Spring 5-18-2019

# Brief, Acceptance-based Intervention for Women with High-risk Pregnancies: A Pilot Case Series

Natalie Tunnell
*Southern Methodist University*, ntunnell@smu.edu

BRIEF, ACCEPTANCE-BASED INTERVENTION FOR WOMEN WITH HIGH-RISK PREGNANCIES: A PILOT CASE SERIES

Approved by:

_____
Prof. Alicia E. Meuret
Professor of Psychology

_____
Prof. Thomas Ritz
Professor of Psychology

_____
Prof. Michael Twohig
Professor of Psychology

# BRIEF, ACCEPTANCE-BASED INTERVENTION FOR WOMEN WITH HIGH-RISK PREGNANCIES: A PILOT CASE SERIES

A Thesis Presented to the Graduate Faculty of

Dedman College

Southern Methodist University

in

Partial Fulfillment of the Requirements

for the degree of

Master of Arts

with a

Major in Psychology

by

Natalie Tunnell

B.A., Psychology, University of Texas, Austin

May 18, 2019

ACKNOWLEDGMENTS

Thank you to the organizations and institutions that made this research possible: Jerry M. Lewis, M.D. Mental Health Research Foundation, Sam Taylor Fellowship, and Baylor University Medical Center. I would also like to acknowledge my graduate advisor, Alicia Meuret, my collaborators at Baylor UMC, and my thesis committee members for being instrumental in the success of this project. I am extremely grateful to my fellow labmates and SMU graduate student cohort for their constant encouragement and solidarity. Ultimately, this research would not have been accomplished without the unwavering support and patience from my loving parents, grandmother, siblings and friends.

Tunnell, Natalie B.A., Psychology, University of Texas at Austin

Brief, Acceptance-based Intervention for Women with High-risk Pregnancies: A Pilot Case Series

Advisor: Professor Alicia E. Meuret

Doctor of Philosophy conferred May 18, 2019
Dissertation completed February 17, 2019

Women hospitalized for medically high-risk pregnancies are at a greater risk for experiencing anxiety and depression than those who have low-risk pregnancies. An acceptance-based intervention (ACT) may be particularly suitable for such women, as it teaches them to stay in the present and experience uncomfortable sensations and thoughts. The aim of this study is to pilot-test the feasibility and acceptability of a brief ACT therapy on coping skills and psychological outcomes for pregnant women on hospitalized bedrest. Five patients admitted to the hospital for medically complicated pregnancies participated in a 7-day ACT intervention. Psychological outcomes (trauma, anxiety, depression and psychological flexibility) were assessed at baseline, mid-intervention, post-intervention and at a 1-month postpartum follow-up. Treatment credibility ratings were high, adherence to the homework modules was good and no adverse events were reported. Feedback from participants was mostly positive. Baseline levels of depression, anxiety, prenatal distress and PTSD symptoms were minimal, though trends of improvement were visible. High negative affect and low positive affect observed at baseline demonstrated the largest improvements during and following the intervention. Psychological flexibility was high at the baseline assessment and scores at the last assessments indicated minor changes. Overall, the brief ACT intervention was acceptable for participants and a feasible intervention to implement in a medical setting. Despite several limitations, the results provide

promising evidence for the benefit of ACT interventions in improving outcomes for women at-risk for psychiatric disorders.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

# INTRODUCTION

Pregnancy is assumed to be a joyful period in a woman's life; however, it can often be accompanied by psychological or physical complications that can have adverse effects on the mother, infant and their support systems. Premature rupture of membranes (breakage of amniotic sac before 38 weeks gestation) is one of the most common forms of physical complications that pregnant women experience, with 8-10% of women being diagnosed with preterm premature rupture of membranes (PPROM) during pregnancy (Huret et al., 2017). PPROM causes one-third of all preterm deliveries (before 37 weeks gestational age) and is considered high-risk because of the life-threatening conditions it creates for both the mother and fetus, including serious infection and fetal developmental delays (Medina & Hill, 2006; Huret et al., 2017). PPROM has become increasingly more common in the past 15 years as a result of advancement in effective medical treatment, improvement in surgical techniques and fertility treatments, which has increased the age in which women may conceive (Stirnemann et al., 2018). Causes for PPROM are largely unknown, though research has identified multiple risk factors, including uterine infection, older age, smoking and illicit drug use during pregnancy, lower socioeconomic status and poor nutrition (Zhang et al., 2017; Bramham et al., 2014).

Due to the high-risk nature, women with a PPROM diagnosis require around-the-clock monitoring on hospitalized bedrest until delivery. Many pregnant women on hospitalized bedrest describe their experience as an "emotional rollercoaster" in which they are simultaneously

fearful for the health of their unborn child and frustrated towards the state of their pregnancy (Rubarth, Schoening, Cosimano & Sandhurst, 2012). The increase in solitude, intense moments

of uncertainty, restriction of activity and loss of control can often leave the women vulnerable to emotional distress and can lead to family and interpersonal disruption (Rubarth, Schoening, Cosimano & Sandhurst, 2012). Reports indicate that as little as three days on bedrest can result in the onset of symptoms of anxiety, depression, fatigue and loss of muscle tone in the short term (Dunn, Handley & Shelton, 2007). For instance, Dunn and colleagues (2007) found that women on hospitalized bedrest had the highest levels of anxiety and depression and the lowest spiritual well-being when compared to healthy non-pregnant controls and healthy pregnant controls. Specifically, evidence suggests that women with high-risk pregnancies have prevalence rates of comorbid depression and anxiety of up to three times greater compared to women with uncomplicated pregnancies (Kingston et al., 2015). Moreover, women with high-risk pregnancies are at an up to five-fold increased risk of developing postpartum post-traumatic stress disorder compared to the normal population (Polachek, Dulitzky, Margolis-Dorfman & Simchen, 2016). That said, only about 5% of inpatient women with high-risk pregnancies receive treatment for psychological distress (Kingston et al., 2015). Left untreated, prenatal stress, anxiety and depression can lead to chronic symptoms that continue through delivery and critical early childhood developmental periods.

Pregnancy complications, such as PPROM, not only affect the mother but may also have a significant impact on the physical and mental well-being of the child. Trajectories for infants exposed to elevated prenatal maternal psychological distress are of significant public health concern and have been to adverse birth outcomes such as low birth weight, preterm delivery and

miscarriage (Fairbrother, 2015). Maternal stress has shown lasting effects on infant outcomes beyond delivery, including anxiety disorders, ADD/ADHD, inflammatory disorders and cognitive deficits (Tomfohr- Madsen et al., 2016). Mothers who experience anxiety or depression during pregnancy are more also likely to present with adverse thoughts and behaviors postpartum, such as withdrawing from the baby or experiencing racing and uncontrollable thoughts, which in turn have been directly linked to a negative effect on the mother-infant relationship (Weidner et al., 2010; Dagklis et al., 2016). Psychological distress of such nature decreases maternal sensitivity and responsiveness to infant cues, resulting in adverse social and behavioral outcomes for the child (Glazebrook et al., 2007).

Despite the documented negative outcomes of high-risk pregnancies for both mothers and infants, no tailored psychological treatment is available. At present, psychotropic medication is the primary treatment for pregnant women with anxiety and depression (Dimidjian et al., 2016; Lupattelli et al., 2015). However, 48.8% of women do not adhere to their prescribed regime (Lupattelli et al., 2015). Health concerns to the mother and potential risks of adverse side effects to the infant, including neonatal withdrawal and poor infant adaptions (difficulty feeding, reduced muscle strength) are among the reasons for non-compliance (Dimidjian et al., 2016; Lupattelli et al., 2015; Wisner et al., 2000). Moreover, survey data reports that the majority of women experiencing psychological distress during pregnancy favor nonpharmacological treatments (Dimidjian et al., 2014). Previous studies have indicated that 77% of high-risk pregnant women express an interest in weekly in-hospital psychological treatment, thus highlighting the demand for psychological therapy programs (Kingston et al., 2015). At present, interpersonal therapy (IPT) and cognitive behavior therapy (CBT) are the most frequently researched psychological interventions for pregnant women. IPT randomized controlled trials,

which focus on cultivating social networks, resolving interpersonal conflicts and increasing partner support, have yielded significant reductions in depressive symptoms compared to control groups (Claridge, 2014; Grote et al., 2009; Reay et al., 2006). Cognitive behavioral interventions have been adapted to fit the need of pregnant women, with RCTs in mindfulness CBT, group and computer-assisted therapy demonstrating greater improvement in symptoms of depression, and occasionally anxiety (Goodman et al., 2014; O'Mahen et al., 2013; Green et al., 2015). While RCTs on interpersonal therapy and cognitive behavioral therapy during pregnancy are emerging, few address psychological distress comprehensively (i.e. anxiety, depression, trauma-related stress) but most often focus solely on relieving symptoms of depression (Nillni, Mehralizade, Mayer & Milanovic, 2018; Goodman et al., 2014; Claridge, 2014; Lemon, Vanderkruik & Dimidjian, 2015). Additionally, these interventions may not be suitable for inpatient pregnant women because they are lengthy interventions (4+ weeks) during gestational period, which often times is not an option for high-risk pregnancies. They also do not address the unique needs of in-patient, high-risk pregnant women, including chronic pain, reduced mobility and uncontrollable unpleasant circumstances. Recent studies involving mindfulness- and acceptance-based interventions for pregnant women show promise in treating various psychological issues, such as elevated stress and anxiety (Vieten & Astin, 2008; Lemon, Vanderkruik & Dimidjian, 2015; Dimidjian et al., 2016), but remain mostly untested for women with high-risk pregnancies.

Among the few studies involving high-risk in-patient pregnant women, Weidner et. al., (2010) found a reduction in mothers' anxiety, but not depression, after a short-term psychosomatic intervention (Weidner et al., 2010). Another by Araujo and colleagues (2016) tested a nursing intervention implemented a relaxation technique for women on hospitalized bedrest, resulting in a decrease in depression symptoms (Araujo, Romero, Zandonade &

Amorim, 2016). Finally, Bonacquisti et al. (2017) reviewed the potential benefits of ACT for women with severe mental illness and discussed the development of a 4-session ACT-based group intervention at a perinatal psychiatric inpatient unit, though this study has yet to produce any results (Bonacquisti, Cohen & Schiller, 2017). To date, no study involving in-patient pregnant women and an acceptance-based intervention has published results.

Acceptance therapy provides a promising approach to reducing symptoms of psychological distress by developing skills intended to increase psychological flexibility. Psychological flexibility is the ability to accept difficult thoughts and feelings, which can arise from situations of great uncertainty, lack of control, or adversity, in order to live a more meaningful and valued life (Scott, Hann & McCracken, 2016). This therapeutic approach is based on the idea that avoidant coping styles and attempts to control negative feelings and thoughts can make psychological problems worse. Acceptance therapy focuses on changing the mother's relationship with their thoughts and emotions by cultivating acceptance and mindfulness skills as a way to respond to internal experiences, such as adverse bodily sensations and feelings. While similar to cognitive behavioral therapy, acceptance therapy does not intend to eliminate or control emotions or thoughts (Hayes, Pistorello & Levin, 2012). Individuals learn to cope with difficult thoughts and feelings by creating a nonjudgmental and open attitude towards one's experiences. Randomized controlled psychological studies have provided positive results for acceptance-based therapies for a large range of somatic and mental health conditions, including cancer, addiction, psychosis and chronic pain (Feros et al., 2013). Acceptance-based therapies are also effective in treating individuals with elevated levels of psychological distress, anxiety and depression (Eifert & Forsyth, 2005; Craske, 2012; Scott, Hann & McCracken, 2016), and for women with low-risk pregnancies (Dimidjian et al. 2016; Guardino et al., 2014).

