Comprehensive Final Report

Grant #: R40 MC29454

PI name and institution: Beth Lewis, University of Minnesota

Title of project: Exercise Intervention for Preventing Perinatal Depression among Low Income Women

Project start and end dates: April 1, 2016-March 31, 2020

Need for embargo of manuscript information: No

2. Introduction

2.a Nature of the research problem. Approximately 15% of women report perinatal depression (defined depression during pregnancy or postpartum). Furthermore, 38% of low income women experience postpartum depression (Pooler et al., 2013).Traditional treatments for depression (e.g. antidepressants, psychotherapy) may not be suitable for perinatal depression. Pregnant women are reluctant to take antidepressants during pregnancy due to fetus-related health concerns (Battle et al., 2013), and antidepressant medication may not perform better than a placebo for treating postpartum depression (O'Hara & McCabe, 2013). Psychosocial approaches appear helpful for preventing and treating perinatal depression (Dennis & Dowswell, 2013); however, there are methodological concerns with these studies. Additionally, only 10% of women with postpartum depression seek treatment, potentially due to cost, time, and childcare constraints (Oppo et al., 2009). Furthermore, a majority of interventions are expensive, do not target women at most risk (i.e., low income women), and are not integrated with existing community-based programs.

2.b Brief overview of relevant background literature. Research indicates that exercise is efficacious for treating depression among adults (Kyam et al., 2016). Exercise interventions are a particularly promising area to research given the effect it can have on both psychiatric symptoms (e.g., depression) and physical health issues (e.g., weight). However, only a few methodologically sound studies have examined the effect of exercise on antenatal or postpartum depression (Carter et al., 2019). Even fewer studies have examined the efficacy of exercise interventions among at risk women (e.g., low income women). Additionally, research indicates that exercise during pregnancy may be associated with a reduced risk of excessive weight gain during pregnancy and less postpartum weight retention (Haakstad and Bo, 2011). There is an urgent need to evaluate low cost, community-based interventions designed to decrease both perinatal depression and improve weight gain/loss during the perinatal period. Exercise participation is lower among low income women relative to women with higher incomes (CDC, 2014) and therefore, exercise interventions may be particularly beneficial for reducing disparities in this area.

2.c Summary of purpose, scope, and methods of the investigation. The purpose of this study was to examine the efficacy of a novel exercise intervention designed to prevent perinatal depression among low income, pregnant (less than 20 weeks) women at risk for perinatal depression (n=111). Effects on gestational weight gain and retention were also explored, along with additional maternal (e.g. mode of delivery, length of gestation, gestational diabetes, perceived stress, sleep quality, fatigue) and infant (e.g. breastfeeding, safe sleep, parent-infant attachment, birth weight) outcomes. Participants were recruited through local community resources (e.g. ads in parenting magazines) and federally qualified health centers serving low-income families (i.e., WIC). Participants were randomly assigned to either a telephone-based exercise intervention (n=56) or usual care (n=55). Assessments (i.e., structured interviews and self-report surveys) were administered by telephone at baseline, 36 weeks gestation, and three months postpartum.

3. Study Design and Methods

3.a Brief description of study design. This study was a randomized controlled single blind study conducted from April 2016 to June 2020. Participants were recruited from federally qualified health programs serving low income families (i.e., WIC) and other local community resources (e.g., parenting magazine). Eligible participants (see section 3.b) who were less than 20 weeks pregnant (n=111) were randomized to either an exercise intervention (n=56) or usual care (n=55). The telephone-based exercise intervention was delivered throughout pregnancy and through three months postpartum. The intervention consisted of three components (i.e., telephone-based counseling sessions, print materials, and exercise log/goal setting). Participants were encouraged to engage in five or more days of exercise for at least 30 minutes or more each day that was at least of moderate intensity, consistent with guidelines (USHDDS, 2018). Counseling sessions were guided by Social Cognitive Theory and Self-Determination Theory with a focus on increasing self-efficacy and intrinsic motivation. Participants in the usual care condition followed their usual standard of care as recommended by their healthcare provider. Following the final assessment, usual care participants were given the option to participate in the exercise intervention. All participants wore a Fitbit (i.e., objective measure of exercise) during the study. Participants completed several structured interviews and questionnaires at baseline, 36 weeks gestation, and 3 months postpartum (see Table 1). All written and verbal components of the study (i.e. recruitment and screening materials, intervention, and assessments) were delivered in English or Spanish, based on the individual participant's preferred language. The primary hypothesis will be tested using an intention-to-treat analysis with repeated measures modeling (see section 3.e for data analysis plan). The randomization schedule was created by the study statistician and randomizations were conducted by the

