Brief Summary

Background: Anxiety and depression are common during the perinatal period and associated with adverse outcomes for the mother and infant if left untreated. Despite the need to improve treatment accessibility and uptake in this population, no studies have investigated internet-delivered cognitive behavioural therapy (iCBT) for generalised anxiety symptoms, or anxiety comorbid with depression in pregnant or postpartum women. In two randomized controlled trials, we examined the efficacy and acceptability of brief, unguided iCBT – *MUMentum* – in pregnant and postpartum women with anxiety and/or depression, compared with usual care.

Methods: Participants meeting clinical threshold for generalized anxiety and/or depression were recruited online and randomised to the iCBT treatment group or treatment-as-usual control group. A total of 87 women participated in the pregnancy RCT and 131 in the postnatal RCT. Each 3-lesson program was completed over a period of 4-6 weeks. Outcomes were assessed at baseline, post-treatment and four-week follow-up; and included anxiety, depression, psychological distress, maternal bonding, quality of life, and treatment acceptability.

Results: The *MUMentum* programs demonstrated large and superior improvements in anxiety, depression, and psychological distress symptom severity, compared to the control group. Both programs also demonstrated meaningful improvements in emotional bonding/attachment, parenting confidence, and quality of life outcomes. Program adherence (i.e. completed all three lessons) and participant satisfaction ratings were high.

Conclusion: These RCTs provide evidence for the efficacy and acceptability of the *MUMentum* programs in reducing anxiety and depressive symptoms in pregnant and postpartum women. Our findings contribute to the existing evidence base for the efficacy of iCBT for perinatal depression, and establishes preliminary efficacy of iCBT for GAD, and comorbid MDD and GAD symptoms. Overall, brief, unguided iCBT offers a scalable, accessible, evidence-based psychological treatment option for women in the perinatal period. The *MUMentum* programs can be implemented as a 'first step' intervention for all women screening positive for anxiety, depression, and distress symptoms, and can be used as an adjunct to existing, more clinician-intensive iCBT programs and face-to-face treatments.

Translational opportunities: The potential clinical value of the *MUMentum* programs is substantial, given many women do not access or engage with traditional psychological treatment services (e.g. face-to-face) during the perinatal period. The *MUMentum* programs can be easily disseminated at a population level as a 'first step' intervention for all women screening positive for distress, anxiety or depression in routine care. This may be particularly attractive to women living in rural and regional Australia. Within a stepped-care approach, *MUMentum* can offer mothers the option to self-refer and self-manage their symptoms and is particularly relevant in terms of scaling up such programs as part of population wide perinatal screening for anxiety and depression as recommended in the Australian Clinical Practice Guidelines (Austin et al., 2017). Moreover, the *MUMentum* programs can be supervised by the patient's nominated clinician, and used as an adjunct to face-to-face treatments.

The *MUMentum* programs are now available on THIS WAY UP Clinic (www.thiswayupclinic.org.au). THIS WAY UP is a non-profit initiative of the Clinical Research Unit for Anxiety and Depression (CRUfAD), a joint facility of St Vincent's Hospital Sydney and the University of New South Wales.

We are now looking to disseminate the *MUMentum* programs and evaluate their effectiveness in 'real-world' settings. This will be achieved through integration with services currently offered in primary care (e.g. maternity hospitals, antenatal clinics), and industry organisations (e.g. Gidget Foundtion, Karitane).

Study 1: A randomized controlled trial of '*MUMentum Pregnancy'*: Internet-delivered cognitive behavioral therapy program for antenatal anxiety and depression- *Manuscript submitted for publication.*

Introduction

During pregnancy, approximately one in five women experience clinically significant symptoms of anxiety and depression, and one in six meet diagnostic criteria for an anxiety and/or major depressive disorder (MDD; Becker, Weinberger, Chandy and Schmukler, 2016; Dennis, Falah-Hassani and Shiri, 2017). Antenatal anxiety and depression are robust predictors of postpartum depression (Austin, Tully and Parker, 2007; Milgrom et al., 2008), and if left untreated, are associated with a range of adverse outcomes for both the mother and infant (e.g., reduced antenatal care; increased risk of preterm birth, low birth weight, and later childhood emotional difficulties; Ding et al., 2014; Goodman and Tyer-Viola, 2010; Grote et al., 2010). Despite this, anxiety and depression during the antenatal period remain under-detected and under-treated (Biaggi, Conroy, Pawlby and Pariante, 2016; Kingston et al., 2015).

Effective face-to-face treatments exist (e.g., Milgrom et al., 2015), with cognitive behavioral therapy (CBT) being the recommended psychological treatment for mild to moderate anxiety and depression during pregnancy (Austin, Highet and Expert Working Group, 2017; NICE, 2014). However, there are a range of social, geographical, and logistical barriers that limit access and engagement with existing services (Kingston et al., 2015; Kopelman et al., 2008; Woolhouse, Brown, Krastev, Perlen and Gunn, 2009). Delivering CBT via the internet (iCBT) provides an alternate option to face-to-face services that could improve treatment uptake in this population. iCBT is a well-established treatment for anxiety and depression in the general adult population (Andrews et al., 2018) and is effective in postpartum populations (Milgrom et al., 2016). iCBT offers several benefits over face-to-face psychotherapy including reduced out-of-pocket cost, increased privacy and convenience, and greater treatment fidelity. iCBT has been shown to be as effective as face-to-face CBT for some disorders (Andersson, Carlbring, Ljótsson and Hedman, 2013; Carlbring, Andersson, Cuijpers, Riper and Hedman-Lagerlöf, 2018).

Whilst the evidence-base for iCBT for anxiety and depression is robust in the general adult population, support for its use within the antenatal period is in its infancy. First, most research to-date has focused only on the postpartum period (see Lau, Htun, Wong, Tam and Klainin-Yobas, 2017). These studies report moderate to large reductions in postpartum depressive symptoms. Only one RCT has evaluated iCBT for antenatal MDD: Forsell and colleagues (2017) found large effect size reductions in depressive symptoms relative to treatment as usual (TAU) (Hedges' $g = 1.21$). It is unclear whether these findings generalize to a wide range of pregnant women, particularly those who may not meet diagnostic criteria for MDD, but still experience disabling depressive symptoms.

Secondly, no study has investigated the effects of iCBT for the treatment of antenatal generalised anxiety disorder (GAD) symptoms or for the treatment of comorbid GAD and MDD. This is concerning given that these disorders frequently co-occur and that antenatal anxiety affects a comparable number of expectant mothers and results in similar adverse outcomes as depression (Dennis et al., 2017; Grigoriadis et al., 2011). Although no study has examined the effects of iCBT in treating GAD in the antenatal period, Nieminen and colleagues (2016) evaluated the feasibility of iCBT for pregnant women with severe fear of childbirth in an open pilot trial, and demonstrated large and significant reductions in their fears (Cohen's $d = 0.95$). iCBT for postpartum depression appears to have a positive but small impact on anxiety symptoms relative to control conditions (Cohen's $d = 0.36$; Lau et al., 2017). This is an important area of investigation given the treatment of perinatal anxiety

in the broader literature has also received very little attention (Goodman and Tyer-Viola, 2010; Loughnan et al., 2018b).

