asked to review the same weekly content from the group sessions on the site electronically and like/not like the material, and to send posts and video clips of interactions with their infants or any confidential questions they have directly to the instructors. Instructors will moderate that group daily, responding to confidential parents' comments and questions, reviewing and providing feedback on parent-child clips, and screen for any inappropriate language or content prior to posting comments. Only instructors will be able to view the video clips.

The participants will be assessed both on the percentage of in-person meetings they attend (group format) or the online check-ins or posts on the Facebook group, established by posting a weekly question on the site as to whether the participants reviewed the content for the week (social media format). Acceptability of the program formats will be assessed by asking participants to complete a satisfaction questionnaire (5-point Likert scale) with open-ended question following each session.

4.2.2. Phase II

There will be no study procedures involving research subjects during this stage. We will review the content of the feasibility and acceptability measures and revise the content of the parenting intervention as needed. If any changes are made to the protocol after Phase I, the study will be amended and submitted for IRB review.

4.2.3 Phase III

Phase III will begin after minor revisions have been made to the parenting information based on subject feedback from Phase 1. Up to sixty women and their infants will be randomly

assigned to either the traditional group format or the social media-based format for a total of 4 groups (60 participants). The study visits will proceed in the same fashion as phase I, with 8 in-person group sessions or 8 weeks of online content sharing and discussion of the DOTs. Following completion of the parent coaching program, the participants will be assessed both on the percentage of in-person meetings they attend (group format) or the online check-ins on the Facebook group, established by posting a weekly question on the site as to whether the participants reviewed the content for the week (social media format). Acceptability of the program formats will be assessed by asking participants to complete a satisfaction questionnaire (5-point Likert scale) and open-ended question. Subjects in phase III will complete the BDI-II and the PSOC before and after the intervention and the TFI8 after the intervention. Finally, a 16-minute parent-child interaction will be obtained from parents and scored using the PICCOLO, a standardized checklist of observations linked to child outcomes, to indicate parenting interactions. Parents will be asked to videotape this interaction and send directly to the research staff.

If mothers from the traditional group format participate in the two study visits, they will also be offered an opportunity to participate in the Facebook sessions following their final study visit. We would like to be sure that, even if they are unable to attend many sessions in person, they are able to access the content after they've completed the study measures.

4.2.4 Phase IV

4.3 After the start of phase I, participants who reported ever breastfeeding will be contacted and asked if they are willing to be interviewed about their experiences with breastfeeding. If so interview dates will be scheduled when the participants can meet with an interviewer at 3535 Market Street or a participating CHOP practice facility. At the interviews participants will be asked to give informed consent, complete a brief questionnaire regarding the pregnancy and birth, and complete an interview lasting 30-60 minutes. Interviews will be audio recorded and will follow interview guide (Appendix 10). An example of an interview question is, "Can you tell me about the first time you attempted to breastfeed your most recent child?" Subject Completion/Withdrawal

Caregivers may withdraw from the study at any time without any adverse effects to their care or their child's care at their participating practice. We will exclude caregivers whose children are placed in foster care, are hospitalized as psychiatric inpatients during the study, or move outside of Philadelphia due to the difficulty with maintaining contact with these families. The Investigator may also withdraw subjects who violate the study plan or to protect the subject for reasons of safety or administrative reasons. It will be documented whether or not each subject completes the study.

If the Investigator becomes aware of any serious, related adverse events after the subject completes or withdraws from the study, they will be recorded.

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Screening and Monitoring Evaluations and Measurements

5.1.1 Beck Depression Inventory (BDI-II) [Appendix 2]

The BDI-II is a 21-item self-report tool that measures the severity of depression and includes two subscales: cognitive and somatic. It has been well validated, with scores 14-19 indicating mild depression, 20-28 moderate depression, and 29-63 severe depression.(Beck, Steer et al. 1996)

5.1.2 Parenting Sense of Competency (PSOC) [Appendix 3]

The Parenting Sense of Competence scale measures parental competence on two dimensions: Satisfaction and Efficacy. It is a 16 item Likert-scale questionnaire (on a 6 point scale ranging from strongly agree [1] to strongly disagree [6]), with nine questions under Satisfaction and seven under Efficacy. Satisfaction section examines the parents' anxiety, motivation and frustration, while the Efficacy section looks at the parents' competence, capability levels, and problem-solving abilities in their parental role.