project coordinator who was not involved in the assessments. This study was approved by the university's institutional review board (IRB). Participants completed the informed consent process including signing a written consent form.

3.b Population studied. The study population included low income, healthy participants less than 20 weeks pregnant. A total of 111 low income women were randomized with 41% (n=46) self-identifying as ethnic minority and 36% (n=40) as Hispanic or Latina.

3.c Sample selection, recruitment and enrollment. The sample included low-income, sedentary (i.e., reported less than 60 minutes per week of exercise at screening), healthy adult women (18 years of age or older) who were less than 20 weeks pregnant with singleton pregnancies. Low income was defined as participation in any government assistance program (e.g., WIC, SNAP, CCAP, MA, EAP, etc.) or net income criteria eligibility for WIC. Additionally, participants were English or Spanish speaking, had access to a telephone, were willing to be randomized into either of the study arms, and were able to obtain healthcare provider consent. Potential participants who reported the inability to exercise for 20 minutes continuously or a history of heart disease, lung disease, anemia, musculoskeletal problems, or any other medical condition that would make exercise unsafe were excluded. Individuals reporting a current depressive episode, hospitalization for a psychiatric disorder in the previous six months, or were receiving antidepressant medication or psychotherapy for depression at the time of screening were also excluded. Participants were recruited primarily through advertisements targeting two large metropolitan areas in the upper Midwest via parenting magazines, targeted emails, online social media, and fliers posted in WIC clinics.

3.d Instruments used. Table 1 summarizes the instruments administered during the study

Table 1. Summary of Instruments and Assessment Timeline

Variable	Measure	Type of Variable	Base	36 Weeks	3 Months
Depressive symptoms	Edinburgh Postnatal Depression Scale, SCID-I, PHQ-9	Dependent	■	■	■
Gestational weight gain/ early postpartum weight retention	Self-report of Height and Weight	Dependent	■	■	■
Exercise (subjective)	7-Day Physical Activity Recall Interview	Adherence	■	■	■
Exercise (objective)	Fitbit	Adherence	■	■	■
Exercise goals/attitudes	Exercise Goals & Exercise Attitudes Scale	Mediator	■	■	■
Perceived stress	Perceived Stress Scale	Mediator	■	■	■
Sleep quality	Pittsburgh Sleep Quality Index	Mediator	■	■	■
Fatigue	Multidimensional Fatigue Inventory	Mediator	■	■	■
Demographics	Demographic Questionnaire	Descriptive	■		
Breastfeeding and safe sleep	Breastfeeding and Safe Sleep Questionnaire	Dependent			■
Attachment	Maternal Antenatal Attachment Scale	Dependent	■	■	
Attachment	Maternal Postnatal Attachment Scale	Dependent			■
Social Support	Postpartum Social Support Questionnaire	Mediator			■
Acceptability of intervention	Consumer Satisfaction Questionnaire	Descriptive			■

3.e Statistical techniques employed. The study design was a 2 (Condition: Exercise Intervention, Wellness Contact Control) X 3 (Time: Baseline [12-20 weeks gestation], 36 weeks gestation, 3 months postpartum) randomized controlled trial. The primary hypothesis will be tested using an intention-to-treat analysis with repeated measures modeling. The unit of analysis is the individual, with Time a within-subjects factor (each individual will be observed at each time point) and with Condition a between-subjects factor (each individual belongs to one and only condition). Condition, Time, and their interaction will be modeled as fixed effects. The constructs of self-efficacy, perceived stress, social support, sleep quality, and fatigue will be

examined as possible mediators of the intervention effect. Using a classic mediation-testing approach, we will regress each of these potential mediators on intervention condition and, for those significantly associated with the intervention, include them as additional predictors in the primary models regressing depression on intervention. Mediation is indicated when a construct is significantly associated with both the intervention and the outcome. The analyses are exploratory and provide insight into the mechanisms by which the intervention affects depression.

