Contemporary Clinical Trials 70 (2018) 15–23

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

Rationale, design, and baseline data for the Healthy Mom II Trial: A randomized trial examining the efficacy of exercise and wellness interventions for the prevention of postpartum depression

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ARTICLE INFO

Keywords:
Exercise
Wellness
Postpartum depression
Stress

ABSTRACT

Approximately 13–19% of women experience postpartum depression and approximately one-third of women who have a history of depression develop depression during the postpartum phase. Exercise is an efficacious intervention for depression among adults; however, few studies have examined the effect of exercise on postpartum depression. The purpose of this study was to conduct a randomized controlled trial examining the effect of exercise and wellness interventions on preventing postpartum depression among women at risk. Specifically, women (n = 450) who were on average 4.35 weeks postpartum and had a history of depression were randomly assigned to one of the following three conditions: (1) Telephone-based exercise intervention; (2) telephone-based wellness/support intervention (covered topics such as sleep, stress, and healthy eating); or (3) usual care. Both interventions lasted six months. The exercise intervention was based on social cognitive theory and the Transtheoretical model and was specifically designed to motivate postpartum women to exercise. The primary dependent variable was depression based on the Structured Clinical Diagnostic Interview (SCID). Secondary dependent variables included the Edinburgh Postnatal Depression Scale, PHQ-9, and Perceived Stress Scale. Potential mediator variables included quality of sleep, postpartum social support, fatigue, and exercise attitudes. Questionnaires were administered at baseline, six, and nine months. The purpose of this paper is to summarize the methodology, study design, and baseline data for this study. This trial will provide important information regarding the efficacy of exercise and wellness interventions for preventing postpartum depression.

1. Introduction

Approximately 13–19% of women experience postpartum depression following childbirth [1,2]. Additionally, 31% of women who have a history of depression will develop postpartum depression [3]. According to the DSM-V, depression symptoms include diminished interest in everyday activities, sad mood, sleep disturbance, agitation or psychomotor retardation, feelings of worthlessness or guilt, fatigue, decreased concentration, and suicidal ideation [4]. Postpartum depression is associated with negative consequences for the mother including difficulty caring for the newborn, poor parent-infant bond, postpartum weight retention, sleep disturbance, and risk of future depression [5–9].

Antidepressant medication does not appear to be effective for treating postpartum depression when compared to placebo [1]. Furthermore, breastfeeding postpartum women are reluctant to take antidepressant medications due to health concerns for the newborn [10]. Psychosocial interventions do appear efficacious for preventing and treating postpartum depression [11,12]. However, only 10% of women with postpartum depression seek treatment potentially due to childcare, transportation, cost, stigma, and time constraints [3]. Exercise interventions are efficacious for preventing and treating depression among the general population [13]. Few studies have examined the effect of exercise interventions on postpartum depression. Specifically, a recent meta-analysis identified only 12 studies that have examined the effect of exercise on treating postpartum depression [14]. However, many of

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https://doi.org/10.1016/j.cct.2018.05.002
Received 24 January 2018; Received in revised form 26 April 2018; Accepted 1 May 2018
Available online 07 May 2018

these studies were limited by small sample sizes, non-randomized designs, short interventions, lack of follow-up after the intervention concluded, a non-diagnostic assessment of depression, and a lack of a true control group. A study by Lewis and colleagues found no differences between an exercise and wellness/support control condition for preventing depression among women at risk for depression (e.g., history of depression among participant or her mother; [15,16]). One problem is both conditions exercised and therefore, the effect of exercise on postpartum depression could not be examined.

Exercise interventions are advantageous to psychosocial interventions during the postpartum phase for several reasons. First, exercise interventions can lead to weight loss during the postpartum phase [17]. Second, psychosocial interventions can be expensive and time-intensive to deliver. Third, exercise interventions during the postpartum phase can serve as a teachable moment in that new mothers may be motivated to make a positive health change (i.e., exercise) that can have a lasting impact on their long-term health.

The purpose of this study was to examine the efficacy of an exercise intervention on the prevention of postpartum depression among women at risk. The participants in our study were considered at risk due to their history of depression (the risk of postpartum depression is over double for postpartum women who have a history of depression vs. postpartum women who do not have a history; [1–3]). Our study adds to the literature by including a usual care condition, large sample size, and a follow-up assessment three months following the conclusion of the intervention. The aims of this paper are to describe the following: (1) study protocol and rationale for design; (2) effectiveness of various recruitment methods; and (3) interrelationships between the baseline variables to better understand their potential effect on the dependent variables.

