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Research paper

Group-based multicomponent treatment to reduce depressive symptoms in women with co-morbid psychiatric and psychosocial problems during pregnancy: A randomized controlled trial

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ABSTRACT

Background: Depressive symptoms in pregnant women, which are common and debilitating, are often co-morbid with other mental disorders (e.g. anxiety and personality disorders), and related to low socioeconomic status (SES). This situation may hamper treatment outcome, which has often been neglected in previous studies on the treatment of depression during pregnancy. We developed a new group-based multicomponent treatment (GMT) comprising cognitive behavioral therapy, psycho-education and body-oriented therapy and compared the effect on depressive symptoms with individual counseling (treatment as usual, TAU) in a heterogeneous group of pregnant women with co-morbid mental disorders and/or low SES.

Methods: An outpatient sample from a university hospital of 158 pregnant women who met DSM-IV criteria for mental disorders were included and 99 participants were randomized to GMT or TAU from January 2010 until January 2013. The Edinburgh Depression Scale (EDS) was used at baseline, every 5 weeks during pregnancy and as the primary outcome measure of depressive symptoms at 6 weeks postpartum. Secondary outcome measures included the clinician-reported Hamilton Depression Rating Scale (HDRS), obstetric outcomes and a 'Patient Satisfaction' questionnaire.

Results: 155 participants were included the intention-to-treat (ITT)-analysis. GMT was not superior above TAU according to estimated EDS ($\beta = 0.13$, CI = − 0.46–0.71, $p = 0.67$) and HDRS scores ($\beta = -0.39$, CI = − 0.82–0.05, $p = 0.08$) at 6 weeks postpartum. There were no differences in secondary outcomes between the GMT and TAU, nor between the randomized condition and patient-preference condition.

Limitations: The ability to detect an effect of GMT may have been limited by sample size, missing data and the ceiling effect of TAU.

Conclusions: GMT is an acceptable treatment for a heterogeneous group of pregnant women with depressive symptoms and co-morbid mental disorders and/or low SES, but not superior to TAU. Further research should focus on understanding and treating co-morbid disorders and psychosocial problems during pregnancy.

Clinical trials registration: Dutch trial registry, www.trialregister.nl under reference number: NTR3015.

1. Introduction

Depression during pregnancy is common, with prevalence rates varying between 3.1% and 11.0% in the general population (Gavin et al., 2005). Fortunately, there is growing awareness of the risks of untreated prenatal depression for both mother and her unborn child (Davalos et al., 2012; Jarde et al., 2016). For example, untreated or incompletely managed depressive symptoms increase the risk of postpartum depression (Beck, 2001) and maternal suicide (Cantwell et al., 2011). Also, indirect influences of prenatal depression (e.g. reduced

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self-care, more smoking and substance use) (Yonkers et al., 2009; Lancaster et al., 2010) and direct influences of maternal stress in utero associated with depression may impair fetal development (Stein, 2014), leading to a lower birth weight (Grote et al., 2010), premature birth (Grigoriadis et al., 2013) and long term infants' neurodevelopment (Barker et al., 2011; Evans et al., 2012). The growing awareness of the negative impact of maternal depression on maternal and child outcomes has led to the development of various psychosocial and psychological therapies to treat depression during pregnancy (Rahman et al., 2013; Stein et al., 2014). Because of unknown risks of psychotropic medication for the unborn child (Kieler et al., 2012), clinicians and patients express a preference for non-pharmacological interventions (Freeman, 2007). There are several studies that investigated the effects of psychotherapy on depression during pregnancy (Claridge, 2014; Howard et al., 2014b; van Ravesteyn et al., 2017). For example, Cognitive Behavioral Therapy (Austin et al., 2008; Burns et al., 2013; O'Mahen et al., 2013; Rahman et al., 2008), Interpersonal Psychotherapy (Grote et al., 2009; Spinelli et al., 2013) and mindfulness-based cognitive therapy (Dimidjian et al., 2015) showed small to moderate effect sizes in pregnant women (Howard et al., 2014b). Various psychosocial and multimodal interventions have been carried out during pregnancy to reduce depressive symptomology, however the evidence is inconclusive (Cunningham and Zayas, 2002; Dennis, 2005; Dennis et al., 2007). The majority of these studies targeted women with sub-clinical symptomatology, or had the primary aim to prevent postpartum depression, for example in antenatal classes (Brugha et al., 2000; Stamp et al., 1995).