3.f Detailed findings. A total of 178 potential participants completed the telephone screening interview and 67 of these participants were excluded or were no longer interested. Therefore, 111 participants were successfully recruited for this study. Of the participants who were randomized to the exercise intervention (n=56), 49 were retained at 3 months postpartum and of those randomized to usual care (n=55), 47 were retained at 3 months postpartum. The final 3 month postpartum assessment was completed in June, 2020 and therefore, findings based on the outcome data are not yet available.

3.g Discussion and interpretation of findings. N/A

3.h Conclusions to be drawn from findings (with reference to data supporting each), including potential public health impact. N/A

3.i Explanation of study limitations. There were several limitations. First, recruitment of 200 low income pregnant women proved to be challenging. Initially, three local clinics serving low income women expressed interest in partnering with study staff. A letter of support was written indicating intention of referring potentially eligible and interested participants to the study. Due to unforeseen circumstances, the clinics were only able to follow through on a few referrals. Consequently, targeted recruitment was challenging; however, a total of 111 participants were successfully recruited for the study. Second, loss of participant access to a landline or mobile phone for study was a concern. However, study staff were able to obtain multiple telephone numbers and email address(es) to decrease the risk of not being able to reach participants during the trial. Finally, compliance with wearing the Fitbit was sporadic throughout the study.

3.j Comparison with findings of other studies, highlighting this study's new contributions to the literature. N/A

3.k Possible application of findings to actual MCH populations and health care delivery situations, including recommendations when appropriate. N/A

References

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4. List of Products (peer-reviewed articles, books, chapters in books, conference presentations, etc.).

The last three month postpartum assessment was completed in June, 2020 and therefore, manuscripts for this study are in progress.

4.a *The Effect of an Exercise Intervention on Depression and Weight among Low Income Pregnant Women.* Peer reviewed manuscript in progress.

4.b The Mediating Effect of Psychosocial Variables on the Relationship Between Exercise and Depression Among Perinatal Women. Peer reviewed manuscript in progress.

4.c *The Effect of Exercise During Pregnancy on Maternal and Infant Outcomes*. Peer reviewed manuscript in progress.

5. Dissemination activities and plans beyond peer-reviewed publications. We plan to send information about our findings to clinics that serve low income pregnant women. We will also create a website describing our findings and implications for practice.

6. Describe plans to continue this line or program of research through additional external funding. We are currently planning a pilot study examining the efficacy of a combined cognitive behavioral therapy with exercise intervention for postpartum women with a history of depression.

7) Research Grants Impact Analysis

MCHB is working to demonstrate the impact of funded research grants to a variety of stakeholders. Using the table below, provide some information on the impact of your research grant:

No. of Research Sites[1]	Total No. of Studies [1]	Total No. of Participants ever Enrolled	No. of Peer-Reviewed Publications [2]	No. of Non-Peer Reviewed Publications [3]	Total No. of Researchers Involved in Research[4]	Total No. of Trainees Mentored [5]	No. of Tools Created [6]	No. of Tool Kits Created [7]	No. of Clinical Guidelines Created or Supported [8]	No. of External Funding Apps Submitted	No. of External Funding Apps Received
1	1	111	0	0	4	0	0	0	0	1	0

Footnotes: [1]Limit data report from study inception to date; [2]Includes only published papers; [3]Includes conferences workshops, webinars, community dissemination products; [4]Includes all Investigators, Co-Investigators, Affiliates, and Researchers; [5]includes pre- and postdoctoral mentees, if available, include demographic information. [6]Tools: screening tools, diagnostic tools, intake forms, referral forms, care coordination forms, assessment tools, and electronic applications that programs developed or significantly modified. [7]Toolkits: a set of materials containing educational tools to support families and providers of children/adults affected by a health condition or disease in the management of their care. [8]Clinical Guidelines: procedures that benefit the health of MCH populations by improving the quality and standards of medical care, diagnostic criteria, and treatment for women and children.