As previously noted, no study to date has tested psychological interventions for women with high-risk pregnancies including acceptance-based therapies. An acceptance-based intervention could be particularly suitable for such women, as it teaches skills to stay in the present, develop willingness to experience uncomfortable sensations and thoughts rather than fighting them, while at the same time taking value-based actions. In addition, acceptance therapy provides the skills necessary for accepting and living with a course of pregnancy that is undesired and generates great uncertainty for the future. While most acceptance therapies are within 10 sessions in length, interventions as short as a single 75-minute session have yielded long-term effects (Hayes, Pistorello & Levin, 2012; Ruiz, Riaño-Hernández, Suárez-Falcón, & Luciano, 2016). Our own four-week treatment for individuals with panic disorder (Meuret et al., 2012) showed participants had a significant reduction in panic symptoms and an increase in the willingness to experience uncomfortable inner conditions. Therefore, we chose to test a brief acceptance-based therapy for women with PPROM for three reasons: (a) it has been shown to be highly effective in treating symptoms of anxiety, depression and/or stress; (b) it provides coping skills for those experiencing medical conditions that can be physically and emotionally distressing; and (c) a brief application of the therapy can result in improvements in mood and quality of life.

## SPECIFIC AIMS

The goal of this study is to test the feasibility and efficacy of a brief acceptance therapy on coping skills and psychological outcomes for women with premature rupture of membranes. The proposed study is the first to assess the benefits of an acceptance therapy on psychological

well-being during high-risk pregnancy and postpartum in those women. With the data collected from the study, we tested the following aims and hypotheses:

**Aim 1**

To assess the feasibility of and acceptance of a brief acceptance therapy for women hospitalized for premature rupture of membranes.

**Hypothesis 1.**

Women on hospitalized bedrest for premature rupture of membranes will find the intervention helpful and feasible based on self-reported treatment credibility, homework compliance and treatment participation.

**Aim 2**

To investigate the efficacy of a brief, acceptance therapy in improving psychological well-being in women during high-risk pregnancy and postpartum

**Hypothesis 1.**

Individuals who receive a brief acceptance therapy will exhibit more acceptance, from pre to post-partum follow-up, based on self-reports of psychological flexibility.

**Hypothesis 2.**

Individuals who receive acceptance therapy will have reductions in symptoms of depression, anxiety and stress at the post-partum follow-up.

**Hypothesis 3.**

Individuals who receive acceptance therapy will report less prenatal distress and PTSD symptoms and negative affect, at the post-partum follow-up.

## METHODS

### Participants

Participants with PPROM were admitted for hospitalized bedrest at from Baylor University Medical Center. Nurses and hospital staff informed study personnel any time a new PPROM patient was admitted to the antepartum unit. Study personnel approached these patients and provided them with information regarding the study protocol and potential benefits associated with participation. The study was offered as an additional resource for women who are distressed or would like to acquire more coping skills. Women with PPROM who expressed interest in the study participated in a prescreen assessment in order to determine eligibility, explain study rationale and evaluate for exclusionary criteria. Eligibility criteria included: a diagnosis of PPROM, English-speaking and 18 years or older. Women also had to be willing to engage in the brief, self-guided acceptance therapy. Women were ineligible to participate in the study for active suicidal ideation or self-harm in the past year, any history of suicide attempts and diagnoses of bipolar disorder, psychosis, mental retardation or organic brain damage. Eligibility was determined by the lead therapist in the proposed study during the prescreening phase by a brief diagnostic interview using the Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) and the Psychiatric Diagnostic Screening Questionnaire (PDSQ, Zimmerman & Mattia, 2001) (see details below). The final sample consisted of five participants who met the inclusion criteria and completed a baseline assessment.

## Procedure

The eligible women completed baseline questionnaires assessing psychological distress, affective states, and mindfulness-related cognitions. Immediately following the baseline assessment, the women participated in a weeklong acceptance therapy program based on an ACT workbook. Given that there are no ACT resources specifically for pregnancy, we chose this generic workbook designed to address anxiety and worries. A study therapist conducted the first acceptance therapy session, lasting about 1.5 hours, in which they explained the treatment rationale and provided an in-depth introduction to the acceptance skill training. During the following six consecutive days, the women completed selected modules from an acceptance-based self-help book. The therapist made daily contact with the participants in order to evaluate adherence and provide guidance or clarification regarding material. A mid-treatment assessment point was administered on day four of the 7-day intervention. Following the intervention week, the series of self-report psychological assessments was re-administered; the assessment was repeated after the week-long intervention and one month postpartum. All mothers involved in the study receive $75 for their completion in the study, as well as the self-help acceptance training book worth $25.

## Measures

There were four assessment points in total. The prescreen and baseline measures were administered during the same visit, with diagnostic measures administered first in order to determine the eligibility of the participants. Following, baseline self-report outcome and process measures were administered. The Credibility/Expectancy Questionnaire was administered after the first therapy session with the study therapist. A mid-treatment assessment point was administered on the fourth day of the acceptance intervention. This assessment consists of the

outcome and process measures. Assessments were repeated at posttreatment and at the last assessment 1-month post-partum.

**Diagnostic evaluations**.

*Demographics/health Questionnaire.* A questionnaire was included to assess for age, marital status, and number of children, race, and ethnicity, highest degree attained, years of education, occupation, and total household income. Additionally, the questionnaire evaluated pregnancy history and related symptoms, such as muscle and joint pain, trouble sleeping and gastrointestinal issues.

*Psychiatric Diagnostic Screening Questionnaire*. The 111-item Psychiatric Diagnostic Screening Questionnaire (PDSQ, Zimmerman & Mattie, 2001) assesses for diagnostic criteria and exclusion criteria (Major Depressive Disorder, Panic Disorder, Psychosis, Social Phobia, among others). The PDSQ has demonstrated good internal consistency ($a$=.85) and test-retest reliability ($a$=.81) (Zimmerman & Mattie, 2001).

*Structured Clinical Interview for DSM-5*. While the PDSQ provides a comprehensive evaluation of various psychological disorders, it does not assess for bipolar disorder I and II. The Structured Clinical Interview for the DSM-V (SCID) Bipolar disorder module was administered at the prescreen appointment to assess for bipolar disorder diagnoses. The SCID has been considered the "gold standard" diagnostic interview for decades. The interview is designed to closely correspond to clinical diagnostic criteria set by the Diagnostic and Statistical Manual. The SCID-5 has good to excellent diagnostic reliability (Chmielewski, Bagby, Clark & Watson, 2015). A member of the research team, who has been trained and supervised by a licensed clinical psychologist, administers the SCID.

**Measure of treatment credibility, feasibility and acceptability**.

*Credibility/Expectancy Questionnaire*. The 6-item Credibility/Expectancy Questionnaire was used to evaluate participants' beliefs about the acceptance intervention (CEQ; Devilly & Borkovec, 2000). The CEQ has good internal consistency ($a$=0.86) and test-retest reliability ($r$=0.82) and is proven adequate at predicting therapeutic outcome (Devilly & Borkovec, 2000).

*Homework compliance.* The study therapist used the daily phone calls with the participants to evaluate understanding of the module content and gauge homework completion. A rating form, which had three degrees of completion ("*fully complete*", "*partially complete*" and "*not at all*"), was used to score daily homework completion.

*Qualitative questions.* Nine open-ended questions were included in order to further assess client satisfaction and acceptability. Questions also prompted for feedback on what and how to improve the intervention. Questions included "*Do you think material included in the program was important and relevant*" and "*Were your expectations of this program met?*" The questions were created after a literature search of similar feasibility studies.

**Outcome measures**.

*Depression Anxiety Stress Scale-21*. The Depression Anxiety Stress Scale (Lovibond & Lovibond, 1995) measures symptoms of depression (DASS-D), anxiety (DASS-A) and stress (DASS-S). The answers on the 21-item Likert scale range from 0 (*Did not apply to me at all)* to 3 (*Applied to me very much, or most of the time*). The DASS has demonstrated excellent internal consistency ($a$=.97) and has high sensitivity to changes in symptoms (Page, Hooke & Morrison, 2007). Scores from the DASS-21 are multiplied by 2, ranging from 0-42, for use of the DASS-42

severity ratings. The DASS-21 has five severity ratings ranging from normal to extremely severe (Tran, Tran & Fisher, 2013).

*Prenatal Distress Questionnaire-Revised*. The Prenatal Distress Questionnaire-Revised (PDQ-R) was determined in a systematic review to have the best psychometric properties when measuring stress related to pregnancy (Yali & Lobel, 1999; Nast, Bolten, Meinlschmidt & Hellhammer, 2013). The PDQ-R has 17 Likert-type items with scores ranging from 0 (*Not at all*) to 2 (*Very much*). The PDQ-R has good internal consistency ($a$=.81) and test-retest reliability ($r$=.75) (Alderdice, Lynn & Lobel, 2012). Previous research has established norms for the PDQ-R in high-risk pregnancies ($M$=14.9, $SD$=7.4; Dias & Lobel, 1997).

*PTSD Checklist for DSM-5*. The 20-item PTSD Checklist assessed for the 20 DSM-5 symptoms of PTSD (PCL-5; Weathers, Litz, Keane, Palmieri, Marx & Schnurr, 2015). PTSD symptom severity was assessed with scores ranging from 0-80, with a cutoff score of 33 typically used to indicate a potential for PTSD diagnosis. An expected mean and standard deviation within civilian populations has been demonstrated (M=15.42, SD=14.72; Blevins, Weathers, Davis, Witte & Domino, 2015). The PCL-5 has excellent internal consistency ($a$=.94), good test-retest reliability ($r$=.66) and is considered superior to other scales measuring PTSD (Conybeare et al., 2012)

*Positive and Negative Affect Schedule*. The Positive and Negative Affect Schedule (PANAS) measured positive and negative affect with 20-items that provide independent scores for positive and negative affect (Watson, Clark & Tellegen, 1988). Scores on the PANAS range from 1 (*Not at all*) to 5 (*Very much*), with higher scores on either affect domains indicating the extent to which the affect has been experienced in the past week. Separate composite scores are calculated for each affect, resulting in scores between 10-50. In a sample of 239 Americans, the

mean for positive affect was 35.31 (8.53) and negative affect had a mean of 19.04 (7.76) (Merz et al., 2013). Additionally, the PANAS has demonstrated good internal consistency for the positive (*a*=.89) and negative (*a*=.85) affect scales (Crawford & Henry, 2004).

**Measure of treatment process**.

*Acceptance and Action Questionnaire*. The Acceptance and Action Questionnaire the most frequently applied measure of psychological flexibility (Fledderus et al., 2012). It consists of 7 self-report items, with scores ranging from 1 (*Never true*) to 7 (*Always true*) (Bond et al., 2011). The AAQ-II evaluated the participants' psychological flexibility, where higher scores indicate greater willingness to experience distressing thoughts and sensations. Scores on the AAQ-II for clinical populations have demonstrated a mean of 24.72 (11.35) (Costa, Maroco, Pinto-Gouveia & Galhardo, 2014). The scale has demonstrated good internal consistency (*a*=.84) and 3- and 12-month test-retest reliability (*r*=.81) (Bond et al., 2011).

**Intervention**

This weeklong, acceptance therapy is based on the theory that rigid attempts to control internal states, thoughts and feelings, can contribute to the worsening of symptoms of depression, anxiety and/or stress (Hayes, Pistorello & Levin, 2012). The therapy aims to educate women about how the willingness to experience uncomfortable pregnancy-related sensations and thoughts, rather than fighting them, can provide relief. "Letting go" of the agenda to gain control over unpleasant feelings and thoughts will be aided by metaphors and mindfulness exercises. Women engaged in daily audio-supported meditation (each practice averaging about 15 minutes in duration) and workbook exercises with the aim of (a) cultivating kindness towards oneself and others, (b) forgiving those who have caused past pain, and (c) learning to be a more accepting

and compassionate observer of ones' thoughts, feelings and behavior. Modifications were made to the classic ACT protocol to account for the specific needs and developmental processes pregnant women experience, including the self-paced nature of the intervention that allows for flexibility in case of frequent interruptions from nurses, fatigue and frequent visitors. This intervention included an increased emphasis on acceptance of physical discomfort and a focus on anxieties associated with delivering a preterm infant. Similarly, mindfulness practices were adjusted to accommodate for barriers, including fatigue and physical limitations, encountered during pregnancy and are often directed toward the baby, as in the loving-kindness meditation where the mother was encouraged to send loving energy towards their unborn child. Women were permitted to continue practicing mindfulness exercises from previous days in addition to exercises for the current day, though it was not required. The lead therapist had daily contact with the mothers over the phone to provide guidance, clarification and supplemental support for their training. These daily follow-ups lasted approximately 15-30 minutes and were scheduled according to the preferences of the participant and investigator. If unable to reach the participant, the principal investigator documented the failed connection and a follow up email was sent to confirm scheduled time for subsequent check-ins.

**Modules.**

*Day 1: What is acceptance?* The first day began with basic descriptions of the therapy and what is to be expected during treatment. Acceptance-therapy was presented as an alternative to the traditional approach to anxiety and worries, in which the women were taught to lean into their uncomfortable thoughts, feelings and sensations rather than fighting or avoiding them. Rationale supporting the acceptance approach was introduced by providing a metaphor of a Chinese finger trap, which highlights the need to create space in order to be set free from anxiety

and worries. The women learned strategies important for developing mindful acceptance, including how to nonjudgmentally pay attention in the present. *Day 2: Trapped in our mind.* This day discussed the consequences of evaluations and judgments that accompany most observations, experiences and thoughts in life. These evaluations, whether positive or negative, can exacerbate feelings of worry, regret, and anxiety by assigning unnecessary labels that elicit a maladaptive response, such as avoidance. For instance, a woman on hospitalized bedrest may believe she is being a "bad" mother because she is unable to care for her other children as usual, which may result in her avoiding other responsibilities she is able to accomplish. Women were encouraged to practice recognizing their evaluative thoughts and responding to them with an open and accepting mind. *Day 3: Becoming an observer.* Day 3 emphasized the importance of an impartial observer's perspective when responding to thoughts and experiences. In this session, women learned to further become an observer of their own thoughts and experiences without evaluating or assigning labels to them. *Day 4: Breaking free with mindful acceptance.* Content from this day focused on teaching the women to remain with their uncomfortable and distressing thoughts and sensations rather than avoiding them. Women engaged in mindfulness exercises designed to assist in reducing experiential avoidance and increasing awareness of bodily sensations and thoughts. An emphasis was placed on increasing the women's willingness to experience distressing thoughts and sensations with mindful acceptance. *Day 5: Comfort in a judgmental mind.* Day 5 further highlighted the benefits of mindful acceptance of difficult images, thoughts and urges. This session provided additional skills and strategies, such as writing difficult thoughts and sensations on note cards, intended to cultivate mindful acceptance. *Day 6: Cultivating compassion.* The sixth day discussed the important role compassion and forgiveness plays in acceptance. During this section, the women were encouraged to make peace with

themselves, their experiences and others who have inflicted emotional or physical pain. Women engaged in a loving-kindness meditation to demonstrate how to bring more compassion and acceptance into their life. Finally, *day 7 (Staying the course)* emphasized the need to practice becoming mindful and building their willingness to lean into the difficulties of life. The women were encouraged to use the skills they've learned to move forward towards their values without becoming entangled by doubts or setbacks. See Table 2 for outline of modules.

## STATISTICAL APPROACH

In order to address the aim and hypothesis regarding the feasibility of the intervention, we examined therapy and homework compliance as well as attrition rates. Interest in the proposed study was evaluated descriptively using participant enrollment and attrition. The study therapist used the daily phone calls with the participants to evaluate understanding and a rating form to assess amount of homework completion, which ranges from "*fully complete*", "*partially complete*" and "*not at all*". Homework compliance was assessed descriptively to gauge the overall feasibility of the proposed intervention. Qualitative data collected from open-ended questions at post-intervention were used to evaluate each participant's satisfaction with services and opinions about the overall structure of the study. The Credibility/Expectancy Questionnaire (CEQ) was also used to evaluate the participant's beliefs and acceptance of the intervention. Acceptability was evaluated based on the reporting of adverse events and observation of change in outcome variables (i.e. evidence of deterioration).

Given the missing data, a scatter plot for each primary and secondary measure was fitted with separate trend lines for each participant. Scores from the DASS-21 were multiplied by a factor of 2 in order to use the normative severity ratings of the DASS-42. Changes in primary (DASS) and secondary outcome variables (PCL, PANAS, PDQ-R), and treatment process variable (AAQ-II), were then evaluated by visual analysis and graphical representation (Richards et al., 1999; Figure 1-6). This method is commonly applied to case studies in which statistical analysis are not possible to demonstrate changes in raw scores across assessment time points. In visual analysis, change in scores over time, the variability in the data, and the overall trend are analyzed considered (Harrington & Velicer, 2015). Inference of the intervention's efficacy is made based on the direction and slope of trend lines.

## RESULTS

### Sample characteristics

Seven participants expressed interest in the study and were screened for inclusion and exclusion criteria. Of those, two patients were excluded due to ineligibility. The reasons for exclusion included not meeting for diagnosis of PPROM (n=1) and delivering before the enrollment process could be completed (n=1). Five participants, mean age 27.6 (*SD*=3.51), met study criteria and received the week-long acceptance intervention. Our sample was diverse, with 2 (40%) identifying as African American/Black, 2 (40%) White, and 1 (20%) Hispanic/Latina. The majority of participants were married 3 (60%), employed full or part-time 4 (80%), and had at least some college education 5 (100%). Three participants (60%) had at least one biological child previously (Table 1). Two of the five participants (Participant 4 and 5) had a history of pregnancy complications, with at least one of their previous pregnancies ending due to

complications. One participant's (Participant 1) current pregnancy began as twins but she lost one fetus early in the pregnancy. At baseline, only one participant (Participant 1) met diagnostic criteria for a psychiatric diagnosis (Major Depressive Disorder) according to the DSM-5. The mean baseline levels on the DASS were in a normal range: depression (*M*=4.80, *SD*=4.60), anxiety (*M*=1.20, *SD*=1.79), stress (*M*=5.20, *SD*=6.42; see Figure 2). Compared to normative data from the general population, negative affect was in the 74$^{th}$ percentile (*M*=18.40, *SD*=4.45) and positive affect was in the 36$^{th}$ percentile (*M*=29.80, *SD*=11.88; Crawford & Henry, 2004; Figure 4). Prenatal distress across participants was within normal range (*M*=11.40, *SD*=4.98; Figure 3), PTSD symptoms were minimal (*M*=5.80, *SD*=5.36; Figure 5) and psychological flexibility was high (*M*=43.40, *SD*=7.67; Figure 6). Three participants reported a range of physical symptoms, including gastrointestinal difficulties, weight loss and pain in the back, chest, muscles and joints assessed by the demographic/health questionnaire at baseline. All five participants indicated that their pregnancy complications, and potential subsequent negative consequences for their unborn baby, as their primary concerns. Following, we give brief descriptions of the five participants that met study criteria and completed the baseline assessment.

**Participant 1.**

Mrs. A was a 33-year-old, Hispanic, married, elementary school teacher whose membrane ruptured at 29 weeks gestation. She had one full-term pregnancy with no complications 3.5 years prior. Her pregnancy began as multiples but lost one of the fetuses at 8 weeks gestation, which had remained a source of worry and distress. Other concerns reported at the baseline assessment included constant bedrest and fetal monitoring for the remaining five weeks of pregnancy and the possibility of her infant ending up in the neonatal intensive care unit

after delivery. Upon the initial interview, she met criteria for Major Depressive Disorder, reporting symptoms of anhedonia, fatigue, hypersomnia and change in appetite, among others. She also reported symptoms of panic attacks and elevated levels of anxiety. Additionally, she reported physical symptoms of weight loss and back pain.

Mrs. A's overall symptoms at the baseline assessment were in the normal range for depression (DASS-D=4), stress (DASS-S=0) and anxiety (DASS-A=0). At the post-assessment, she presented with an increase in symptoms of depression and stress that continued to increase at the follow-up, though her levels remained within the normal range. Her normal level of anxiety was stable across the intervention (Figure 2). There was an improvement in her pregnancy-related distress from the post-assessment to the follow-up appointment, reducing her level of distress below typical levels observed in high-risk pregnancies (Figure 3; Dias & Lobel, 1997). Her baseline negative affect was within the 84$^{th}$ percentile and her positive affect was 1$^{st}$ percentile according to normative values reported in the general population (Crawford & Henry, 2004). Levels of negative and positive affect increased at both the post-assessment and follow-up, however her increase in positive affect was substantially more than in her negative affect, with almost a 146% increase (Figure 4). She experienced an increase in PTSD symptoms from baseline to the post-assessment, though her scores did not meet the clinical cutoff of 33 and eventually returned to minimal levels by the follow-up assessment (Figure 5). Mrs. A's psychological flexibility was initially high, with a baseline level of 48 out of 49. At the follow-up assessment, there was a slight decrease in her score on psychological flexibility, though she remained well above the average observed in similar populations (Figure 6; Costa et al., 2014).

**Participant 2.**

Mrs. B was a 24-year-old, White, married, female employed as a receptionist. Her membrane ruptured at 19.5 weeks, but was not admitted to the hospital until 24.5 weeks. She had no previous pregnancies and no co-existing medical conditions. At the initial intake, she reported symptoms of fatigue, depression and insomnia, but did not meet criteria for any formal psychiatric diagnosis. Additionally, her self-reports indicated elevated levels of worry and feelings of isolation or being "cutoff" from others. Her primary concerns included preterm birth, pain during labor and the health of her infant after delivery. Mrs. B reported physical symptoms of chest pain, constipation, muscle and joint paint.

At baseline, her symptoms were in the normal range for depression (DASS-D=6), anxiety (DASS-A=2) and stress (DASS-S=2). At the post-assessment, Mrs. B demonstrated a slight decrease in depression and anxiety, with her levels of depression continuing to decrease slightly at follow-up. There was a small increase in her levels of stress at the post-assessment, which eventually returned to baseline levels at follow-up. These changes were minimal as her depression, anxiety and stress scores remained in the normal range throughout treatment (Figure 2). She started out with levels of pregnancy distress slightly below average, which were reduced consistently from baseline to post, and then the follow-up assessment (Figure 3; Dias & Lobel, 1997). Her average levels of negative affect remained virtually unchanged across the assessments. Positive affect, initially in the 21$^{st}$ percentile, decreased slightly at the post-assessment but made a steep incline (60%) from post to follow-up, resulting in a score within the 88$^{th}$ percentile (Figure 4; Crawford & Henry, 2004). Symptoms of PTSD, initially below average, reduced continually across the study period (Figure 5). Very high levels of psychological flexibility were constant from baseline to follow-up (Figure 6).

**Participant 3.**

Mrs. C was a 26-year-old, White female employed as a teacher. She was married and had two previous full-term pregnancies. Mrs. C was admitted to the antepartum at 25 weeks gestation for preterm premature rupture of membranes. She had a history of post-partum depression with her 2nd child, but reported symptoms of depression within the normal range at the initial intake. She endorsed few pregnancy-related worries, including financial needs of the infant and preterm delivery but one of her main concerns was her current home renovation.

Mrs. C completed all 7 modules but was unable to complete the post-assessment before she delivered her baby, though she did complete the follow-assessment. Mrs. C did not report any physical symptoms or pain. Her reported symptoms of depression (DASS-D=2), anxiety (DASS-A=6) and stress (DASS-S=4) were in the normal range at baseline. Scores on the DASS-21 changed marginally, with stress increasing and anxiety decreasing, though these scores were within normal ranges throughout the study. Depression levels were constant, being rated within the normal range at every assessment (Figure 2). Her levels of pregnancy distress and PTSD symptoms, both below expected average, remained virtually unchanged across the assessment points (Figure 3, 5; Dias & Lobel, 1997; Blevins et al., 2015). Affect did not seem to change much in response to the intervention, with her negative affect, initially in the 55th percentile at baseline, remaining within the average range. Her positive affect, in the 85th percentile at baseline, remained above average (Figure 4; Crawford & Henry, 2004). Compared to similar populations, her psychological flexibility was well above the average throughout the study, though she did demonstrate a slight improvement at follow-up (Figure 6; Costa et al., 2014).

**Participant 4.**

Ms. D was a 26-year-old, Black medical practice assistant whose membrane ruptured at 31 weeks gestation. She was unmarried, though reported being in a committed relationship. Ms. D had three previous pregnancies, with two ending due to complications. Her third pregnancy was full-term and delivered by emergency cesarean section. She did not report any physical symptoms or pain. At the initial intake, she endorsed symptoms of generalized anxiety, such as worrying about a number of situations or events and restlessness, though did not meet diagnostic criteria for GAD. She also noted pregnancy-related concerns including preterm delivery, the health of her infant post-partum and pain during labor. Ms. D went into labor shortly after initiating the study, thus she only completed one module. She did not complete the post or follow up assessment.

At baseline, she rated her symptoms of depression (DASS-D=0), anxiety (DASS-A=0) and stress (DASS-S=2) in the normal range at baseline (Figure 2). Pregnancy distress was below the mean observed in other women with high-risk pregnancies (Figure 3; Dias & Lobel, 1997). She reported an average level of negative affect ($78^{th}$ percentile) and positive affect that was above average (>99%) compared to normative data (Figure 4; Crawford & Henry, 2004). She did not report any symptoms of PTSD at baseline (Figure 5). Ms. D's baseline psychological flexibility was high, with a score of 47 out of the possible 49 (Figure 6).

**Participant 5.**

Ms. E was a 29-year-old, Black woman who was unemployed. Ms. E was unmarried but in a committed relationship. She was admitted to the antepartum unit after her membrane ruptured at 25 weeks gestation. She had one previous pregnancy 1.5 years ago that ended in a

miscarriage at 8 weeks gestation, which she indicated as very distressing. She reported a history of substance use and depression, but did not meet criteria currently or during the time of her current pregnancy. At the initial intake, Ms. E's main concerns included events during upcoming labor, preterm birth and the health of her baby post-partum. She was also experiencing gastrointestinal difficulties.

At the baseline assessment, she rated herself in the mild range for depression (DASS-D=12) and stress (DASS-S=16) and in the normal range for anxiety (DASS-A=0). Ms. E went into labor shortly after initiating the study, thus she only complete 2 modules. She completed a post-assessment but was unable to complete the follow-up. At the post-assessment, she demonstrated a significant improvement in depression and stress, achieving levels in the normal range. However, levels of anxiety increased from the normal range to mild (Figure 2). There were no changes in her pregnancy distress, which remained above the average for women with high-risk pregnancies, from baseline to the post-assessment (Figure 3). Symptoms of PTSD were below average and were stable across the assessment points (Figure 5; Blevins et al., 2015). Her negative affect, beginning in 90$^{th}$ percentile at baseline, was reduced by 54% (18$^{th}$ percentile) at the post-assessment. A 28% increase in her positive affect from baseline (36$^{th}$ percentile) to the post-assessment (77$^{th}$ percentile) was achieved (Figure 4; Crawford & Henry, 2004). Psychological flexibility began above average, compared to similar populations, however levels were improved by 33.33% at the post-assessment (Figure 6; Costa et al., 2014).

**Feasibility, acceptability, and credibility**

No adverse consequences were reported, and there was no clear decline in symptoms or functioning during or following intervention. No participant voluntarily chose to drop out or discontinue participation in the study, though two participants (4 and 5) were unable to complete

all seven sessions due to unexpected preterm delivery. Though these two patients completed less than 2 sessions, an average of 4.6 sessions were completed among the five participants. Of the sessions that were completed, adherence to the homework modules was good, with 69.57% of the homework being "*fully complete*" and the remaining 30.43% being "*partially complete*". Participant 1 was the only participant to not fully complete the homework, the other four participants adhered 100% to the homework modules. Participants in the study have been extremely receptive to the program and all of the women stated they believed the program would improve their functioning. Treatment credibility ratings, completed by three participants, were high 8.33 (*SD*=.58). Additionally, many of the women have reported benefits from the program, one participant quoting that it encouraged her "to be in touch with [her] feelings and emotions" and decide "where [she] wants… to take things in life."

## DISCUSSION

This study was an exploratory case series with the purpose of examining the feasibility and acceptability of a brief acceptance-based intervention for women admitted to the hospital for preterm premature rupture of membranes (PPROM). Our first aim was to assess the feasibility and acceptability of a brief acceptance therapy for women on hospitalized bedrest. We hypothesized that the intervention would be acceptable and feasible given patient participation, and self-reports of credibility and satisfaction. We found that the brief self-guided ACT intervention was generally acceptable to all of the participants, given that no participant experienced a significant increase in symptoms and there were no reports of adverse effects. Though there were unavoidable complications (i.e. unexpected delivery during intervention) that reduced the amount of participation, there was a high level of engagement and adherence. The

three participants who did not deliver during the intervention, Participants 1, 2, and 3, completed all 7 of the modules. And, of all five of the participants, only Participant 1 did not adhere completely to the prescribed homework, with the other four participants fully completed every module they were capable of. Treatment credibility was high, indicating that the participants believed the intervention was logical and would successfully reduce symptoms, with a mean of 8.33 (*SD*=.58) out of 9 . Qualitative feedback was largely positive, though one participant did report that the assessments were burdensome. All the women proposed the study indicated they would like some type of therapeutic or supportive service during their stay at the hospital. These data confirm our hypothesis that the ACT intervention was acceptable and feasible for the participants, though improvements may be made to decrease attrition and missing data. As demonstrated in previous literature, the unique stress of hospitalized bedrest was a major concern for the participants, as all of the women indicated that their hospital stay interrupted their daily lives and exacerbated their symptoms (Rubarth, Schoening, Cosimano & Sandhurst, 2012). Overall, the demand for services intended to teach coping skills and reduce stress was high and the intervention was received well.

Our second aim was to investigate the efficacy of a weeklong acceptance therapy in improving psychological outcomes and improve psychological flexibility during and following a high-risk pregnancy. First, we hypothesized that individuals who receive the ACT intervention will have reductions in our primary (depression, anxiety, stress, DASS-21) and secondary (prenatal distress, PTSD symptoms and affect) psychological outcomes at the post-partum follow-up. Four of the five participants had depression, anxiety and stress levels within normal ranges at baseline, thus any improvements were minor. Participant 5 had depression and stress scores in the mild range that were reduced to the normal range at her last assessment. That said,

her anxiety level, which was in the normal range at baseline, increased to the mild range at post-intervention assessment. Overall, the trends for the DASS indicated a reduction in symptoms over time (Figure 1). Though participant 1, whom met criteria for MDD at baseline, reported DASS scores within normal ranges, her positive affect was largely below average, which is indicative of depression (Brown, Chorpita, Korotitsch & Barlow, 1997). Trends in negative affect were varied, as half of the sample demonstrated an increase and the others demonstrating a decrease. Overall, the average for negative affect decreased slightly and positive affect increased significantly, increasing from the 36$^{th}$ percentile to the 77$^{th}$ percentile (Figure 4; Crawford & Henry, 2004). Pregnancy-related distress was rated low at baseline, compared to scores from a similar population, and improved over the course of treatment and follow-up for most of the participants (Dias & Lobel, 1997). However, Participant 5's pregnancy distress remained at a high level across the assessment points (Figure 3). At participant's final assessments, PTSD symptoms for all of the participants were maintained at a minimal level (Figure 5; Blevins et al., 2015).

Our second hypothesis was that individuals who receive acceptance therapy would exhibit more acceptance and adaptive coping skills at the post assessment, based on self-reports of psychological flexibility. Levels of psychological flexibility were high at the baseline assessment and scores at the last assessments indicated minor changes. The largest change in psychological flexibility was in Participant 5, whom increased her score by 10 points (33.33%) at the post-assessment. Overall, psychological flexibility was above the expected values throughout the study (Figure 6; Costa et al., 2014).

Considering the novelty of the project design and the processes required when collaborating with medical centers, the study gained considerable understanding of the

population and intervention. Contrary to previous literature, most of women in our study did not endorse elevated baseline levels of emotional and psychological distress (Rubarth, Schoening, Cosimano & Sandhurst, 2012; Dunn, Handley & Shelton, 2007). No participant demonstrated a worsening of symptoms, which also contradicts previous research stating that women with high-risk pregnancies are at an increased risk of developing psychiatric disorders such as postpartum post-traumatic stress disorder and postpartum depression (Polachek, Dulitzky, Margolis-Dorfman & Simchen, 2016; Milgrom et al,. 2008). However, most of the participants reported disordered emotional experience, characterized high negative affect and/or low positive affect. Though unexpected, this discrepancy may be attributed to a number of aspects, such as underreporting or population and setting characteristics. Our sample was racially and ethnically diverse, thus there may be protective factors specific to minorities that moderate how they experience and interpret stressful or traumatic events (Bonanno, Galea, Bucciarelli & Vlahov, 2007). Additionally, measurement data (i.e. norms, means, etc.) for these specific or similar racial and ethnic populations does not exist, therefore we are unable to determine how our results compare to other observations. Given the novelty of this study design and lack of literature on this particular population, there may be unique and unknown factors that impact responses to the self-reports.

The largest improvement was observed in positive affect, which increased by an average of 7.45 (25%), successfully raising our post-intervention mean to above average (Figure 4; Crawford & Henry, 2004). Research suggests that positive affect is a crucial facilitator for therapeutic engagement among inpatient populations, thus highlighting the importance of these findings (Ramanathan-Elion, McWhorter, Wegener & Bechtold, 2016). Additionally, it is apparent that the participant experiencing the most psychological distress, participant 5,

exhibited the most improvement on multiple domains (including depression, stress, affect and psychological flexibility) despite having not completed all 7 days. It is possible that improvements were minimal due to the ceiling and floor effects, limiting the variance of scores and interfering with our ability to capture sufficient changes in symptoms (Urbina, 2014). Though most changes were small, trends of improvement were visible among most variables and participants (Figure 1-6). These results do not provide evidence for efficacy but the study itself provides important knowledge and foundation for future studies. Ultimately, results from the case studies have informed our conceptualization of the population and provided valuable information on interventions for hospitalized pregnant women.

As expected with pilot studies of this type, there are multiple limiting factors. The number of participants was small and it is not possible to generalize findings from this case study to women with high-risk pregnancies in general. The lack of a control condition prevents us from confidently discriminating between effects of time and confounding factors from the effects of the treatment itself. Three cases were missing data from the post assessment or follow-up, or both, due to the sudden and unexpected delivery of the baby. This missing data limited our understanding of the responses to the intervention across time. Due to floor and ceiling effects, we were unable to assess for reliable change in our data, which would have required baseline values that allowed for improvements to be observed (Jacobson & Truax, 1991; Duff, 2012). Additionally, there was only one study therapist, a female, administering the intervention and it may be that results found are due, in part, by her characteristics, such as gender, age and ethnicity.

The data and feedback from this pilot study will be used to improve the efficiency and feasibility for future studies, particularly a randomized controlled trial. This study encountered

multiple unforeseen factors: 1) An OB/GYN provider group, consisting of over ten physicians, left Baylor University Medical Center, reducing the patient flow by 90% and 2) changes in insurance coverage has reduced the amount of time women are encouraged to remain hospitalized during their high-risk pregnancies. Consequently, our participant flow was not as expected. Despite the low N and limitations, this type of feasibility study is relevant and highly crucial when working with a population and intervention that has very little research available. We acknowledge the limitations of this study and have made significant efforts to improve upon these aspects for future studies. Specifically, the length of therapy (previously 7 days) will be shortened, given that four of the seven women whom expressed interest in the study delivered before the completion. To ensure that we increase recruitment numbers for future studies, we are expanding our inclusion criteria to include all women with high-risk pregnancies who are admitted to hospitalized bedrest. We are also extending the study to additional medical center antepartum units, with an IRB application currently being processed. Given the racial and ethnic composition of our sample, and of high-risk pregnancy in general, it is important for future research to consider components that are culturally sensitive and acknowledge the numerous variations in the population (e.g. including more culturally sensitive measures and involving more aspects that incorporate social support). Additionally, the data acquired from this pilot study will inform an adaptation to the treatment protocol so that it is more suitable for the population and their presenting concerns.

Overall, the outcomes for maternal and infant health in Texas is concerning. Despite the advancement in technology and medical practices, Texas has one of the highest maternal mortality rates in the country, particularly for low-income women, and has been rated above the national average for preterm birth for a decade (Kormondy & Archer, 2017). This may be

attributed to an increase in certain risk factors for high-risk pregnancy, including obesity, diabetes, hypertension and poor nutrition (Zhang et al., 2017). The disparities in health care not only increase prevalence of these risk factors, but also limit the amount of resources available, such as appropriate prenatal care (Lee, Ayers & Holden, 2012). Thus, women of racial minorities and lower socioeconomic statuses are at a higher risk for having a high-risk pregnancy (Kormondy & Archer, 2017; Lee, Ayers & Holden, 2012). Our sample, over half (60%) of which were of a racial minority, provides evidence for these apparent disparities. As prevalence in risk factors rises, the availability of affordable resources designed to reduce impact of high-risk pregnancy is imperative.

Research has only recently begun to focus on the prevention and treatment for perinatal psychological distress, especially within women with high-risk pregnancies. As maternal and infant outcomes have yet to improve, or even worsened, it has become increasingly important to focus of interventions that may benefit or improve their outcomes. The development of effective, novel and feasible interventions is crucial for both the mother and baby. To our knowledge, this is the first study to implement a self-guided acceptance-based intervention for inpatient pregnant women. These results provide a promising evaluation of a novel acceptance-based intervention for high-risk pregnancies. Ultimately, this study not only makes a valuable contribution to the literature but also has the potential to improve the lives of many women whom have historically had little psychological support.

REFERENCES

Alderdice, F., Lynn, F., & Lobel, M. (2012). A review and psychometric evaluation of pregnancy-specific stress measures. *Journal of Psychosomatic Obstetrics & Gynecology*, 33(2), 62-77. doi:10.3109/0167482x.2012.6

Araújo, W. S., Romero, W. G., Zandonade, E., & Amorim, M. H. (2016). Effects of relaxation on depression levels in women with high-risk pregnancies: a randomised clinical trial. *Revista latino-americana de enfermagem*, *24*(0), e2806. doi:10.1590/1518-8345.1249.2806

Beck, A.T., Ward, C. H., Mendelson, M., Mock, J., & Erbaugh, J. (1961) An inventory for measuring depression. *Archives of General Psychiatry,* 4, 561-571.

Blevins, C. A., Weathers, F. W., Davis, M. T., Witte, T. K., & Domino, J. L. (2015). The posttraumatic stress disorder checklist for DSM-5 (PCL-5): Development and initial psychometric evaluation. *Journal of Traumatic Stress*, 28(6), 489–498. https://doi.org/10.1002/jts.22059

Bonacquisti, A., Cohen, M. J., & Schiller, C. E. (2017). Acceptance and commitment therapy for perinatal mood and anxiety disorders: Development of an inpatient group intervention. *Archives of Women's Mental Health*, 20(5), 645–654. https://doi.org/10.1007/s00737-017-0735-8

Bonanno, G. A., Galea, S., Bucciarelli, A., & Vlahov, D. (2007). What predicts psychological resilience after disaster? The role of demographics, resources, and life stress. Journal of Consulting and Clinical Psychology, 75(5), 671–682. https://doi.org/10.1037/0022-006X.75.5.671

Bond, F. W., Hayes, S. C., Baer, R. A., Carpenter, K. M., Guenole, N., Orcutt, H. K., . . . Zettle, R. D. (2011). Preliminary Psychometric Properties of the Acceptance and Action Questionnaire–II: A Revised Measure of Psychological Inflexibility and Experiential Avoidance. *Behavior Therapy*, 42(4), 676-688. doi:10.1016/j.beth.2011.03.00773040

Bramham, K., Parnell, B., Nelson-Piercy, C., Seed, P. T., Poston, L., & Chappell, L. C. (2014). Chronic hypertension and pregnancy outcomes: systematic review and meta-analysis. *BMJ (Clinical research ed.)*, *348*, g2301. doi:10.1136/bmj.g2301

Brown, T. A., Chorpita, B. F., Korotitsch, W., & Barlow, D. H. (1997). Psychometric properties of the Depression Anxiety Stress Scales (DASS) in clinical samples. *Behaviour Research and Therapy*, 35(1), 79-89. doi:10.1016/s0005-7967(96)00068-x

Carver, C. S., Scheier, M. F., & Weintraub, J. K. (1989). Assessing coping strategies: A theoretically based approach. Journal of Personality and Social Psychology, 56(2), 267-283. doi:10.1037//0022-3514.56.2.267

Chmielewski, M., Clark, L. A., Bagby, R. M., & Watson, D. (2015). Method matters: Understanding diagnostic reliability in DSM-IV and DSM-5. *Journal Of Abnormal Psychology*, *124*(3), 764-769. doi:10.1037/abn0000069

Claridge, A. M. (2014). Efficacy of systemically oriented psychotherapies in the treatment of perinatal depression: A meta-analysis. *Archives Of Women's Mental Health*, 17(1), 3-15. doi:10.1007/s00737-013-0391-6

Conybeare, D., Behar, E., Solomon, A., Newman, M. G., & Borkovec, T. D. (2012). The PTSD Checklist—Civilian Version: Reliability, validity, and factor structure in a nonclinical sample. *Journal Of Clinical Psychology*, 68(6), 699-713. doi:10.1002/jclp.21845

Costa, J., Marôco, J., Pinto-Gouveia, J., & Galhardo, A. (2014). Validation of the psychometric properties of Acceptance and Action Questionnaire-II in clinical and nonclinical groups of Portuguese population. *International Journal of Psychology & Psychological Therapy*, 14(3), 353–364. DOI: 10.1037/t11921-000

Craske, M. G. (2012). Transdiagnostic Treatment For Anxiety And Depression. Depression and Anxiety, 29(9), 749-753. doi:10.1002/da.21992

Crawford, J. R., & Henry, J. D. (2004). The Positive and Negative Affect Schedule (PANAS): Construct validity, measurement properties and normative data in a large non-clinical sample. British *Journal of Clinical Psychology*, 43(3), 245-265. doi:10.1348/0144665031752934

Dagklis, T., Papazisis, G., Tsakiridis, I., Chouliara, F., Mamopoulos, A., & Rousso, D. (2016). Prevalence of antenatal depression and associated factors among pregnant women hospitalized in a high-risk pregnancy unit in Greece. *Social Psychiatry And Psychiatric Epidemiology*, *51*(7), 1025-1031. doi:10.1007/s00127-016-1230-7

Dias, L., & Lobel, M. (1997). Social comparison in medically high-risk pregnant women. *Journal of Applied Social Psychology*, 27(18), 1629–1649. https://doi.org/10.1111/j.1559-1816.1997.tb01617.x

Dimidjian, S., Goodman, S. H., Felder, J. N., Gallop, R., Brown, A. P., & Beck, A. (2014). An open trial of mindfulness-based cognitive therapy for the prevention of perinatal depressive relapse/recurrence. *Archives of Women's Mental Health*, 18(1), 85-94. doi:10.1007/s00737-014-0468

Dimidjian, S., Goodman, S. H., Felder, J. N., Gallop, R., Brown, A. P., & Beck, A. (2016). Staying well during pregnancy and the postpartum: A pilot randomized trial of mindfulness-based cognitive therapy for the prevention of depressive relapse/recurrence. *Journal of Consulting and Clinical Psychology*, 84(2), 134-145. doi:10.1037/ccp0000068

Duff, K. (2012). Evidence-based indicators of neuropsychological change in the individual patient: Relevant concepts and methods. *Archives of Clinical Neuropsychology*, 27(3), 248–261. https://doi.org/10.1093/arclin/acr120

Dunn, C., Hanieh, E., Roberts, R., & Powrie, R. (2012). Mindful pregnancy and childbirth: effects of a mindfulness-based intervention on women's psychological distress and well-being in the perinatal period. *Archives Of Women's Mental Health*, *15*(2), 139-143. doi:10.1007/s00737-012-0264-4

Dunn, L. L., Shelton, M. M., & Handley, M. (2007). Spiritual Well-Being, Anxiety, And Depression In Antepartal Women On Bedrest. *Issues in Mental Health Nursing*, 28(11), 1235-1246. doi:10.1080/01612840701651504

Eifert, G. H., & Forsyth, J. P. (2005). *Acceptance and commitment therapy for anxiety disorders: A practitioner's treatment guide to using mindfulness, acceptance, and values-based behavior change strategies*. Oakland, CA: New Harbinger Publications. Retrieved from http://proxy.libraries.smu.edu/login?url=http://search.ebscohost.com/login.aspx?direct=true&db=psyh&AN=2005-08147-000&site=ehost-live&scope=site

Enders, C. K. (2011). Missing not at random models for latent growth curve analyses. *Psychological Methods*, *16*(1), 1-16. doi:10.1037/a0022640

Fairbrother, N., Young, A., Janssen, P., Antony, M., & Tucker, E. (2015). Depression and anxiety during the perinatal period. *BMC Psychiatry*, *15*(1). http://dx.doi.org/10.1186/s12888-015-0526-6

Feros, D., Lane, L., Ciarrochi, J., & Blackledge, J. (2011). Acceptance and Commitment Therapy (ACT) for improving the lives of cancer patients: a preliminary study. *Psycho-Oncology*,. doi:10.1002/pon.2083

First, M., Williams, J., Karg, R., & Spitzer, R. (2015). Structured Clinical Interview for DSM-5 Disorders. *American Psychological Association.*

Fledderus M, Oude Voshaar MA, ten Klooster PM, Bohlmeijer ET (2012). Further evaluation of the psychometric properties of the Acceptance and Action Questionnaire-II. *Psychological Assessment* 24, 925.

Glazebrook, C., Marlow, N., Israel, C., Croudace, T., Johnson, S., White, I. R., & Whitelaw, A. (2007). Randomised trial of a parenting intervention during neonatal intensive care. *Archives of Disease in Childhood - Fetal and Neonatal* Edition, 92(6). doi:10.1136/adc.2006.103135

Goodman, J. H., Guarino, A., Chenausky, K., Klein, L., Prager, J., Petersen, R., … Freeman, M. (2014). CALM Pregnancy: Results of a Pilot Study of Mindfulness-Based Cognitive Therapy for Perinatal Anxiety. Archives of Women's Mental Health, 17(5), 373–387. http://doi.org/10.1007/s00737-013-0402-7

Gratz, K. L., & Roemer, L. (2004). Multidimensional Assessment of Emotion Regulation and Dysregulation: Development, Factor Structure, and Initial Validation of the Difficulties in Emotion Regulation Scale. *Journal of Psychopathology and Behavioral Assessment*, 26(1), 41-54. doi:10.1023/b:joba.0000007455.08539.94

Green, S. M., Haber, E., Frey, B. N., & McCabe, R. E. (2015). Cognitive-behavioral group treatment for perinatal anxiety: A pilot study. Archives Of Women's Mental Health, 18(4), 631-638. doi:10.1007/s00737-015-0498-z

Grote, N. K., Swartz, H. A., Geibel, S. L., Zuckoff, A., Houck, P. R., & Frank, E. (2009). A randomized controlled trial of culturally relevant, brief interpersonal psychotherapy for perinatal depression. Psychiatric Services, 60(3), 313-321. doi:10.1176/appi.ps.60.3.313

Guardino, C. M., Schetter, C. D., Bower, J. E., Lu, M. C., & Smalley, S. L. (2014). Randomised controlled pilot trial of mindfulness training for stress reduction during pregnancy. *Psychology & Health*, *29*(3), 334-349. doi:10.1080/08870446.2013.852670

Hamer, R. M., & Simpson, P. M. (2009). Last observation carried forward versus mixed models in the analysis of psychiatric clinical trials. The American Journal Of Psychiatry, 166(6), 639-641. doi:10.1176/appi.ajp.2009.09040458

Harrington, M., & Velicer, W. F. (2015). Comparing visual and statistical analysis in single case studies using published studies. *Multivariate Behavioral Research* 50, 162–183. doi:10.1080/00273171.2014.973989

Hayes, S. C., Strosahl, K., Wilson, K. G., Bissett, R. T., Pistorello, J., Toarmino, D., . . . Mccurry, S. M. (2004). Measuring experiential avoidance: A preliminary test of a working model. The Psychological Record, 54(4), 553-578. doi:10.1007/bf03395492

Hayes, S. C., Pistorello, J., & Levin, M. E. (2012). Acceptance and commitment therapy as a unified model of behavior change. *The Counseling Psychologist*, 40(7), 976-100

Heck, R. H., Thomas, S. L., & Tabata, L. N. (2014). Multilevel *and longitudinal modeling with IBM SPSS*. New York: Routledge, Taylor & Francis Group.

Huret, C., Perriera, B., Collange, V., Delabaere, A., Rouzaire, M., Lemery, D., . . . Gallot, D. (2017). Premature rupture of membranes ≥37 weeks of gestation: Predictive factors for labour onset within 24 hours. *Gynocologie, Obstetrique, Fertilite & Senologie*, 45(6), 348-352. doi:10.1016/j.gofs.2017.05.001

Jacobson, N. S., & Truax, P. (1991). Clinical significance: A statistical approach to defining meaningful change in psychotherapy research. *Journal of Consulting and Clinical Psychology*, 59, 12–19.

Kingston, D., Janes-Kelley, S., Tyrrell, J., Clark, L., Hamza, D., & Holmes, P. et al. (2015). An Integrated Web-Based Mental Health Intervention of Assessment-Referral-Care to Reduce Stress, Anxiety, and Depression in Hospitalized Pregnant Women With Medically High-Risk Pregnancies: A Feasibility Study Protocol of Hospital-Based Implementation. *JMIR Research Protocols*, *4*(1), e9. doi:10.2196/resprot.4037

Kormondy, M. and Archer, N. 2017 Healthy Texas Babies Data Book. Austin, TX: Division for Community Health Improvement, Texas Department of State Health Services, 2017.

Kroenke, K., Spitzer, R. L., & Williams, J. W. (2001). The PHQ-9: Validity of a brief depression severity measure. *Journal Of General Internal Medicine*, *16*(9), 606-613. doi:10.1046/j.1525-1497.2001.016009606.x

Lee, S., Ayers, S., & Holden, D. (2012). Risk perception of women during high risk pregnancy: A systematic review. Health, Risk & Society, 14(6), 511–531. https://doi.org/10.1080/13698575.2012.701277

Lemon, E. L., Vanderkruik, R., & Dimidjian, S. (2015). Treatment of anxiety during pregnancy: Room to grow. *Archives Of Women's Mental Health*, 18(3), 569-570. doi:10.1007/s00737-015-0514-3

Lovibond, S.H. & Lovibond, P.F. (1995). *Manual for the Depression Anxiety Stress Scales*. (2nd. Ed.) Sydney: Psychology Foundation.

Lupattelli, A., Spigset, O., Björnsdóttir, I., Hämeen-Anttila, K., Mårdby, A., Panchaud, A., & ... Nordeng, H. (2015). Patterns and factors associated with low adherence to psychotropic medications during pregnancy—a cross-sectional, multinational web-based study. *Depression And Anxiety*, *32*(6), 426-436. doi:10.1002/da.22352

Medina, T., & Hill, A. (2006). Preterm Premature Rupture of Membranes: Diagnosis and Management. *American Family Physician*, 73(4):659-664.

Milgrom, J., Gemmill, A. W., Bilszta, J. L., Hayes, B., Barnett, B., Brooks, J., . . . Buist, A. (2008). Antenatal risk factors for postnatal depression: A large prospective study. Journal of Affective Disorders, 108(1-2), 147-157. doi:10.1016/j.jad.2007.10.014

Merz, E. L., Malcarne, V. L., Roesch, S. C., Ko, C. M., Emerson, M., Roma, V. G., & Sadler, G. R. (2013). Psychometric properties of Positive and Negative Affect Schedule (PANAS) original and short forms in an African American community sample. *Journal of affective disorders*, 151(3), 942-9.

Moos, R. H., & Moos, B. S. (1994). *Family Environment Scale manual*. CA: Consulting Psychologist Press.

Nast, I., Bolten, M., Meinlschmidt, G., & Hellhammer, D. H. (2013). How to Measure Prenatal Stress? A Systematic Review of Psychometric Instruments to Assess Psychosocial Stress during Pregnancy. *Paediatric and Perinatal Epidemiology*, 27(4), 313-322. doi:10.1111/ppe.12051

Nillni, Y. I., Mehralizade, A., Mayer, L., & Milanovic, S. (2018). Treatment of depression, anxiety, and trauma-related disorders during the perinatal period: A systematic review. *Clinical Psychology Review*. https://doi.org/10.1016/j.cpr.2018.06.004

O'Mahen, H., Himle, J. A., Fedock, G., Henshaw, E., & Flynn, H. (2013). A pilot randomized controlled trial of cognitive behavioral therapy for perinatal depression adapted for women with low incomes. Depression And Anxiety, 30(7), 679-687. doi:10.1002/da.22050

Page, A. C., Hooke, G. R., & Morrison, D. L. (2007). Psychometric properties of the Depression Anxiety Stress Scales (DASS) in depressed clinical samples. *British Journal Of Clinical Psychology*, 46(3), 283-297. doi:10.1348/014466506X158996

Polachek, I. S., Dulitzky, M., Margolis-Dorfman, L., & Simchen, M. J. (2015). A simple model for prediction postpartum PTSD in high-risk pregnancies. *Archives of Womens Mental Health*, 19(3), 483-490. doi:10.1007/s00737-015-0582-4

Ramanathan-Elion, D. M., McWhorter, J. W., Wegener, S. T., & Bechtold, K. T. (2016). The role of psychological facilitators and barriers to therapeutic engagement in acute, inpatient rehabilitation. *Rehabilitation Psychology*, 61(3), 277–287. https://doi.org/10.1037/rep0000095

Reay, R., Fisher, Y., Robertson, M., Adams, E., & Owen, C. (2006). Group interpersonal psychotherapy for postnatal depression: A pilot study. Archives Of Women's Mental Health, 9(1), 31-39. doi:10.1007/s00737-005-0104-x

Richards, S., Taylor, R., Ramasamy, R., & Richards, R. (1999). *Single subject research: Applications in educational and clinical settings*. San Diego: Singular.

Rubarth, L., Schoening, A., Cosimano, A., & Sandhurst, H. (2012). Women's Experience of Hospitalized Bed Rest During High-Risk Pregnancy. *Journal Of Obstetric, Gynecologic & Neonatal Nursing*, *41*(3), 398-407. dio:10.1111/j.1552-6909.2012.01349.x

Ruiz, F. J., Hernándezx, D. R., Suárez Falcón, J. C., & Luciano, C. (2016). Effect of a One-Session ACT Protocol in Disrupting Repetitive Negative Thinking: A Randomized Multiple-Baseline Design. *International Journal Of Psychology & Psychological Therapy*, *16*(3), 213-233.

Scott, W., Hann, K. J., & McCracken, L. M. (2016). A comprehensive examination of changes in psychological flexibility following acceptance and commitment therapy for chronic pain. *Journal Of Contemporary Psychotherapy*, *46*(3), 139-148. doi:10.1007/s10879-016-9328-5

Spitzer, R. L., Kroenke, K., & Williams, J. (1999). Validation and Utility of a Self-report Version of The PHQ: Primary Care Study. *Jama*, 282(18), 1737. doi:10.1001/jama.282.18.1737

Stirnemann, J., Djaafri, F., Kim, A., Mediouni, I., Bussieres, L., Spaggiari, E., . . . Ville, Y. (2018). Preterm premature rupture of membranes is a collateral effect of improvement in perinatal outcomes following fetoscopic coagulation of chorionic vessels for twin-twin transfusion syndrome: A retrospective observational study of 1092 cases. BJOG: *An International Journal of Obstetrics & Gynaecology*, 125(9), 1154-1162. doi:10.1111/1471-0528.15147

Tomfohr-Madsen, L. M., Campbell, T. S., Giesbrecht, G. F., Letourneau, N. L., Carlson, L. E., Madsen, J. W., & Dimidjian, S. (2016). Mindfulness-based cognitive therapy for psychological distress in pregnancy: study protocol for a randomized controlled trial. *Trials*, 17(1). doi:10.1186/s13063-016-1601-0

Tran, T. D., Tran, T., & Fisher, J. (2013). Validation of the depression anxiety stress scales (DASS) 21 as a screening instrument for depression and anxiety in a rural community-based cohort of northern Vietnamese women. *BMC psychiatry*, *13*, 24. doi:10.1186/1471-244X-13-24

Urbina, Susana. Essentials of Psychological Testing, 2nd Edition. John Wiley & Sons, 2014.

Vieten, C., & Astin, J. (2008). Effects of a mindfulness-based intervention during pregnancy on prenatal stress and mood: results of a pilot study. *Archives of Womens Mental Health*, 11(1), 67-74. doi:10.1007/s00737-008-0214-3

Vliegen, N., Casalin, S., Luyten, P., Docx, R., Lenaerts, M., Tang, E., & Kempke, S. (2013). Hospitalization-based treatment for postpartum depressed mothers and their babies: Rationale, principles, and preliminary follow-up data. *Psychiatry: Interpersonal and Biological Processes*, 76(2), 150–168. https://doi.org/10.1521/psyc.2013.76.2.150

Wang, Y., & Gorenstein, C. (2013). Psychometric properties of the Beck Depression Inventory-II: a comprehensive review. *Revista Brasileira de Psiquiatria*, 35(4), 416-431. doi:10.1590/1516-4446-2012-1048

Watson, D., Clark, L. A., & Tellegen, A. (1988). Development and validation of brief measures of positive and negative affect: The PANAS scales. *Journal of Personality and Social Psychology*, 54(6), 1063-1070. doi:10.1037//0022-3514.54.6.1063

Weathers, F.W., Litz, B.T., Keane, T.M., Palmieri, P.A., Marx, B.P., & Schnurr, P.P. (2013). The PTSD Checklist for *DSM-5* (PCL-5).

Weidner, K., Bittner, A., Junge-Hoffmeister, J., Zimmermann, K., Siedentopf, F., Richter, J., & ... Stöbel-Richter, Y. (2010). A psychosomatic intervention in pregnant in-patient women with prenatal somatic risks. *Journal Of Psychosomatic Obstetrics & Gynecology*, 31(3), 188-198. doi:10.3109/0167482X.2010.497233

Wisner, K. L., Zarin, D. A., Holmboe, E. S., Applebaum, P. S., Gelenberg, A. J., Leonard, H. L., & Frank, E. (2000). Risk-benefit decision making for treatment of depression during pregnancy. *The American Journal Of Psychiatry*, 157(12), 1933-1940. doi:10.1176/appi.ajp.157.12.1933

Yali, A. M., & Lobel, M. (1999). Coping and distress in pregnancy: An investigation of medically high risk women. *Journal of Psychosomatic Obstetrics and Gynaecology, 20,* 39–52.

Yusoff, N., Low, W., & Yip, C. (2010). Reliability and Validity of the Brief COPE Scale (English Version) Among Women with Breast Cancer Undergoing Treatment of Adjuvant Chemotherapy: A Malaysian Study. *Med J Malaysia*, 6(1), 41-44.

Zhang, L. X., Sun, Y., Zhao, H., Zhu, N., Sun, X. D., Jin, X., Zou, A. M., Mi, Y., … Xu, J. R. (2017). A Bayesian Stepwise Discriminant Model for Predicting Risk Factors of Preterm Premature Rupture of Membranes: A Case-control Study. *Chinese medical journal*, *130*(20), 2416-2422.

Zimmerman, M., & Mattia, J. I. (2001a). The Psychiatric Diagnostic Screening Questionnaire: Development, reliability and validity. *Comprehensive Psychiatry*, 42, 175–189.

| Characteristics | Total (N = 5) |
|---|---|
| Age, mean (SD) | 27.6 (3.51) |
| Race/Ethnicity (%) | |
| White | 2 (40) |
| African American | 2 (40) |
| Hispanic | 1 (10) |
| Marital Status (%) | |
| Married | 3 (60) |
| Single, in a relationship | 2 (40) |
| Employed full or part time (%) | 4 (80) |
| Education Level (%) | |
| Some college/2 year degree | 3 (60) |
| College degree (4 year) | 2 (40) |
| Income (%) | |
| 20,001 – 30,000 | 1 (20) |
| 60,001 – 80,000 | 3 (60) |
| >110,000 | 1 (20) |
| Number of children (%) | |
| 0 | 2 (40) |
| 1 | 2 (40) |
| 2 | 1 (20) |
| Length of current pregnancy, mean (SD) | 27 (2.83) |

Table 1. Baseline demographic information of participants

| Day | Lesson | Objectives |
|---|---|---|
| **1** | *What is acceptance?* | • The importance of taking care of oneself<br>• What acceptance is and how it can help<br>• Four qualities of mindful acceptance |
| **2** | *How we become trapped in our mind.* | • How avoiding experiences can worsen them<br>• How to evaluate one's experiences nonjudgementally<br>• Making the choice to be self-compassionate |
| **3** | *Becoming an observer.* | • Separating thoughts and feelings from who one is as a person<br>• Learning to be in the present |
| **4** | *Breaking free with mindful acceptance* | • Learning skills to cope when facing fears, anxieties or sadness |
| **5** | *Finding comfort with a judgmental mind* | • How choosing to let go can end suffering<br>• Practice becoming comfortable with struggles |
| **6** | *Cultivating compassion* | • Practice loving kindness towards oneself and others<br>• Learning to forgive and letting go of past hurts |
| **7** | *Staying the course* | • Keep moving forward towards goals<br>• A meaningful life is built one step at a time<br>• Lean on loved ones |

Table 2. Description of treatment modules

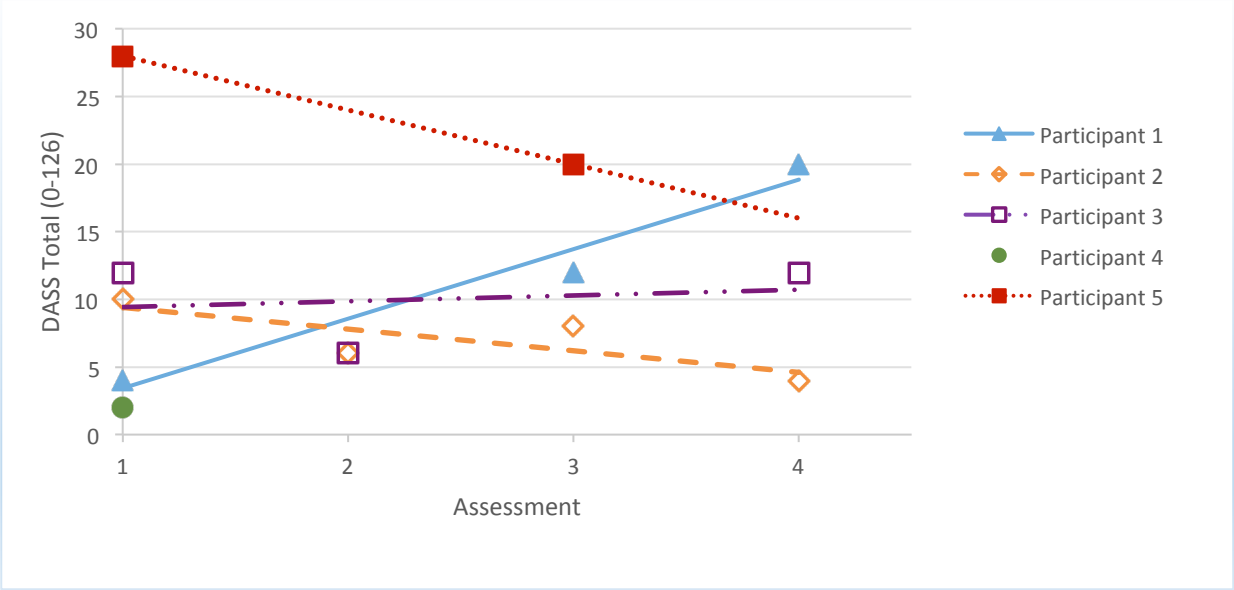



*Figure 1*. Individual scores for total depression, anxiety and stress (DASS-21) and regression across baseline, mid-intervention, post-intervention and follow-up assessments.

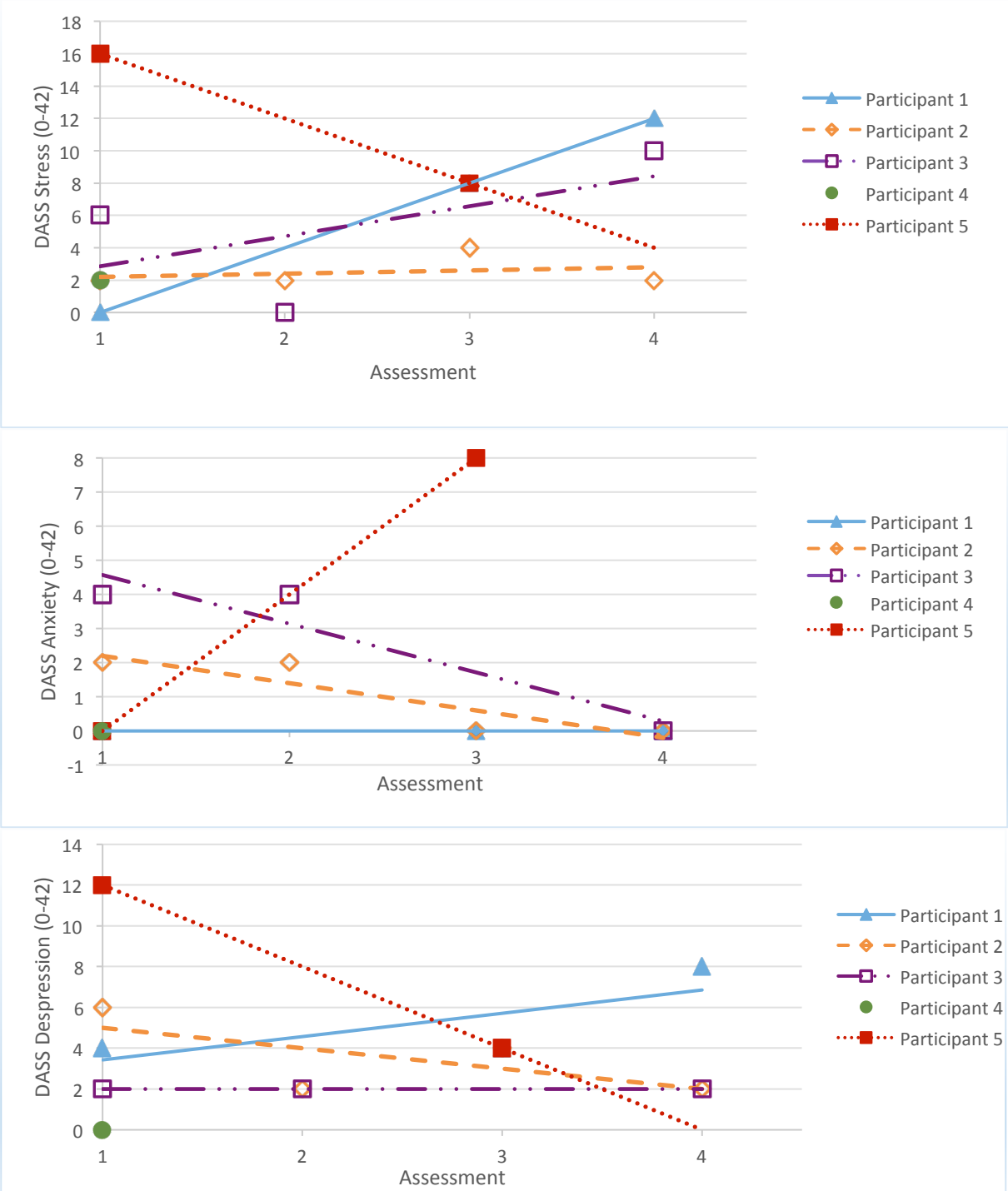



*Figure 2*. Individual scores for depression, anxiety and stress subscales (DASS-21) and regression across baseline, mid-intervention, post-intervention and follow-up assessments.

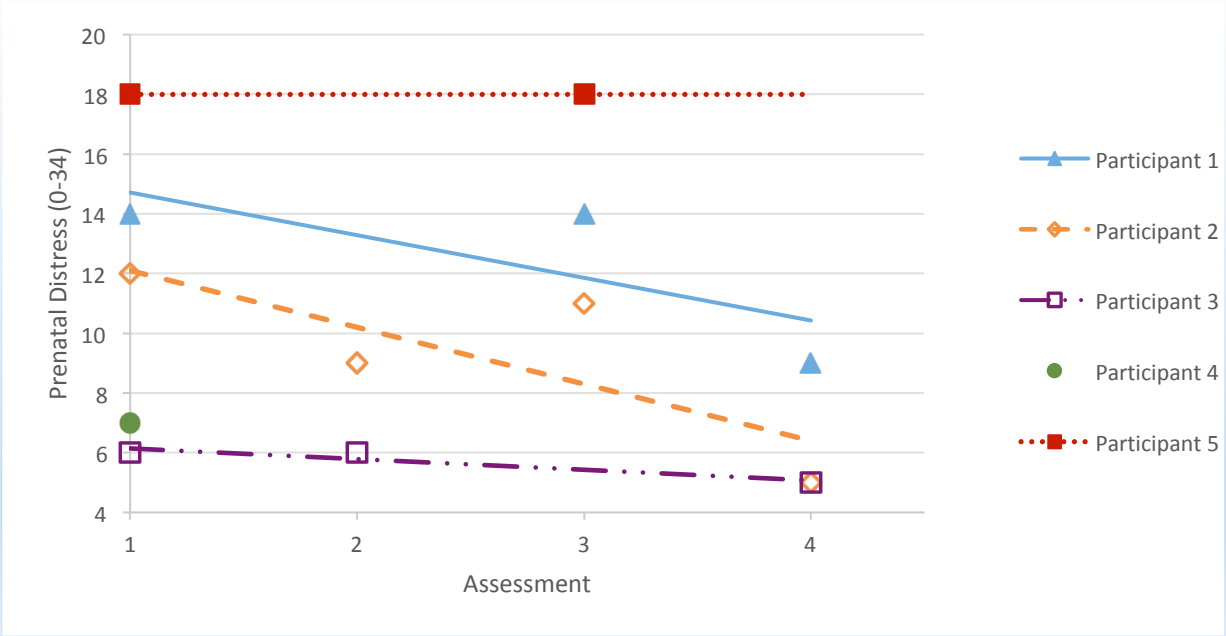
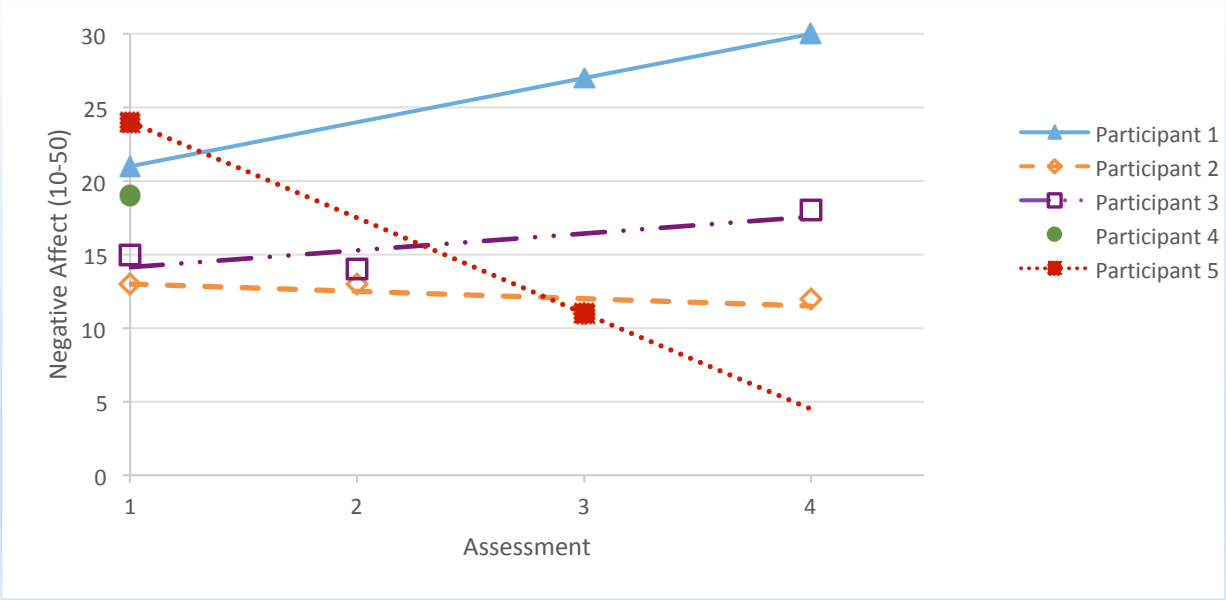



*Figure 3*. Individual scores for pregnancy-related distress (PDQ) and regression across baseline, mid-intervention, post-intervention and follow-up assessments.



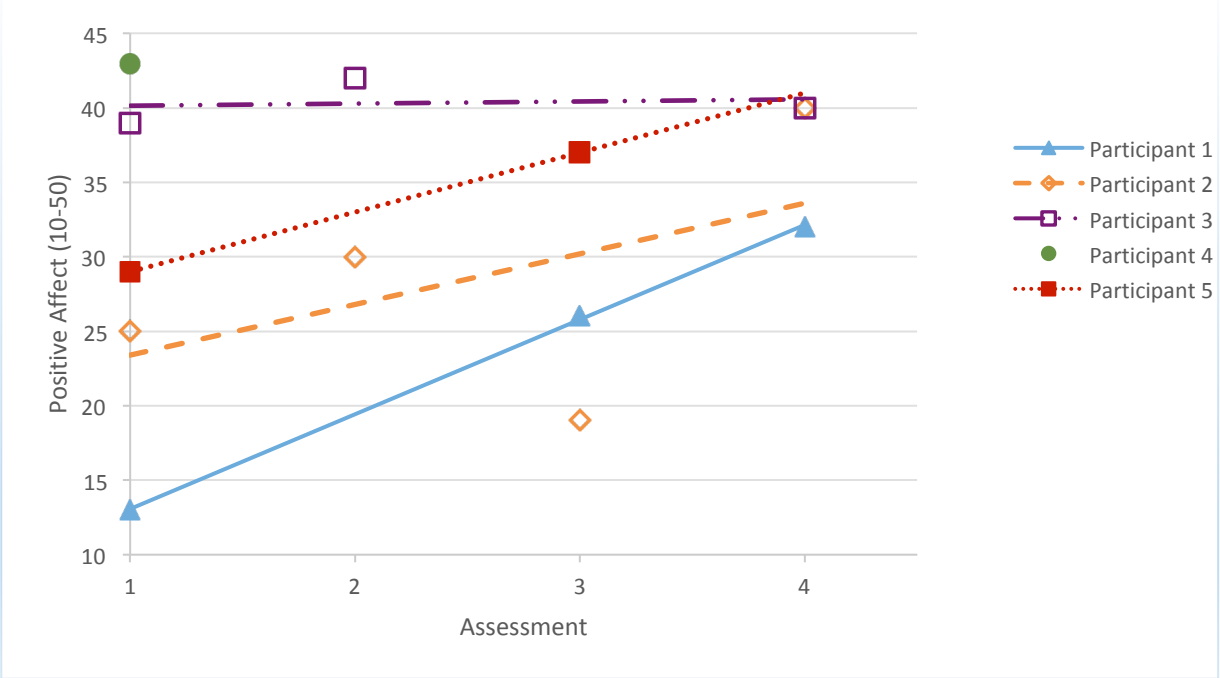




*Figure 4*. Individual scores for positive affect and negative affect (PANAS) and regression across baseline, mid-intervention, post-intervention and follow-up assessments.

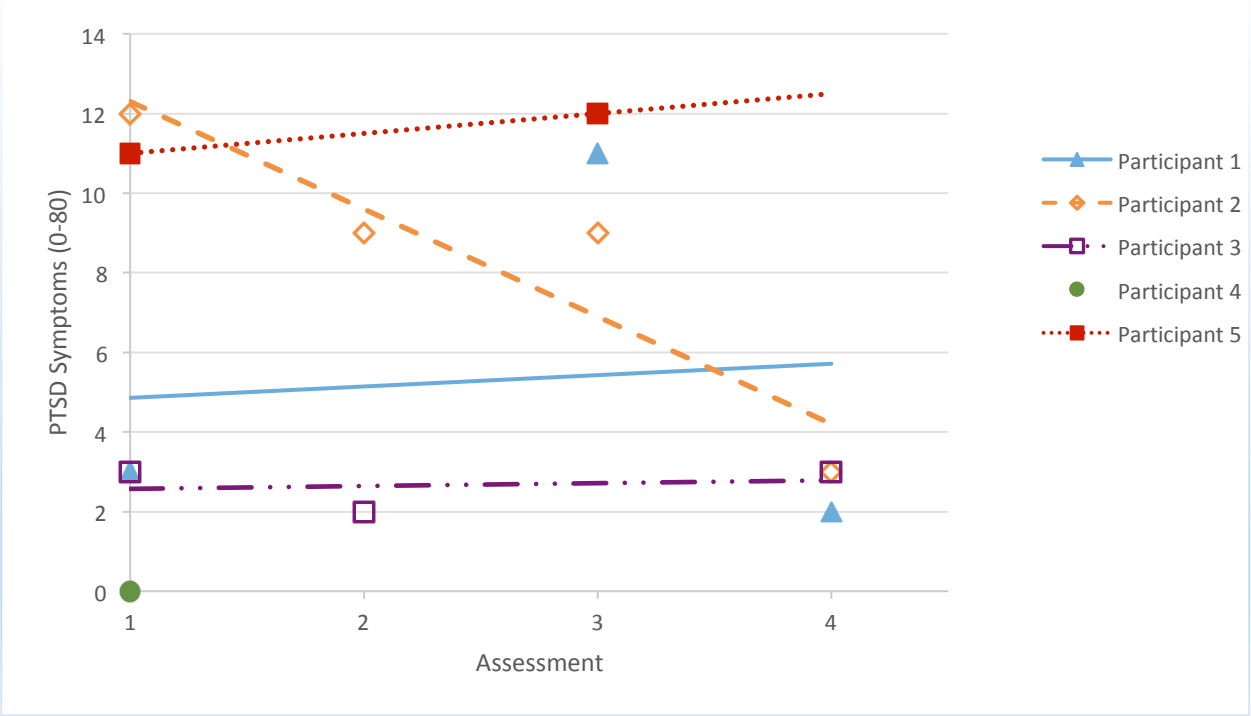



*Figure 5*. Individual scores for PTSD symptoms (PCL-5) and regression across baseline, mid-intervention, post-intervention and follow-up assessments.

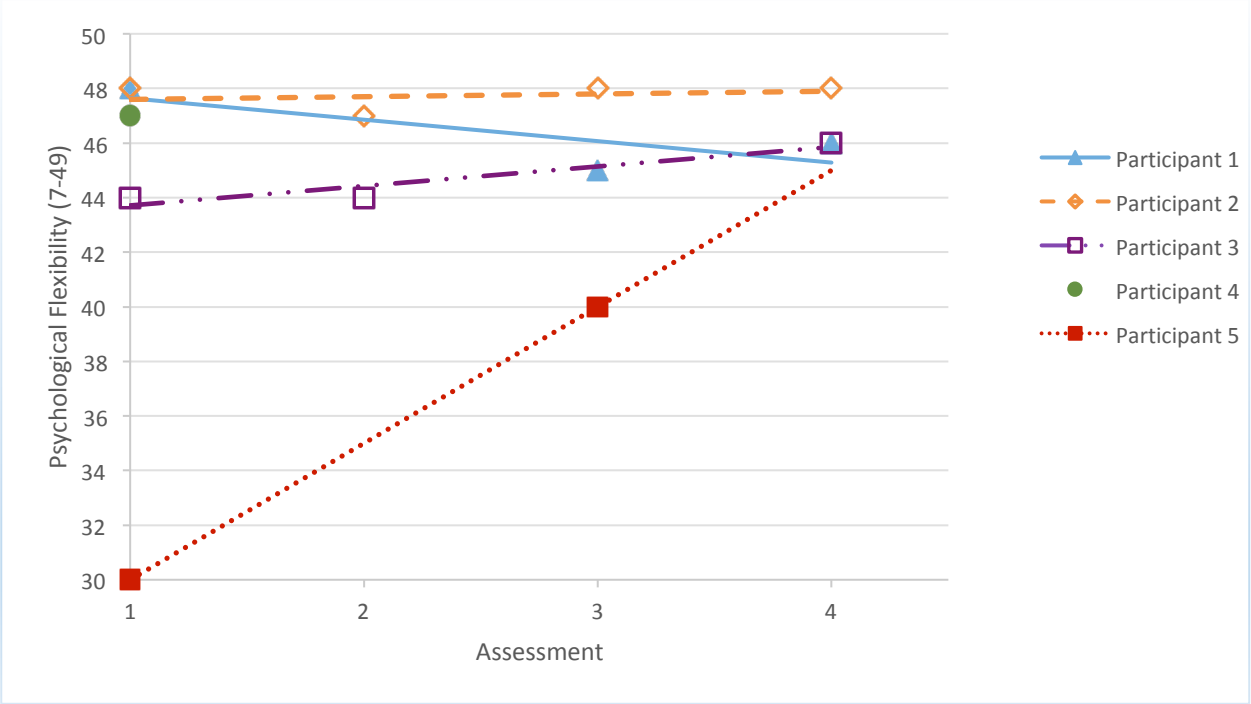



*Figure 6*. Individual scores for psychological flexibility (AAQ-II) and regression across baseline, mid-intervention, post-intervention and follow-up assessments.