However, next to depression, other psychiatric disorders may coexist during pregnancy (Fisher et al., 2012; Goodman and Freeman, 2014; Paschetta et al., 2013); 5.0–24.0% of patients in a clinical setting have two or more diagnosed co-morbid psychiatric disorders (Andersson et al., 2003; Borri et al., 2008; Cook et al., 2010), with a high incidence of anxiety-related disorders. To our knowledge, only one study focused on the prevalence of personality disorders during pregnancy, which turned out to be 6% based on a self-report measure (Borjesson et al., 2005). Emerging evidence suggests that comorbidity and psychosocial problems, including low socioeconomic status (SES) are important risk factors in the pathway of depression leading to adverse obstetric outcomes (Quispel et al., 2014). Also, women with pre-existing psychiatric vulnerability might relapse during pregnancy (Borjesson et al., 2005), for example due to unplanned pregnancy or inadequate social support or unhealthy life style. Moreover, treatment of pregnant women with psychiatric disorders puts extra challenge in a limited period of time because of lower rates of engagement and compliance, comorbidity, stigma and other barriers to seek treatment (Boyd et al., 2011; Goodman and Tyer-Viola, 2010; Ko et al., 2012; O'Mahen and Flynn, 2008). Women in large urban areas might be more at risk due to clustering of a multi-ethnic population and large socioeconomically deprived neighborhoods, which is associated with adverse birth outcomes (Scholmerich et al., 2014; Vos et al., 2014). As a consequence, in clinical practice, psychiatrists are often faced with a heterogeneous group of pregnant women with psychiatric co-morbidity and low SES who are not eligible for routine treatments mainly focusing on depression.

Based on longstanding clinical experience and relying on evidence-based components from other treatments during pregnancy (van Ravesteyn et al., 2017), we composed a Group-based Multicomponent Treatment (GMT) that aims to reduce stress, depressive and anxiety symptoms in women with co-morbid psychiatric and psychosocial problems with a special focus on emotional and practical preparation for motherhood. This weekly one-day treatment is provided in an open group, as positively viewed by women in a recent Cochrane review (Catling et al., 2015), to encourage peer-support and decrease social isolation and stigma. The treatment consisted of the following 5 consecutive components, based on our longstanding clinical experience and the existing evidence to treat mental disorders during pregnancy (Raats and Van Ravesteyn, 2015; van Ravesteyn et al., 2017): 1) weekly evaluation of treatment goals by a social psychiatric nurse; 2) psychoeducation by a perinatal psychiatrist; 3) cognitive behavioral therapy (CBT) by a clinical psychologist; 4) body-oriented therapy by an Infant Mental Health specialist, and 5) relaxation therapy by a creative arts therapist. Treatment as usual (TAU) comprised low frequent, individual counseling sessions provided by a social psychiatric nurse or a medical doctor. Both treatments were provided at the outpatient clinic and the number of sessions was based on an assessment of the patient's needs.

We hypothesized that Group-based Multicomponent Treatment (GMT) would be more effective than treatment as usual (TAU) in reducing depressive symptoms in women with co-morbid psychiatric and psychosocial problems. Because of known low recruitment and engagement rates in this hard-to-reach population (O'Mahen and Flynn, 2008), we introduced a patient-preference condition, for women not willing to randomize, to additionally investigate the effect of patients' preference for a group-based or individual therapy on treatment response (Preference Collaborative Review, 2008). This patient-preference randomized controlled trial enabled us to compare the effectiveness of our GMT vs. TAU and randomized vs. patient-preference conditions, in terms of reduction of depressive symptoms, obstetric outcomes, feasibility and patient's satisfaction on the treatment.

2. Methods

2.1. Study design and procedure

The study design was a single center patient-preference randomized controlled trial, comparing Group-based Multicomponent Treatment (GMT) versus individual counseling (treatment as usual, TAU). Eligible participants were randomized to GMT and TAU condition (1-to-1), stratified for gestational age less $<$ 24 weeks or more than $\geq$ 24 weeks. Participants who rejected randomization were invited to participate in parallel non-randomized patient-preference treatment conditions. Participants in the patient-preference treatment conditions underwent the same procedures as the randomized patients. This design provided four arms: a) randomized GMT; b) randomized TAU; c) patient-preference GMT and d) patient-preference TAU. We compared treatment effect of GMT versus TAU, and randomized versus patient-preference conditions.

2.2. Participants

Pregnant women were recruited between January 2010 and January 2013 after a diagnostic procedure at the tertiary outpatient clinic for perinatal psychiatry of the Department of Psychiatry, Erasmus University Medical Center (Erasmus MC), Rotterdam, the Netherlands. Rotterdam is the second largest city of the Netherlands and is characterized by a multi-ethnic population and large socioeconomically deprived neighborhoods. Patients were referred by general practitioners, midwives, gynecologists and psychiatrists from the bigger area of Rotterdam-Rijnmond. Inclusion criteria were: a) psychiatric and/or personality disorder verified with the Structured Clinical Interview for DSM-IV-TR Disorders (SCID) (First et al., 2002) by a trained medical doctor; b) gestational age between 12 and 33 weeks; and c) written informed consent. Exclusion criteria were: a) indication for hospital admission; b) inability to function in a group due to severe behavioral problems e.g. aggression, suicidal behavior, uncontrollable addictive behavior; c) insufficient command of the Dutch language; or d) inability to visit the outpatient clinic. Ethical approval was obtained from the hospital's Medical Ethics Committee of the Erasmus Medical Center. The trial was registered in the Dutch Trial Registry (www.trialregister.nl, number NTR3015).