2. Methods

The Healthy Mom 2 study is a randomized controlled trial examining the efficacy of exercise and wellness/support interventions for preventing postpartum depression among women at risk for depression. Postpartum women who had a history of depression (n = 450) were randomly assigned to one of the following three conditions each lasting six months: (1) telephone-based behavioral exercise intervention; (2) telephone-based wellness/support intervention; or (3) usual care. We chose telephone-based interventions and assessments (there were no in-person components to the study) because this reduces the time, childcare, cost, and transportation barriers associated with face-to-face interventions but still includes personal contact with a counselor. Furthermore, we have had high adherence to this type of intervention in previous studies with postpartum women [15,16]. The primary dependent variable was depression based on the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I). The secondary dependent variables were depressive symptoms based on the Edinburgh Postnatal Depression Scale and stress based on the Perceived Stress Scale. We assessed exercise adherence using the 7-Day Physical Activity Recall Interview and the ActiGraph. Potential mediating variables included sleep, fatigue, stress, and social support. We recruited participants through advertising in local parenting magazines, targeted emails, Craig's list (e.g., website consisting of free advertisements), and Facebook. The Facebook advertising consisted of creating a study Facebook page and paid advertisements on the target demographics' Facebook News Feeds. This study was approved by our university's Institutional Review Board (IRB).

2.1. Participants

Participants were healthy women who were between 2 days to 11 weeks postpartum (average was 4.35 weeks postpartum) and had a history of depression prior to childbirth. Exclusion criteria were assessed during a telephone screening interview and included the following: (1) < 18 years of age; (2) another member of the household participating in the study; (3) participation in regular exercise during the month prior to the telephone screening interview (defined as exercising 90 min or more per week); (4) enrolled in another exercise or weight management study; (5) unable to walk for 30 min continuously prior to childbirth; (6) pre-existing hypertension or diabetes; (7) musculoskeletal problems (e.g., gout, arthritis, osteoporosis, or back, hip or knee pain) that may interfere with exercise; (8) exercise-induced asthma; (9) any condition that would make exercise unsafe or unwise; (10) taking medication that could interfere with heart rate response to exercise (e.g., beta blockers); (11) hospitalization for a psychiatric disorder during the past six months; or (12) current depressive episode based on the SCID and/or currently receiving antidepressant medication or psychotherapy for depression (anyone who was depressed at baseline and not in treatment were referred to their healthcare provider).

2.2. Procedure

2.2.1. Telephone screening interview

Potential participants responded to our study advertisement either via telephone, email, or text. Participants next completed a telephone screening interview to determine eligibility for the study. The eligibility criteria described above were assessed via the telephone screening interview. We also assessed basic demographic information and how the participant heard about the study (e.g., magazine advertisement, targeted email). History of depression was defined as ever being told by a healthcare provider that she had depression or being prescribed a medication for depression.

2.2.2. Consent forms

The research assistant explained the study to potential participants during the telephone screening interview. Eligible and interested individuals were mailed a consent form and demographic questionnaire. For those who were already postpartum at the telephone screening interview, the consent form was read over the telephone and consent was obtained verbally to expedite the randomization process. Although verbal consent was obtained in these cases, participants were also mailed consent forms and instructed to return them via the provided self-addressed envelope. Individuals who completed the screening interview during pregnancy were instructed to return the consent form via the self-addressed stamped envelope. When consent was obtained during pregnancy, participants were also instructed to call, email, or text the study line once the baby was born. If the participant's due date passed and we did not hear from the participant, the research assistant called the participant to check in. Participants also indicated that they were willing to be randomized to any of the three study conditions. The consent form and procedures were approved by our university's institutional review board.

During the telephone interview, the research assistant also obtained verbal consent to contact the participant's healthcare provider. For women who completed the screening during postpartum, the consent form was faxed immediately to the provider. For women screened during pregnancy, the consent form was faxed after the baby was born. The healthcare provider returned the consent via fax and indicated whether or not it was safe for the participant to begin an exercise program and if yes, when they could begin. Even though the healthcare provider indicated consent for their patient to participate, they were not directly involved in the study. This method of healthcare provider consent has been used efficiently in our previous studies [16,18]. Participants were enrolled into the study on a rolling basis over 3.5 years.

2.2.3. Study protocol

Once informed and healthcare provider consent were obtained, participants completed the baseline/randomization session. In this session, participants completed the baseline questionnaires over the