Third, no study has examined the effects of brief, and/or unguided (i.e., no therapist or clinician support or coaching) iCBT for antenatal symptoms of GAD and/or MDD. The evaluation of brief unguided interventions is important within the context of the antenatal period particularly given shorter programs may be more appealing to busy women, and unguided iCBT programs offering greater scalability and cost-effectiveness for large-scale dissemination. Finally, no study has explored the impact of iCBT beyond symptom change to other antenatal factors, such as maternal bonding. The development of a relationship with the unborn child is thought to be a key development task in successful psychological adjustment to pregnancy, and is associated with health behaviours of the mother and wellbeing of the child before and after birth (Dubber, Reck, Müller and Gawlik, 2015; Van den Bergh and Simons, 2009). However, little is known about the effects of anxiety and depression on the mother's bonding during pregnancy. These are important areas of investigation if we are to maximise treatment benefits for both the mother and infant.

To address these gaps in the literature, we developed a brief unguided iCBT program, "*MUMentum Pregnancy"*, designed to target symptoms of anxiety and depression during pregnancy (Loughnan et al., 2018a). This study aimed to test the efficacy and acceptability of this program compared to TAU control group. We hypothesized that the *MUMentum Pregnancy* program would: (1) significantly reduce symptoms of anxiety, depression, and general psychological distress; (2) be significantly more effective at reducing these symptoms than TAU; (3) improve maternal feelings of emotional bonding to the fetus and maternal quality of life; and (4) be acceptable to participants.

Method

Design

A CONSORT-revised 2010 compliant (Schulz, Altman and Moher, 2010) randomized, controlled superiority trial (RCT) design was used to compare the *MUMentum Pregnancy* program to a TAU control. The trial protocol was approved by the Human Research Ethics Committee of St. Vincent's Hospital, Sydney (HREC/16/SVH/63) and is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12616000560493). The protocol for this study has been published previously (Loughnan et al., 2018a).

Participant Recruitment

Prior to the commencement of the trial, power calculations were conducted to determine the minimum sample size. As there was no research outlining the efficacy of transdiagnostic or brief unguided iCBT in this population, power calculations were informed by published RCTs of iCBT for postpartum depression (Milgrom et al., 2016) and transdiagnostic iCBT for anxiety and depression in the general adult population (Newby et al., 2013). To detect a between-group effect corresponding to Hedges' *g* of 0.80, the minimum sample size for each group ($\alpha = 0.05$, power of 80%) was 25 participants per group. We therefore aimed to recruit a minimum sample of 80 participants to allow for expected attrition. Participants were recruited over approximately 12-months (05 October 2016 to 20 September 2017) by advertisements posted on social media websites, online forums and flyers distributed in maternity hospitals in Sydney, Australia.

Inclusion criteria. All participants met the following inclusion criteria: (i) aged over 18 years; (ii) fluent in written and spoken English; (iii) Australian resident; (iv) had computer and internet access; (v) met criteria for a probable diagnosis of GAD and/or MDD (described further below); (vi) willing to provide their name, telephone number, address, email address,

and the name and contact details of their general practitioner (GP); and (v) between 13-30 weeks pregnant.

Exclusion criteria. Applicants were excluded if they reported: (i) current substance abuse or dependence; (ii) current use of benzodiazepines; (iii) diagnosis of schizophrenia or bipolar disorder; (iv) they had commenced psychological therapy less than four weeks before intake assessment or had commenced medication for anxiety/depression less than eight weeks before intake assessment. Applicants reporting severe depression or current suicidality were excluded and referred to appropriate services (Loughnan et al., 2018a).

Procedure

All women applied online to www.virtualclinic.org.au, provided online informed consent, and completed brief online screening questionnaires to determine if they met eligibility criteria. Applicants meeting criteria yet reporting occasional suicidal ideation were contacted by the study clinician by phone to determine suitability. All those who met inclusion criteria were randomized to either the iCBT or TAU arm of the RCT. Randomisation was completed by an independent person according to a 1:1 ratio within blocks of 20 using a random number generator (www.random.org). Allocation was concealed from the investigators using sequentially numbered, sealed opaque envelopes. A member of the research team assigned participants manually and notified them via email.

Participants allocated to iCBT logged in to their individual Virtual Clinic account, completed baseline questionnaires and started Lesson 1. All three lessons were required to be completed within four weeks. Participants were withdrawn from the study if they commenced a new treatment during the course of the trial period, for example starting psychotherapy or medication for anxiety or depression. At the beginning of each lesson, participants completed the Kessler-10 psychological distress scale (K-10; Kessler et al., 2002a), as well as two brief questions relating to how much time they spent completing the previous lesson and homework activities. Participants completed post-treatment assessment one week after the active treatment period (i.e., Week 5), with follow-up assessment completed four weeks post-treatment (i.e., Week 9). Clinical contact only occurred when a participant's K-10 score, depression symptom severity, or suicidal ideation was significantly elevated.

Participants allocated to TAU were not required to login to the Virtual Clinic and received access to their assessment questionnaires via email, with automated email and SMS reminders. During the study period, participants in TAU were able to access usual care from their health services (i.e. continue with any course of treatment already specified at intake) but were withdrawn from the study if they commenced a new treatment during the course of the trial period. Participants in TAU only received clinical contact when distress scores, depression symptom severity, or suicidal ideation was significantly elevated. At conclusion of the trial at approximately week nine, participants in TAU were provided with access to the *MUMentum Pregnancy* program.

Measures

Primary Outcomes. The *Patient Health Questionnaire 9-item scale (PHQ-9*; Kroenke, Spitzer and Williams, 2001) is a self-report measure of depressive symptoms that have been experienced in the past two weeks. Participants rated the frequency of their symptoms (e.g., "Feeling down, depressed, or hopeless") on a 4-point scale ranging from 0 (not at all) to 3 (nearly every day) with total score over nine indicative of a probable diagnosis of MDD. The PHQ-9 has been extensively used in iCBT studies and validated in perinatal samples (e.g., Sidebottom, Harrison, Godecker and Kim, 2012). Internal consistency for the current sample at baseline was acceptable ($\alpha = 0.72$).

The *Generalized Anxiety Disorder 7-item scale* (GAD-7; Spitzer, Kroenke, Williams and Löwe, 2006) is a self-report measure of GAD symptoms that have been experienced over the past two weeks. Items are rated on a 4-point scale ranging from 0 (not at all) to 3 (nearly every day) with a total score over nine indicative of GAD. The GAD-7 has been validated in adult (e.g., Sunderland, Wong, Hilvert-Bruce and Andrews, 2012) and perinatal samples (e.g., Gjerdingen, Crow, McGovern, Miner and Center, 2009; Simpson, Glazer, Michalski, Steiner and Frey, 2014; current sample $\alpha = 0.81$).

Secondary outcomes. The *Kessler 10-item Psychological Distress scale*[1] (K-10; Kessler et al., 2002b) measured non-specific psychological distress over the past two weeks, with scores over 20 indicative of a mild mental disorder. The K-10 demonstrates strong psychometric properties in non-perinatal samples (e.g., Furukawa, Kessler, Slade and Andrews, 2003), has acceptable validity in antenatal samples (e.g., Spies et al., 2009); and its psychometric properties are stable across the lifespan (e.g., Andrews and Slade, 2001; current sample $\alpha = 0.77$).

The *Edinburgh Postnatal Depression Scale* (EPDS; Cox, Holden and Sagovsky, 1987) was also administered to assess depressive symptoms. Total scores range from 0 to 30 with a score of 13 and above being indicative of MDD. This scale was developed to screen for perinatal depression and has been validated in pregnant women (Bergink et al., 2011; current sample $\alpha = 0.71$).

The *World Health Organisation Quality of Life scale* (WHOQOL-BREF; Skevington, Lotfy and O'Connell, 2004) assessed quality of life (QOL) over the past four weeks according to four domains: physical health, psychological health, social relationships, and environment. The WHOQOL-BREF has been validated in postpartum samples (e.g., Webster, Nicholas, Velacott, Cridland and Fawcett, 2010) with current sample α's for each domain = 0.78, 0.70, 0.58, 0.79, respectively.

The *Maternal Antenatal Attachment Scale* (MAAS; Condon, 1993) assessed maternal feelings of emotional bonding to the fetus with higher scores indicative of better maternal attachment. The MAAS has demonstrated acceptable psychometric properties in pregnant women (Condon and Corkindale, 1997; current sample $\alpha = 0.77$).

The *Beck Depression Inventory, second edition* (Item 9 only, BDI-II; Beck, Steer and Brown, 1996) assessed the presence and severity of suicidal ideation and suicide risk over the past two weeks.

Acceptability of the MUMentum Pregnancy Program. Participants who were randomized to the *MUMentum Pregnancy* program rated how much they believed that treatment would improve their mental health before Lesson 1 and Lesson 2 using the Treatment Credibility and Expectancy Questionnaire (CEQ; Devilly and Borkovec, 2000). Additionally, these participants rated their satisfaction with their treatment at post-treatment assessment using items from the Treatment Satisfaction Questionnaire (TSQ; Cox, Fergus and Swinson, 1994).

The *MUMentum Pregnancy* Program

The *MUMentum Pregnancy* program is a brief unguided iCBT intervention tailored specifically to women experiencing generalised anxiety and depressive symptoms in the antenatal period. The program was adapted from our validated six-lesson, clinician-guided iCBT program for mixed anxiety and depression (Newby et al., 2013; Newby, Mewton, Williams and Andrews, 2014). Given the importance of treatment brevity in this population

[1] In addition to being measured at each time-point, the K-10 was administered before each lesson for those in iCBT for the purpose of monitoring potential adverse outcomes during treatment.

(i.e., limited time to complete the program before the end of pregnancy), course content was condensed and presented over three lessons rather than six, with a key focus on introducing women to core CBT skills to help manage anxiety and depressive symptoms (see Table 1). Content for this program was presented in the form of a shortened illustrated story, in which two fictional characters experiencing anxiety and depression during their pregnancy learn to self-manage their symptoms which improve with CBT skills practice. Each lesson consisted of a set of lesson slides depicting the characters' stories and introduction to core CBT skills (e.g., thought challenging); a brief lesson summary and action plan to implement skills; and a range of supplementary resources (e.g., sleep hygiene, FAQs). Further course information is provided in the published protocol (Loughnan et al., 2018a).

Table 1. Content of *MUMentum Pregnancy* program

Lesson	Skills	Extra resources

1	• Psychoeducation:
	  ○ About anxiety and depression
	  ○ Identifying symptoms
	  ○ Cognitive behavioural model
	  ○ Prioritising self-care
	  ○ Physical symptoms
	  ○ Partners and supporters
	• Controlled breathing
	• Progressive muscle relaxation
		• Medication for anxiety and depression during pregnancy and breastfeeding
		• Sleep hygiene
		• Fight-or-flight response
		• Pleasant activities
		• FAQs
		• Further skill examples

2	• Psychoeducation:
	  ○ About thoughts
	  ○ Identifying unhelpful thoughts
	  ○ Shifting unhelpful thoughts
	  ○ Accepting uncertainty
	• Thought challenging
	• Coping cards
	• Structured problem-solving
		• Understanding intrusive thoughts and images
		• FAQs
		• Further skill examples

3	• Psychoeducation:
	  ○ Unhelpful behaviours (low activity; avoidance)
	  ○ Facing your fears
	• Activity planning and monitoring
	• Graded exposure
	• Assertive communication
	• Relapse prevention
		• Self-care plan
		• FAQs
		• Further skill examples

Participants completed treatment over a four-week period and were encouraged to complete one lesson per week with an additional week for revision. All lessons were accessed sequentially via the online Virtual Clinic system, with a seven-day lockout period implemented between lessons to ensure participants spend time revising and implementing the lesson material before moving onto the next lesson. Participants were notified of new

lessons and reminded to stay on schedule via email and SMS reminders. As this is an unguided intervention, technician assistance was available (i.e., for technical issues only) however no coaching or clinical support from a trained therapist was provided. Technician time spent was recorded as the number of minutes spent in contact with the participant via email or telephone.

Analyses

All analyses were undertaken in Statistical Package for the Social Sciences (SPSS) version 24 (IBM SPSS, IBM Corp., Armonk, NY, USA). Cross-tabulations were used to examine participants' demographic characteristics stratified by group. Independent *t*-tests were used to examine group differences in baseline clinical characteristics and regression analyses were used to examine group differences in adherence.

To explore treatment efficacy, intention-to-treat linear mixed models with random intercepts for participants were estimated for each outcome measure, with restricted maximum likelihood (REML) estimation methods. These models, which account for the unbalanced nature of the data, yield more accurate estimates of effect compared to completer (Salim, Mackinnon, Christensen and Griffiths, 2008). Each model included time, treatment group, and time by group interaction as fixed factors with models estimated separately for each outcome variable. Significant effects were followed up with pairwise contrasts comparing group differences in pre-to-post and pre-to-follow-up total scores. Effect sizes were calculated using the pooled standard deviation and adjusted for sample size (e.g., Hedges' *g*). Effect sizes were calculated so that positive effect sizes represent a reduction in symptoms from pre- to post-treatment, with effect sizes of 0.20, 0.50, and 0.80 considered small, moderate, and large respectively (Cohen, 1988)

Results

Baseline characteristics

Participant flow through the trial is depicted in Figure 1. A total of 409 women applied, with 87 randomized to iCBT (n = 43) or TAU (n = 44). Of those women, 77 (iCBT: n = 36, TAU: n = 41) completed baseline questionnaires and were included in the analysis.

Participants' demographics and baseline clinical characteristics are shown in Table 2. In general, the women were aged 31.61 years (SD = 4.00; R = 23-40) and 21.66 weeks gestational age (SD = 5.93). The majority of women were multiparous (i.e., having experienced one or more previous childbirths; 65%), married (77%), had a University degree (79%), and were born in Australia (82%). Most participants reported moderately severe symptoms of depression (e.g., PHQ-9 total score ≥10; 64%), generalized anxiety (e.g., GAD-7 total score ≥ 10; 71%), and psychological distress (K-10 scores ≥ 25; 65%). Approximately 13% met clinical threshold (total score ≥ 10) for depression only, 18% for anxiety only, and half for comorbid depression and anxiety (53%). Less than 6% of participants indicated thoughts of self-harm or suicide. No significant group differences were noted with respect to participants' symptom severity, maternal or gestational age (see Table 2).

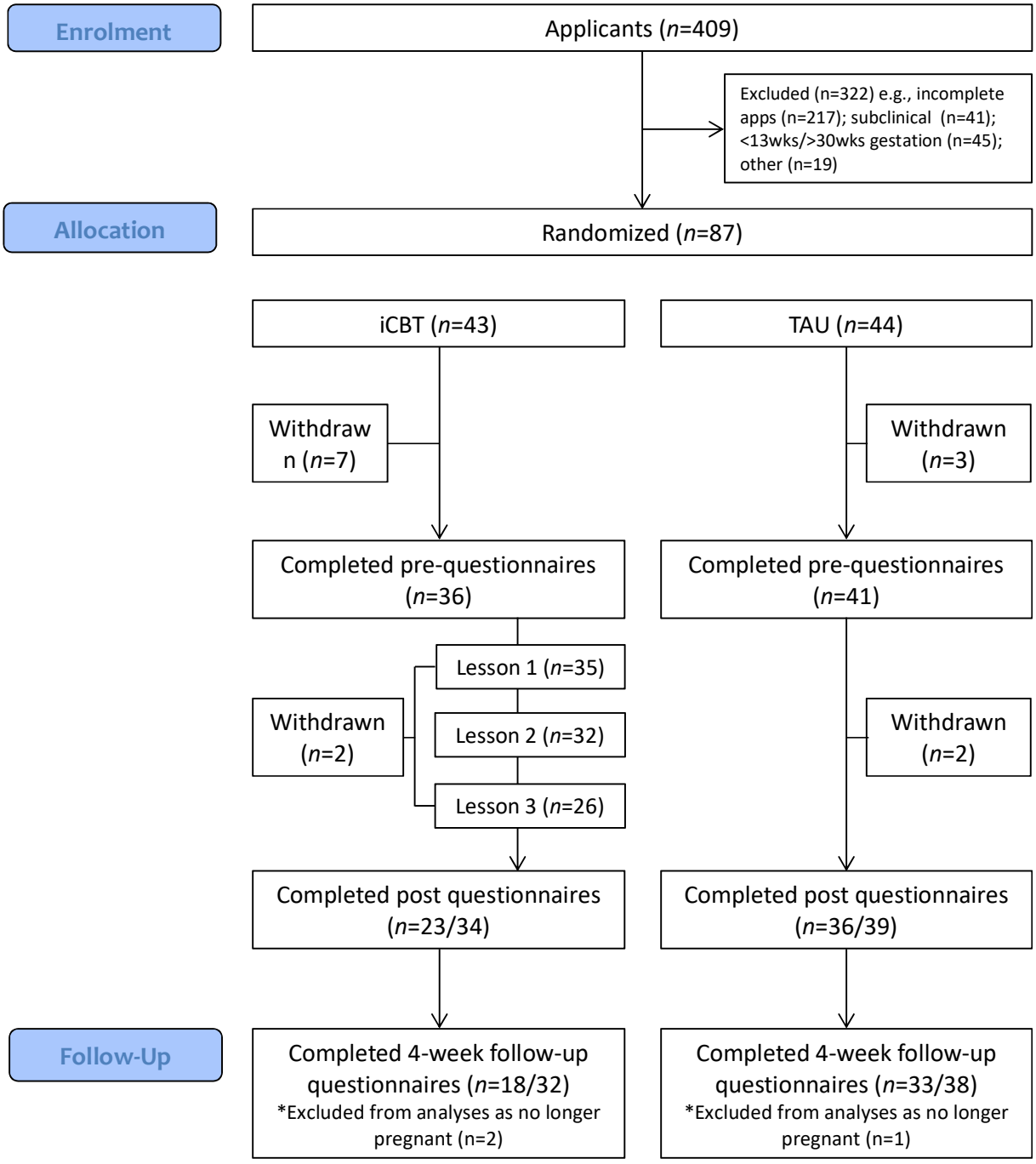

Figure 1. Participant flow diagram

Table 2. Participant characteristics

	Total *N* = 77	iCBT *n* = 36	TAU *n* = 41	iCBT vs TAU
Age (years), mean (SD)	31.61 (4.00)	31.69 (4.44)	31.54 (3.63)	($t_{(75)}$ = 0.17, p = 0.86)
Gestation (weeks) , mean (SD)	21.66 (5.93)	20.54 (6.01)	22.63 (5.76)	($t_{(75)}$ = -1.56, p = 0.12)
Parity, n (%)				
First pregnancy	25 (32)	10 (28)	15 (37)	
Two or more pregnancies	52 (68)	26 (72)	26 (63)	
Number of children, n (%)[a]				
None	40 (53)	16 (46)	24 (59)	
One or more	36 (47)	19 (54)	17 (41)	
Country of birth, n (%)				
Australia	63 (82)	29 (81)	34 (93)	
Other	14 (18)	7 (19)	7 (17)	
Rurality, n (%)				
Major cities	46 (60)	21 (58)	25 (61)	
Regional or rural areas	31 (40)	15 (42)	16 (39)	
Relationship status, n (%)				
In a relationship/de facto	14 (18)	10 (28)	4 (10)	
Separated or divorced	1 (1)	1 (3)	0 (0)	
Married	59 (77)	23 (64)	36 (88)	
Single	3 (4)	2 (6)	1 (2)	
Level of education, n (%)				
School-level	4 (5)	3 (8)	1 (2)	
Trade/certificate/diploma	12 (16)	8 (22)	4 (10)	
University undergraduate degree	46 (60)	17 (47)	29 (71)	
University post-graduate degree	15 (19)	8 (22)	7 (17)	
Employment status, n (%)				

Full-time paid work	40 (52)	19 (53)	21 (51)	
Part-time paid work	24 (31)	11 (31)	13 (32)	
Full-time student	2 (3)	1 (3)	1 (2)	
Part-time student	3 (4)	2 (6)	1 (2)	
At home parent	7 (9)	2 (5)	5 (12)	
Unemployed	1 (1)	1 (3)	0 (0)	
Recruitment, n (%)[a]				
Facebook	57 (75)	23 (66)	34 (83)	
Word of mouth	6 (8)	3 (9)	3 (7)	
Health professional/hospital	6 (8)	5 (14)	1 (2)	
Other	7 (9)	4 (11)	3 (7)	
Probable diagnosis at baseline, n (%)				
Depression	10 (13)	3 (8)	7 (17)	
Anxiety	14 (18)	8 (22)	6 (15)	
Comorbid	41 (53)	21 (58)	20 (49)	
Subclinical	12 (16)	4 (11)	8 (20)	
Current medications, *n* (%)	6 (8)	2 (6)	4(10)	
Current psychological treatment, *n* (%)	13 (17)	5 (14)	8 (20)	
Baseline variables, mean (SD)				
PHQ-9[b]	11.34 (4.14)	11.53 (4.96)	11.17 (3.32)	$t_{(59.80)} = 0.37$, $p = .72$
GAD-7	12.22 (4.33)	12.61 (4.31)	11.88 (4.37)	$t_{(75)} = 0.74$, $p = .46$
K-10	26.69 (5.80)	26.94 (6.57)	26.46 (5.09)	$t_{(75)} = 0.36$, $p = .72$
EPDS	14.09 (3.94)	13.47 (4.29)	14.63 (3.58)	$t_{(75)} = -1.30$, $p = .20$
MAAS	69.81 (10.58)	69.64 (8.65)	69.95 (12.14)	$t_{(78)} = -0.138$, $p = .90$
WHOQOL-BREF				
Domain 1: Physical health	57.51 (17.04)	58.13 (17.05)	56.97 (17.24)	$t_{(75)} = 0.30$, $p = .77$
Domain 2: Psychological	50.49 (14.50)	50.46 (15.39)	50.51 (13.86)	$t_{(75)} = -0.01$, $p = .99$
Domain 3: Social relationships	55.3 (21.20)	51.85 (22.55)	58.33 (19.72)	$t_{(75)} = -1.35$, $p = .18$
Domain 4: Environment	70.62 (15.83)	69.44 (17.39)	71.65 (14.46)	$t_{(75)} = -0.61$, $p = .55$

Note. [a]Variable data not available for one participant: total $N = 76$; iCBT $n = 35$; TAU $n = 41$; [b]The assumption of homogeneity of variances was violated for baseline variable PHQ-9, as assessed by Levene's test for equality of variances (p=0.02).

Treatment adherence

Of the 36 iCBT participants who completed baseline questionnaires, and were eligible for analysis, two withdrew from the RCT. Of the remaining 34 women, 26 completed all three lessons of treatment (76% adherence) with 68% and 56% providing post-treatment and follow-up data, respectively. A total of 44 women were randomized to TAU. Three were withdrawn after randomization, as they did not start their questionnaires. Of the 41 women who completed baseline assessment, 92% provided data at post-treatment and 87% at follow-up. Two participants were withdrawn before post-treatment assessment, one who was no longer pregnant and one was no longer interested in participating in the RCT. Those in TAU were more likely than those in the iCBT group to complete post-treatment ($\chi^2(1) = 8.40$, $p = <0.01$; OR(95% CI) = 5.13(1.59, 16.57)) and follow-up assessments ($\chi^2(1) = 7.41$, $p = <0.01$; OR(95% CI) = 5.74(1.44, 22.81)).

Effects of the *MUMentum Pregnancy* Program

Table 3 presents the estimated marginal means of participants' symptom severity at baseline, post-treatment and follow-up assessments, and the respective within and between group effect size reductions.

Depression outcomes. There were no significant group by time interactions for depression symptom severity according to the PHQ-9 ($F(2, 53.65) = 1.93$, $p = 0.16$) or EPDS ($F(2, 54.99) = 0.18$, $p = 0.84$). According to the PHQ-9, there were small non-significant effect sizes favouring the iCBT group at post-assessment (g(95%CI) = 0.30(-0.24, 0.81)) and follow-up assessment (g(95%CI) = 0.35(-0.23, 0.93)). The same pattern of findings was observed on the EPDS, with small, but not significant effect sizes favouring the iCBT group at post-assessment (g(95%CI) = 0.20(-0.32, 0.73)) and follow-up assessment (g(95%CI) = 0.35(-0.23, 0.93)).

Anxiety and psychological distress outcomes. The group by time interactions for K-10 (psychological distress) ($F(2,53.93) = 7.07$, $p = <0.01$), and GAD-7 (anxiety) ($F(2,54.67) = 6.48$, $p = <0.01$) were significant. Participants in the iCBT demonstrated large and superior reductions in distress (K-10) at post-assessment compared to TAU (g(95%CI) = 0.88(0.34, 1.43)), and moderate differences at follow-up, although these were not statistically significant (g(95%CI) = 0.52(-0.07, 1.10)). The between group differences for anxiety severity were small and non-significant post-assessment (g(95%CI) = 0.40(-0.13, 0.93)). However, iCBT demonstrated a moderate to large effect size reduction in anxiety symptom severity at follow-up assessment compared to TAU ($g = 0.76$; 95% CI: 0.17, 1.35).

Maternal bonding and quality of life outcomes. No significant group by time interactions were noted for antenatal bonding as measured by the MAAS ($F(2, 53.32) = 0.50$, $p = 0.61$), or quality of life domains according to the WHOQOL-BREF (all Fs (2, 47.05 - 55.04) = 0.07 - 0.14, ps = >.87). Whilst maternal bonding did not significantly improve from pre- to post-treatment, large and significant improvements were observed between baseline and follow-up (within-group $g = -1.35$); the changes in the TAU group were small and not significant ($g = -0.43$). Those in TAU experienced moderate to large improvements between pre- and post-treatment in the *psychological* quality of life domain with gains maintained at follow-up (within-group gs = >0.64). In contrast, those in iCBT experienced moderate to large improvements only between pre- and follow-up (within-group $g = 0.68$). There were no notable between-group differences observed for antenatal bonding (gs = <-0.16) or quality of life domains (gs = <-0.19) at post-assessment or follow-up assessment.

Table 3. Within- and between-group effect sizes for pre- to post-, and pre- to follow-up (FU) assessments.

	Pre-treatment		Post-treatment		Follow-up		Pre-post within-group ES		Pre-FU within-group ES		Post between-group ES		FU between-group ES	
	EMM	**SD**	**EMM**	**SD**	**EMM**	**SD**	***g***	**(95% CI)**	***g***	**(95% CI)**	***g***	**(95% CI)**	***g***	**(95% CI)**
K-10[a]														
iCBT	27.00	6.40	18.93	5.03	20.02	5.45	1.11*	(0.55, 1.67)	0.84*	(0.25, 1.42)	0.88*	(0.34, 1.43)	0.52	(-0.07, 1.10)
TAU	26.37	6.27	23.53	5.21	22.98	5.74	0.67*	(0.21, 1.13)	0.69*	(0.22, 1.16)				
GAD-7[a]														
iCBT	12.66	4.69	7.49	4.66	5.76	4.22	1.19*	(0.62, 1.75)	1.63*	(0.99, 2.28)	0.40	(-0.13, 0.93)	0.76*	(0.17, 1.35)
TAU	11.84	4.58	9.43	4.83	9.17	4.51	0.52*	(0.06, 0.97)	0.61*	(0.14, 1.07)				
PHQ-9[a]														
iCBT	11.69	4.56	7.67	4.51	6.75	3.99	0.81*	(0.26, 1.35)	0.87*	(0.28, 1.46)	0.30	(-0.24, 0.81)	0.35	(-0.23, 0.93)
TAU	11.05	4.48	8.99	4.56	8.25	4.37	0.56*	(0.11, 1.02)	0.81*	(0.33, 1.29)				
EPDS[a]														
iCBT	13.41	4.31	10.01	4.64	8.98	4.43	0.65*	(0.12, 1.19)	0.90*	(0.31, 1.49)	0.20	(-0.32, 0.73)	0.35	(-0.23, 0.93)
TAU	14.50	4.23	10.97	4.78	10.62	4.67	0.95*	(0.48, 1.42)	1.01*	(0.52, 1.50)				
MAAS[b]														
iCBT	70.44	11.08	73.92	9.37	77.14	8.49	-0.43	(-0.96, 0.10)	-1.35*	(-1.97, -0.73)	0.03	(-0.49, 0.55)	-0.16	(-0.74, 0.41)
TAU	69.92	10.85	74.22	10.10	75.62	9.60	-0.39	(-0.84, 0.06)	-0.43	(-0.90, 0.03)				
WHOQOL: Physical health[b]														
iCBT	57.81	17.57	63.92	14.04	62.93	14.34	-0.36	(-0.88, 0.17)	-0.28	(-0.84, 0.29)	-0.19	(-0.71, 0.34)	-0.13	(-0.70, 0.45)
TAU	56.58	17.21	61.18	14.61	60.99	15.29	-0.30	(-0.75, 0.15)	-0.29	(-0.75, 0.17)				
WHOQOL: Psychological[b]														
iCBT	50.39	15.85	58.43	13.55	62.44	13.56	-0.48	(-1.01, 0.05)	-0.68*	(-1.26, -0.10)	-0.01	(-0.54, 0.51)	-0.14	(-0.71, 0.44)
TAU	50.44	15.52	58.23	14.47	60.49	13.90	-0.64*	(-1.10, -0.18)	-0.81*	(-1.29, -0.33)				
WHOQOL: Social[b]														
iCBT	52.87	22.48	59.17	16.45	57.56	16.95	-0.33	(-0.86, 0.19)	-0.29	(-0.86, 0.27)	0.28	(-0.25, 0.80)	0.26	(-0.32, 0.84)
TAU	58.99	22.02	63.95	17.45	62.18	17.89	-0.30	(-0.91, -0.01)	-0.17	(-0.63, 0.29)				
WHOQOL: Environment [b]														
iCBT	69.53	16.97	74.97	11.59	74.84	13.70	-0.44	(-0.97, 0.09)	-0.35	(-0.92, 0.22)	0.07	(-0.45, 0.59)		
TAU	71.30	16.62	75.85	12.57	74.86	15.22	-0.31	(-0.76, 0.14)	-0.23	(-0.69, 0.23)				

Note. [a]positive scores indicate symptom reduction; [b]negative scores indicate symptom improvement; *indicate significant effect sizes, $p<.05$; ESS = estimated marginal means; SD = standard deviation; ES = effect size; g = Hedges' g; K-10 = Kessler Psychological Distress 10-item scale; PHQ-9 = Patient Health Questionnaire 9-item scale; GAD-7 = Generalized Anxiety Disorder 7-item scale; EPDS = Edinburgh Postnatal Depression Scale; MAAS = Maternal Antenatal Attachment Scale; WHOQOL = World Health Organisation Quality of Life-BREF scale

Treatment satisfaction and time spent

All participants in the iCBT group rated the program to be 'somewhat' to 'very logical' at Lesson 1 (30/30; 100%; *M*(*SD*) = 7.52(1.54); *R* = 5-9) and most at Lesson 2 (29/30; 97%; *M*(*SD*) = 6.06(1.58); *R* = 2-9). Most also reported that they expected that the program would be 'somewhat' to 'very successful' in reducing symptoms of antenatal anxiety and depression at both Lesson 1 (32/33; 97%; *M*(*SD*) = 7.17(1.60); *R* = 3-9) and at Lesson 2 (29/30; 97%; *M*(*SD*) = 5.93(1.46); *R* = 3-9).

After treatment, the majority of participants reported feeling 'mostly' to 'very satisfied' with the program (20/23; 87%). Participants judged the quality of the program to be 'good' to 'excellent' (21/23; 91%) and felt that they could relate to the program characters (74%). On average, participants reported the program as 'logical' (*M*(*SD*)=8.54(1.16); *R* =6-10); were confident that the program was successful in teaching them techniques for managing symptoms (*M*(*SD*) = 7.13(2.07); *R* = 2-10), and would recommend the program to a friend experiencing anxiety and depression (*M*(*SD*) = 7.96(1.80); *R* = 5-10). Just over half of participants reported that they preferred to receive help for their symptoms via an online program rather than another type of treatment (e.g., face-to-face; 64%).

On average, participants in iCBT reported spending approximately 60 minutes completing each lesson (*M*(*SD*) = 61.52(32.34)) and 55 minutes revising and practising the skills learned (*M*(*SD*) = 54.62(70.64)). Over the course of the nine-week trial period, technician time spent per participant was approximately 16 minutes for those in iCBT (*M*(*SD*) = 15.93(11.75), R = 0-38min) and approximately nine minutes for TAU (*M*(*SD*) = 8.93(6.44), R = 1-32min).

Discussion

The current study examined the efficacy and acceptability of an internet-delivered CBT program, the *MUMentum Pregnancy* program for antenatal anxiety and depression compared to TAU. We found that a brief unguided iCBT program reduced psychological distress, anxiety and depressive symptom severity from pre- to post-treatment in an Australian sample of pregnant women, and was superior to usual care in reducing distress and generalised anxiety symptoms. The *MUMentum Pregnancy* program resulted in high participant engagement and good adherence rates (76% completed all components of the program). These findings are particularly important given that no iCBT studies have targeted generalized anxiety symptoms, or comorbid anxiety and depression during pregnancy.

Those in iCBT demonstrated superior reductions in anxiety symptom severity at follow-up assessment, yet not at post-treatment. In contrast, we found superior reductions in psychological distress for iCBT at post-treatment, yet not at follow-up assessment. The current study was underpowered to detect the small to moderate between group differences Moderate to large improvements were observed in TAU group for distress and anxiety symptom severity. This highlights the importance of assessing both distress and anxiety symptoms in pregnant women, as clinically significant distress may manifest as anxiety symptoms, which can be missed with depression-only screening (Matthey, 2008; McCabe-Beane, Stasik-O'Brien and Segre, 2018). It is also important to understand the course of anxiety during pregnancy, particularly pregnancy-specific symptoms. This will help inform the development of targeted iCBT interventions for anxiety disorders, and comorbid anxiety and depression. While further research is required, our findings have important clinical implications given that the evidence-base of treating perinatal anxiety in general has received very little attention to date (e.g., Goodman, Watson and Stubbs, 2016; Loughnan et al., 2018b).

We found small differences between the iCBT and TAU groups with respect to reductions in depression symptom severity at post-treatment (g = 0.30) and follow-up assessments (g = 0.35). Similar findings were observed using the PHQ-9 and EPDS, a perinatal specific depression measure. The current study was underpowered to detect the small group differences in depressive symptoms. However, they are consistent with a recent meta-analysis which found smaller effect sizes (g = 0.49) for antenatal CBT interventions compared to postpartum samples (g = 0.69; Sockol, 2015). The lack of difference between the groups is likely because both groups experienced moderate to large reductions in depressive symptoms over the nine-week trial period, with the TAU group experiencing significant improvements. This suggests that brief unguided iCBT programs may not have a substantial impact on depressive symptoms above that of usual antenatal care, particularly over such a short time period. Future RCTs should investigate whether reductions in depressive symptom severity are maintained long-term, particularly postpartum. Research into iCBT for antenatal and postpartum depression while limited, has found large and significant reductions in depressive symptom severity relative to control conditions, however these studies were evaluated in samples with a diagnosis of MDD and investigated iCBT programs that were clinician-guided (i.e. weekly contact) and much longer (i.e., 6 to 8 modules; Forsell et al., 2017; Milgrom et al., 2016). The size of the improvements in depression symptoms, however, were large and similar to findings from a pilot RCT of face-to-face CBT for antenatal depression in an Australian sample (Milgrom et al., 2015). Future studies should investigate the impact of varying levels of clinician coaching and whether the severity of symptoms or diagnostic status influences treatment response.

Most iCBT studies have focused on the effects of treatment on symptom severity. Whilst there is emerging evidence that face-to-face CBT in pregnancy can have a positive impact on infant development (Milgrom et al., 2015), few iCBT studies have extended their investigations to focus on other outcomes related to mother- and mother-infant wellbeing. We found that participants in the iCBT group experienced improved feelings of emotional bonding from pre- to follow-up assessment; these significant improvements were not observed in the control group. Participants in both groups also appeared to experience better *psychological* quality of life (e.g., body image, self-esteem, concentration) during the trial period. Future research should explore whether improvements in these factors during pregnancy offers any additional benefits to the mother and infant at postpartum.

Unguided iCBT appears to be an acceptable and feasible treatment option for pregnant women self-reporting clinically significant symptoms of anxiety and depression as demonstrated by our treatment adherence rates, and participant satisfaction. We found three quarters of participants (76%) completed all lessons of the program. Interestingly, the only RCT that has evaluated clinician-guided iCBT for antenatal depression found the proportion of patients completing modules one to six was 96%, 96%, 86%, 77%, 59%, and 46% (Forsell et al., 2017). While shorter programs may improve treatment adherence for pregnant women, further research is required to determine the optimal duration and number of treatment sessions to achieve treatment effects, and to understand what factors promote adherence and influence program completion.

Participant credibility and satisfaction ratings were high, with the majority of participants relating to the program characters and their stories. Our findings suggest that clinician guidance or coaching may not be a requirement for brief iCBT that is specifically tailored to women in the antenatal period. Importantly, interventions that require no specialist training or clinician coaching to achieve treatment outcomes have the potential to be implemented into a stepped-care model to make clinician resources more available to high-risk mothers, or those experiencing more severe anxiety and depressive disorders. This is particularly relevant in terms of scaling up such programs as part of population wide

antenatal screening for anxiety and depression as recommended in the Australian Clinical Practice Guidelines (Austin et al., 2017).

Our sample was recruited over a 12-month period, with women residing in major cities (60%) and regional or rural areas (40%) in Australia with the majority recruited via social media. Most participants in this study were educated and self-referred, and therefore motivated. A recent Australian study showed that 29% of women giving birth, live in regional and remote areas and that these women lag behind their urban counterparts in accessing face to face psychological treatment (Chambers et al., 2016). iCBT is likely more attractive for this group of non-urban women, as shown by the disproportionate number of rural women in our study. Only 8% of participants came via clinician referral despite our recruitment strategy including several maternity hospitals. Future studies should aim to increase the number of participants from clinician referrals, and examine whether this impacts treatment outcomes and adherence.

While our findings are promising, there are several limitations to be noted. This study utilized a TAU control condition in which it was not possible to control for additional healthcare services accessed throughout the trial period (e.g., GP, maternal child health nurse) or examine rates of spontaneous remission. The follow-up period for this study was limited to four weeks post-treatment to ensure participants were still pregnant at the latter assessment and we did not include a postpartum follow-up. It is therefore difficult to determine if positive treatment effects were sustained long-term, or if treatment during pregnancy offers any preventative benefits at postpartum. Participants were not assessed using a diagnostic interview, which may have impacted on treatment outcomes. Finally, our sample consisted of mostly partnered, well-educated women which may limit generalisability of our findings.

Conclusion

This study provides preliminary support for the efficacy and acceptability of brief, unguided iCBT for anxiety and depression in pregnant women, and provides a range of future research directions. Although we found iCBT led to larger improvements in distress and anxiety than the control group, only small differences were found in depressive symptom severity which appeared to improve at a similar rate in the iCBT group to usual care. Further RCTs are required to replicate our findings and investigate whether reductions in symptoms persist long-term and postpartum. Given many women do not access or engage with traditional psychological treatment services during the antenatal period, the most promising aspect of our findings is the potential for brief, unguided iCBT to be easily disseminated at a population level and be particularly attractive to women living in rural and regional Australia. *MUMentum Pregnancy* can be used as a 'first step' intervention for all women screening positive for distress, anxiety or depression and can be used as an adjunct to existing, more clinician-intensive iCBT programs and face-to-face treatments. Understanding whether unguided iCBT is cost-effective and how best to implement such programs in routine antenatal care is therefore an important area of focus for clinicians and researchers.

References

Andersson, G., Carlbring, P., Ljótsson, B., Hedman, E., 2013. Guided internet-based CBT for common mental disorders. Journal of Contemporary Psychotherapy 43, 223-233.

Andrews, G., Basu, A., Cuijpers, P., Craske, M.G., McEvoy, P., English, C., Newby, J.M., 2018. Computer therapy for the anxiety and depressive disorders is effective, acceptable and practical health care: an updated meta-analysis (in press). J Anxiety Disord.

Andrews, G., Slade, T., 2001. Interpreting scores on the Kessler psychological distress scale (K10). Australian and New Zealand journal of public health 25, 494-497.

Austin, M.-P., Highet, N., Group, a.t.E.W., 2017. Mental healthcare in the perinatal period: Australian Clinical Practice Guideline. Centre for Perinatal Excellence, Melbourne.

Austin, M.-P., Tully, L., Parker, G., 2007. Examining the relationship between antenatal anxiety and postnatal depression. J Affect Disord 101, 169-174.

Beck, A.T., Steer, R.A., Brown, G.K., 1996. Beck depression inventory (2nd edition) - manual. The Psychological Corporation San Antonio, TX.

Becker, M., Weinberger, T., Chandy, A., Schmukler, S., 2016. Depression during pregnancy and postpartum. Current psychiatry reports 18, 32.

Bergink, V., Kooistra, L., Lambregtse-van den Berg, M.P., Wijnen, H., Bunevicius, R., van Baar, A., Pop, V., 2011. Validation of the Edinburgh Depression Scale during pregnancy. J Psychosom Red 70, 385-389.

Biaggi, A., Conroy, S., Pawlby, S., Pariante, C.M., 2016. Identifying the women at risk of antenatal anxiety and depression: A systematic review. J Affect Disord 191, 62-77.

Carlbring, P., Andersson, G., Cuijpers, P., Riper, H., Hedman-Lagerlöf, E., 2018. Internet-based vs. face-to-face cognitive behavior therapy for psychiatric and somatic disorders: an updated systematic review and meta-analysis. Cognitive behaviour therapy 47, 1-18.

Chambers, G.M., Randall, S., Hoang, V.P., Sullivan, E.A., Highet, N., Croft, M., Mihalopoulos, C., Morgan, V.A., Reilly, N., Austin, M.-P., 2016. The National Perinatal Depression Initiative: An evaluation of access to general practitioners, psychologists and psychiatrists through the Medicare Benefits Schedule. Australian & New Zealand Journal of Psychiatry 50, 264-274.

Cohen, J., 1988. Statistical power analysis for the behavioral sciences (2nd ed.). Lawrence Earlbaum Associates, Hillsdale, NJ.

Condon, J.T., 1993. The assessment of antenatal emotional attachment: development of a questionnaire instrument. PSYCHOL PSYCHOTHER-T 66, 167-183.

Condon, J.T., Corkindale, C., 1997. The correlates of antenatal attachment in pregnant women. PSYCHOL PSYCHOTHER-T 70, 359-372.

Cox, B.J., Fergus, K.D., Swinson, R.P., 1994. Patient satisfaction with behavioral treatments for panic disorder with agoraphobia. J Anxiety Disord 8, 193-206.

Cox, J.L., Holden, J.M., Sagovsky, R., 1987. Detection of postnatal depression: Development of the 10-item Edinburgh Postnatal Depression Scale Br J Psychiatry 150, 782-786.

Dennis, C.L., Falah-Hassani, K., Shiri, R., 2017. Prevalence of antenatal and postnatal anxiety: Systematic review and meta-analysis. The British Journal of Psychiatry 210, 315-323.

Devilly, G.J., Borkovec, T.D., 2000. Psychometric properties of the credibility/expectancy questionnaire. J Behav Ther Exp Psychiatry 31, 73-86.

Ding, X.-X., Wu, Y.-L., Xu, S.-J., Zhu, R.-P., Jia, X.-M., Zhang, S.-F., Huang, K., Zhu, P., Hao, J.-H., Tao, F.-B., 2014. Maternal anxiety during pregnancy and adverse birth outcomes: a systematic review and meta-analysis of prospective cohort studies. J Affect Disord 159, 103-110.

Dubber, S., Reck, C., Müller, M., Gawlik, S., 2015. Postpartum bonding: the role of perinatal depression, anxiety and maternal–fetal bonding during pregnancy. Arch Womens Ment Health 18, 187-195.

Forsell, E., Bendix, M., Holländare, F., von Schultz, B.S., Nasiell, J., Blomdahl-Wetterholm, M., Eriksson, C., Kvarned, S., van Soderbergder Linden, J.L., Söderberg, E., 2017. Internet delivered Cognitive Behavior Therapy for Antenatal Depression: A Randomised Controlled Trial. J Affect Disord.

Furukawa, T.A., Kessler, R.C., Slade, T., Andrews, G., 2003. The performance of the K6 and K10 screening scales for psychological distress in the Australian National Survey of Mental Health and Well-Being. Psychol. Med. 33, 357-362.

Gjerdingen, D., Crow, S., McGovern, P., Miner, M., Center, B., 2009. Postpartum depression screening at well-child visits: validity of a 2-question screen and the PHQ-9. Ann Fam Med 7, 63-70.

Goodman, J.H., Tyer-Viola, L., 2010. Detection, treatment, and referral of perinatal depression and anxiety by obstetrical providers. J. Women's Health 19, 477-490.

Goodman, J.H., Watson, G.R., Stubbs, B., 2016. Anxiety disorders in postpartum women: A systematic review and meta-analysis. J Affect Disord 203, 292-331.

Grigoriadis, S., de Camps Meschino, D., Barrons, E., Bradley, L., Eady, A., Fishell, A., Mamisachvili, L., Cook, G.S., O'Keefe, M., Romans, S., 2011. Mood and anxiety disorders in a sample of Canadian perinatal women referred for psychiatric care. Arch Womens Ment Health 14, 325-333.

Grote, N.K., Bridge, J.A., Gavin, A.R., Melville, J.L., Iyengar, S., Katon, W.J., 2010. A meta-analysis of depression during pregnancy and the risk of preterm birth, low birth weight, and intrauterine growth restriction. Arch Gen Psychiatry 67, 1012-1024.

Kessler, R.C., Andrews, G., Colpe, L.J., Hiripi, E., Mroczek, D.K., Normand, S.-L., Walters, E.E., Zaslavsky, A.M., 2002a. Short screening scales to monitor population prevalences and trends in non-specific psychological distress. Psychological Medicine 32, 959-976.

Kessler, R.C., Andrews, G., Colpe, L.J., Hiripi, E., Mroczek, D.K., Normand, S.-L., Walters, E.E., Zaslavsky, A.M., 2002b. Short screening scales to monitor population prevalences and trends in non-specific psychological distress. Psychol. Med. 32, 959-976.

Kingston, D., Austin, M.-P., Heaman, M., McDonald, S., Lasiuk, G., Sword, W., Giallo, R., Hegadoren, K., Vermeyden, L., van Zanten, S.V., 2015. Barriers and facilitators of mental health screening in pregnancy. J Affect Disord 186, 350-357.

Kopelman, R.C., Moel, J., Mertens, C., Stuart, S., Arndt, S., O'hara, M.W., 2008. Barriers to care for antenatal depression. Psychiatr. Serv. 59, 429-432.

Kroenke, K., Spitzer, R., Williams, J., 2001. The PHQ-9: validity of a brief depression severity measure [Electronic version]. J. Gen. Intern. Med. 16, 606-613.

Lau, Y., Htun, T.P., Wong, S.N., Tam, W.S.W., Klainin-Yobas, P., 2017. Therapist-supported internet-based cognitive behavior therapy for stress, anxiety, and depressive symptoms among postpartum women: a systematic review and meta-analysis. J. Med. Internet Res. 19.

Loughnan, S.A., Newby, J.M., Haskelberg, H., Mahoney, A., Kladnitski, N., Smith, J., Black, E., Holt, C.J., Milgrom, J., Austin, M.-P., Andrews, G., 2018a. Internet-based cognitive behavioural therapy (iCBT) for perinatal anxiety and depression versus treatment as usual: study protocol for a randomized controlled trial. Trials.

Loughnan, S.A., Wallace, M., Joubert, A.E., Haskelberg, H., Andrews, G., Newby, J.M., 2018b. A systematic review of psychological treatments for clinical anxiety during the perinatal period. Arch Womens Ment Health.

Matthey, S., 2008. Using the Edinburgh Postnatal Depression Scale to screen for anxiety disorders. Depression and Anxiety 25, 926-931.

McCabe-Beane, J.E., Stasik-O'Brien, S.M., Segre, L.S., 2018. Anxiety Screening During Assessment of Emotional Distress in Mothers of Hospitalized Newborns. Journal of Obstetric, Gynecologic & Neonatal Nursing 47, 105-113.

Milgrom, J., Danaher, B.G., Gemmill, A.W., Holt, C., Holt, C.J., Seeley, J.R., Tyler, M.S., Ross, J., Ericksen, J., 2016. Internet cognitive behavioral therapy for women with postnatal depression: a randomized controlled trial of MumMoodBooster. J. Med. Internet Res. 18.

Milgrom, J., Gemmill, A.W., Bilszta, J.L., Hayes, B., Barnett, B., Brooks, J., Ericksen, J., Ellwood, D., Buist, A., 2008. Antenatal risk factors for postnatal deperssion: A large prospective study. J Affect Disord 108, 147-157.

Milgrom, J., Holt, C., Holt, C.J., Ross, J., Ericksen, J., Gemmill, A.W., 2015. Feasibility study and pilot randomised trial of an antenatal depression treatment with infant follow-up. Arch Womens Ment Health 18, 717-730.

Newby, J.M., Mackenzie, A., Williams, A.D., McIntyre, K., Watts, S., Wong, N., Andrews, G., 2013. Internet cognitive behavioural therapy for mixed anxiety and depression: a randomized controlled trial and evidence of effectiveness in primary care. Psychol. Med. 43, 2635-2648.

Newby, J.M., Mewton, L., Williams, A.D., Andrews, G., 2014. Effectiveness of transdiagnostic internet cognitive behavioural treatment for mixed anxiety and depression in primary care. J Affect Disord 165, 45-52.

NICE, 2014. Antenatal and postnatal mental health: Clinical management and service guidance. NICE clinical guideline (CG192), 1-50.

Nieminen, K., Andersson, G., Wijma, B., Ryding, E.-L., Wijma, K., 2016. Treatment of nulliparous women with severe fear of childbirth via the Internet: a feasibility study. Journal of Psychosomatic Obstetrics & Gynecology 37, 37-43.

Salim, A., Mackinnon, A., Christensen, H., Griffiths, K., 2008. Comparison of data analysis strategies for intent-to-treat analysis in pre-test–post-test designs with substantial dropout rates. Psychiatry Res 160, 335-345.

Schulz, K.F., Altman, D.G., Moher, D., 2010. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMC medicine 8, 18.

Sidebottom, A.C., Harrison, P.A., Godecker, A., Kim, H., 2012. Validation of the Patient Health Questionnaire (PHQ)-9 for prenatal depression screening. Arch Womens Ment Health 15, 367-374.

Simpson, W., Glazer, M., Michalski, N., Steiner, M., Frey, B.N., 2014. Comparative efficacy of the generalized anxiety disorder 7-item scale and the Edinburgh Postnatal Depression Scale as screening tools for generalized anxiety disorder in pregnancy and the postpartum period. Can J Psychiatry 59, 434-440.

Skevington, S.M., Lotfy, M., O'Connell, K.A., 2004. The World Health Organization's WHOQOL-BREF quality of life assessment: psychometric properties and results of the international field trial. A report from the WHOQOL group. Qual Life Res 13, 299-310.

Sockol, L.E., 2015. A systematic review of the efficacy of cognitive behavioral therapy for treating and preventing perinatal depression. J Affect Disord 177, 7-21.

Spies, G., Stein, D., Roos, A., Faure, S., Mostert, J., Seedat, S., