Contemporary Clinical Trials 41 (2015) 287–297

Contents lists available at ScienceDirect

Contemporary Clinical Trials

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

Mindfulness-based stress reduction for overweight/obese women with and without polycystic ovary syndrome: Design and methods of a pilot randomized controlled trial ☆

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ARTICLE INFO

Article history:
Received 17 November 2014
Received in revised form 30 January 2015
Accepted 31 January 2015
Available online 7 February 2015

Keywords:
Glucose
Obesity
Stress

ABSTRACT

Introduction: Mindfulness-based stress reduction (MBSR) may be beneficial for overweight/obese women, including women with polycystic ovary syndrome (PCOS), as it has been shown to reduce psychological distress and improve quality of life in other patient populations. Preliminary studies suggest that MBSR may also have salutary effects on blood pressure and blood glucose. This paper describes the design and methods of an ongoing pilot randomized controlled trial evaluating the feasibility and effects of MBSR in PCOS and non-PCOS women who are overweight or obese (NCT01464398).

Methods and design: Eighty six (86) women with body mass index ≥ 25 kg/m^2, including 31 women with PCOS, have been randomized to 8 weeks of MBSR or health education control, and followed for 16 weeks. The primary outcome is mindfulness assessed with the Toronto Mindfulness Scale. Secondary outcomes include measures of blood pressure, blood glucose, quality of life, anxiety and depression.

Discussion: Our overall hypothesis is that MBSR will increase mindfulness and ultimately lead to favorable changes in blood pressure, blood glucose, psychological distress and quality of life in PCOS and non-PCOS women. This would support the integration of MBSR with conventional medical treatments to reduce psychological distress, cardiovascular disease and diabetes in PCOS and non-PCOS women who are overweight or obese.

Abbreviations: BMI, body mass index; BSI-18, Brief Symptom Inventory-18; DHEAS, dehydroepiandrosterone sulfate; FFMQ, Five Facet Mindfulness Questionnaire; F–G, Ferriman–Gallwey hirsutism score; FSDS, Female Sexual Distress Scale; HbA1c, hemoglobin A1c; HEC, health education control; HOMA-IR, homeostatic index of insulin resistance; hsCRP, high sensitive C-reactive protein; MAP, mean arterial pressure; MBSR, mindfulness-based stress reduction; PANAS, Positive and Negative Affect Schedule; PCOS, polycystic ovary syndrome; PCOSQ, PCOS Questionnaire; PHQ, Patient Health Questionnaire; PROMIS, Patient-Reported Outcomes Measurement Information System; PSS-10, Perceived Stress Scale-10; SF-36, Short Form-36; TMS, Toronto Mindfulness Scale; TSH, thyroid stimulating hormone.

☆ Disclosure statement: The authors declare that there is no conflict of interests regarding the publication of this paper.

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http://dx.doi.org/10.1016/j.cct.2015.01.021
1551-7144/

1. Introduction

Polycystic ovary syndrome (PCOS), defined as chronic hyperandrogenic anovulation, is a common endocrine disorder that affects 5–10% of reproductive-aged women [1]. Insulin resistance almost always underlies PCOS and increases the risk for impaired glucose tolerance and type 2 diabetes, major risk factors for cardiovascular disease [2–5]. Additional cardiometabolic risk factors associated with PCOS include obesity, hypertension, dyslipidemia, inflammation, endothelial dysfunction, and subclinical atherosclerosis [6–11]. Women with PCOS are also at increased risk for psychological distress, body dissatisfaction and reduced quality of life due to their obesity, hirsutism, acne, irregular menses and infertility [12–14]. In women with PCOS the reported prevalence of emotional distress is 38%, depression 21–46%, and anxiety 34% [15–17]. Structured clinical interviews reveal that among women with PCOS, the lifetime incidence of any major depressive episode is 67%, social phobia 27%, eating disorder 21%, and suicide attempt 14% [18].

As more than two thirds (69%) of adults in the U.S. are overweight or obese, non-PCOS women who are overweight/obese represent a large at-risk group that shares some of the same cardiometabolic risks and psychological stressors seen in PCOS women [19–24]. In both PCOS and non-PCOS women, psychological distress could contribute to increased risk of cardiovascular disease and diabetes by: 1) promoting unhealthy behaviors, 2) impeding adherence to medical treatment, 3) contributing to obesity and insulin resistance by altering the activities of the hypothalamic–pituitary–adrenal axis and sympathetic nervous system, and 4) increasing chronic inflammation through effects on the immune system [17,25–28]. Despite this, current treatment strategies emphasize diet and exercise to reduce obesity and insulin resistance, but fail to address the management of psychological distress in these at-risk patient populations.

In both PCOS and non-PCOS women, psychological distress is a potentially modifiable cardiometabolic risk factor that can be targeted with mindfulness-based stress reduction (MBSR), a standardized mindfulness meditation program that is increasingly being offered in medical and health care settings to enhance psychological health and overall well-being [29]. MBSR has been shown to reduce psychological distress and improve quality of life in various patient populations [30–33].

In this paper, we describe the design and methods of an ongoing pilot randomized controlled trial (RCT) evaluating the feasibility and effects of MBSR in PCOS and non-PCOS women who are overweight or obese. The primary outcome is mindfulness assessed with the Toronto Mindfulness Scale. Secondary outcomes include measures of blood pressure, blood glucose, quality of life, anxiety and depression. Our overall hypothesis is that MBSR will increase mindfulness and ultimately lead to favorable changes in blood pressure, blood glucose, psychological distress and quality of life in PCOS and non-PCOS women. This would support the integration of MBSR with conventional medical treatments to reduce psychological distress, cardiovascular disease and diabetes in PCOS and non-PCOS women who are overweight or obese.

2. Materials and methods

2.1. Recruitment, screening and consent

2.1.1. Study population

Subjects were recruited through Medicine and Obstetrics and Gynecology clinics at Penn State Hershey Medical Center, as well as through paper, radio and website advertisements, from November 2011 to December 2013 (ClinicalTrials.gov Identifier: NCT01464398). They were eligible if they met the following inclusion and exclusion criteria.

Inclusion criteria:

(1) Women, age 18 years or older
(2) Body mass index (BMI) $\geq$ 25 kg/m^2 (overweight or obese).

Women who were on metformin, insulin, medications for hypertension, ovarian suppressive therapy etc. were allowed to participate in the study on such medical therapy provided that they have been on a stable medical regimen for at least the previous 6 weeks. Information on the use of medications, including those for diabetes and hypertension, was collected to be evaluated as a potential covariate in the analyses.

Exclusion criteria:

(1) Current pregnancy
(2) Secondary causes of hyperandrogenemia, such as known or suspected androgen secreting tumors, Cushing's syndrome, or hyperprolactinemia (prolactin > 30)
(3) Untreated hypothyroidism or hyperthyroidism (defined as thyroid stimulating hormone (TSH) <0.2 or >5.5 mIU/mL)
(4) Severe active neuropsychological disorder such as psychosis or suicidal ideation
(5) Severe untreated depression or anxiety. Women with severe depression or anxiety will be allowed to participate if they are under the care of a mental health specialist as long as they have permission to do so from their mental health specialist and will continue to follow-up with their mental health specialist during the study.
(6) History of an inpatient admission for psychiatric disorder within the past two years
(7) Active alcohol or drug abuse
(8) Inability to read, speak or write English
(9) Inability to commit to the intervention and follow-up
(10) Current enrollment in a stress reduction program
(11) Mindfulness practice within the past 6 months (regular formal practice at least once a week)
(12) Current enrollment in other investigative studies
(13) Type 1 diabetes.

2.1.2. Screening and consent process

The Institutional Review Board (IRB) of the Pennsylvania State University College of Medicine approved the study. At initial contact, by email or telephone, the research coordinator pre-screened potential subjects with a brief eligibility questionnaire with the major inclusion and exclusion criteria. A phone script and a recruitment intake form were used to minimize any bias in the presentation of the study. Subjects who qualified for further screening were then scheduled for a