5.1.3 Acceptability Scale (Appendix 5)

The Acceptability Scale is a measure that will provide feedback on study participants' overall experiences participating in the study. Mothers will fill out a single acceptability question relevant to each DOT at the completion of the week, as well as a final, overall acceptability question about the entire program at the end of all eight weeks. On a scale of 1 to 5, 1 being "strongly disagree" and 5 being "strongly agree", mothers will evaluate how much the preceding DOT helped them to understand the different observational topics and how to parent their baby.

5.1.4 Parenting Interactions with Children: Checklist of Observations Linked to Outcomes (PICCOLO)

The Parenting Interactions with Children: Checklist of Observations Linked to Outcomes is a checklist of 29 observable developmentally supportive parenting behaviors with children ages 10–47 months in four domains: affection, responsiveness, encouragement, and teaching. It is a positive, practical, versatile, culturally sensitive, valid, and reliable tool for practitioners that shows what parents can do to support their children's development. Currently, the PICCOLO is being validated for infants down to 6 months of age.

5.1.5 Therapeutic Factors Inventory-8 (TFI8)

The Therapeutic Factors Inventory-8 is a brief version of the 23-item Therapeutic Factors Inventory-Short Form (TFI-S), based on the Therapeutic Factors Inventory, initially developed to assess group psychotherapy factors, the key mechanisms by which change occurs in all types of therapy groups. The TFI8 was developed to make completion more feasible in clinical settings and provide regular feedback to providers about the group's interpersonal learning and functioning in a user-friendly manner (Giorgio et al., 2014).

6 STATISTICAL CONSIDERATIONS

6.1 Primary Endpoint

The primary endpoint will be a feasible and acceptable parent coaching program for women with postpartum depressive symptoms utilizing a social media format.

6.2 Secondary Endpoints

Secondary endpoints will include the following:

- The difference in outcomes between a traditional in-person group format and a social media-based format parenting program.

6.3 Statistical Methods

Data will be collected by the investigators at The Children's Hospital and will become protected individual health information for purposes of HIPAA. As the University of Pennsylvania is a different covered entity, all data will first be de-identified prior to transfer for analysis. Any limited datasets used outside of Children's Hospital will be subject to a formal data use agreement.

The primary analysis for phases I and III will be differences in feasibility and acceptability measures between the group and social media formats. The exploratory analysis for phase III will be differences in BDI-II, PSOC, and PICCOLO measures between groups using intention-to-treat, i.e. analyzing participants according to their treatment assignment and including all participants' data regardless of dropout or adherence status. This analysis requires excellent levels of recruitment and retention not only to avoid bias from differential loss to follow-up but also to maintain adequate sample sizes

To determine feasibility of the intervention, we will assess the percentage of participants who attend a group session or check in on-line for a Facebook session for 1 session, half of the sessions, or all of the sessions. We will consider the intervention format to be feasible if 80% of participants attend one or more sessions, 70% completed half the sessions, and 50% completed all the sessions based on prior data from Incredible Years in-person parenting groups.[44] To determine the acceptability of the intervention, we will assess mean satisfaction scores across the two formats. We will consider the intervention to be acceptable if mean satisfaction scores are ≥4.0. We will assess differences in attendance and satisfaction using Chi-square and t-statistics. We will explore the effects of the intervention formats on outcome measures. Each participant will provide two repeated measures over time for the scores of multiple ratings (BDI-II and PSOC). We will then assess differences between changes in scores by intervention formats using t-statistics. We will also assess differences in TFI8 and PICCOLO measures between intervention formats.

6.3.1 Baseline Data

Mothers will complete the following assessments prior to the intervention: demographic questionnaire found in Appendix 1 (assessing age, race/ethnicity, child gender, family composition, family income, and mother's education level), BDI-II, PSOC. Responses to questions on the Beck Depression Scale will be checked to determine whether the caregiver

has endorsed suicidal ideation. If they have endorsed any of the suicide questions, research staff will administer additional follow up questions and call one of the study licensed psychologists to determine course of action (see Appendix 4-Suicide Protocol). This procedure has been implemented successfully in other studies of maternal depression. During the study visits, if a participant was to endorse suicidal ideations, the Appendix 4: 'Suicide Protocol' will be followed to maximize the safety of the participant. At any time, caregivers who endorse suicidal ideations will require immediate follow up with the licensed psychologist on call.

7 SAFETY MANAGEMENT

7.1 Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study.

7.2 Adverse Event Reporting

All on-site adverse events will be reported to the IRB in accordance with CHOP's and the IRB policies. Adverse events that are not serious will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

Since the study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study (including SAEs) these will be reported to the IRB in accordance with CHOP IRB SOP 408: Unanticipated Problems Involving Risks to Subjects. AEs that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

8. STUDY ADMINISTRATION

8.1 Data Collection and Management

All records generated during this study will be kept confidential in accordance with Institutional policies and HIPAA on subject privacy. The Investigator and other site personnel will not use such data and records for any purpose other than conducting the study.

Unique identifiers will be created for each subject in the study. REDCap will be used to store the data. Since we are using REDCap, we will not need to maintain a Master List separate from the rest of the data. Participants' information will be stored in the REDCap database and configured to export data without PHI. All de-identified records will be retained forever. Coded, de-identified data will be shared with the University of Pennsylvania and the Oscar Mayer Family Foundation.

Any paper copies of research instruments will be stored using the patient's ID code and will be kept in the department of General Pediatrics at The Children's Hospital of Philadelphia.

Digital copies of video recordings of participants and children in Phase III will be stored on a password protected secure server to be coded and analyzed. Following analysis, videos will be destroyed. Only study staff will have access to any identifying records, and sponsors will only have access to de-identified records.

Audio recordings of interviews will be stored on a password protected secured server at CHOP to be coded and analyzed. Following analysis, recordings will be destroyed. Interviews will be transcribed without any identifying information on the participants.

8.2 Confidentiality

All data and records generated during this study will be kept confidential in accordance with Institutional policies and HIPAA on subject privacy and that the Investigator and other site personnel will not use such data and records for any purpose other than conducting the study with the exception of mandatory reporting requirements for child maltreatment.

No identifiable data will be used for future study without first obtaining IRB approval. The research staff will obtain a data use agreement between the provider (the PI) of the data and any recipient researchers (including others at CHOP) before sharing a limited dataset (PHI limited to dates and zip codes).

8.3 Regulatory and Ethical Considerations

8.3.1 Data and Safety Monitoring Plan

Monitoring of adverse events, mainly disclosure of PHI from medical records and study assessment responses, will be ongoing during the intervention period until all data have been de-identified. Participants will be asked whether they know of any breaches of confidentiality at all contacts with subjects. All non-serious adverse events including disclosure of information will be reported to the CHOP IRB at the time of continuing review and to the funding agency annually. The PI will be responsible for overseeing the monitoring plan. Monitoring of data and safety will be conducted monthly by trained research assistants under the supervision of the Principal Investigator.

8.3.2 Risk Assessment

There is minimal risk for harm to the participant in this study. Some information collected from the study participants on the study assessments is sensitive information and may cause the subjects discomfort. In addition, some sensitive topics may arise during the intervention parenting sessions, which may also cause discomfort for the participants. This could include assessment of caregiver's suicidal ideations (See Appendix 4). This risk is considered minimal and no more than what is normally associated with being in a physician's or mental health practitioner's office. Furthermore, families incur a risk of disclosure of private health information to individuals not connected with this study. This could occur through inadvertent disclosure of PHI by research staff or participants attending group classes. This risk will be minimized by using the study identifier on all study instruments and the research database as well as storing identifying information in a separate place than study information. A password-protected Excel file will link the study identifier to the family's identifying information, but will be kept on a password protected computer in the Division of General Pediatrics. Hard copies of study instruments will be kept in a locked file cabinet in the Division of General Pediatrics. In addition, once all data analysis has been completed, the linkage file will be destroyed. Participants will be reminded at the beginning of each group session to not discuss information outside of the group classes. Participants in the social media-based groups will join a Facebook secret user group, which restricts

membership to those invited by the group administrators, allowing presentation of educational materials in video or text format, permitting individual user comments and posts to be viewed only by user group members, and allowing private and confidential questions to instructors. Participants will be reminded not to share any information about the group or program outside of the Facebook user group. Instructors will moderate the Facebook user group daily, respond to comments and questions, review and provided feedback on parent-child video clips, and screen for any inappropriate postings which will immediately be removed.

8.3.3 Potential Benefits of Trial Participation

Participants in the intervention may not benefit from the parenting program. They may be more likely than those who receive mental health referrals and follow up to improve their parenting competence and reduce parent stress and may be more likely to increase the strength and support of their social network, but this cannot be guaranteed. Mothers may also be more likely to access mental health supports for themselves and early intervention for their children, if needed, but these outcomes can also not be guaranteed. Access to mental health referrals and follow up by staff along with information about depression is likely beneficial for all study participants.

There may be benefits from generalizable information from the study to include knowledge about the acceptability, feasibility, and effectiveness of an adapted version of PIWI program based on a social media platform.

8.3.4 Risk-Benefit Assessment

The risks to participants are minimal and further minimized through protections. The benefits of mothers receiving support and education through the different formats of the intervention outweigh the risks of participating in this study. Therefore, the risk-benefit ratio is considered favorable.

8.4 Recruitment Strategy

Recruitment for all phases will be conducted from three urban practices affiliated with The Children's Hospital of Philadelphia (CHOP). The participating practice routinely screens mothers for depressive symptoms using the Edinburgh Postnatal Depression Scale (EPDS) during their child's 2-month well child visit. To be eligible to participate in the study, women must be at least 15 years old, the mother of a child 1-3 months old, have internet access on a computer or a smart phone, and screen positive (EPDS $\geq$9) for depressive symptoms. If an eligible participant has screened positive for depressive symptoms, they will be asked to consent to be contacted by research staff.

8.5 Informed Consent/Assent and HIPAA Authorization

During the research staff visit after screening, written informed consent will be completed. Research staff will discuss the study aims, procedures, risks and benefits, alternatives to

participation, and confidentiality protocols with the mother. Research staff will speak to mothers about the voluntary nature of participation and provide the potential subject with the opportunity to ask questions about the study and its risks and benefits. Mothers who agree to participate will sign two copies of the informed consent form and be given one for their personal files. Mothers will be provided with plenty of time to ask questions and to decide whether they want to participate. Mothers will be explicitly instructed that they are free to choose to participate and that their decision to participate will not affect the health care they or their children receive at participating practices. Mothers who choose to participate will be asked to sign the written informed consent documents in duplicate: one will be kept for study purposes and the other will be provided to the consenting parent.

8.6 Payment to Subjects/Families

8.6.1 Reimbursement for travel, parking and meals

N/A

8.6.2 Payments to subjects for time and inconvenience (i.e. compensation)

Mothers in Phase I of the study will be paid $20 at the end of the pre-study visit. Mothers in the Phase 3 of the study will be paid $30 at the end of the pre-intervention visit and $50 after the post-intervention visit as they will be completing more measures and study questionnaires, and a video recording during the post-intervention visit. All payments will be made in the form of pre-paid, CHOP-issued debit cards. Mothers in the Facebook group will receive their payments at the completion of the second in-person study visit or, if they are unable to meet in person for the second study visit, they will be paid via mail. Mothers who agree to be interviewed will be paid $20 at the end of the interview in the form of a gift card to CVS

PUBLICATION

The results of this study will be disseminated in a number of ways. We will distribute information or findings from the study locally through Policylab and the Maternity Care Coalition. In addition, results will be submitted for publication in peer-reviewed manuscripts and for presentations at professional meetings, however, no individual subjects will be identified. Only aggregate data will be published..

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APPENDIX

Append relevant information.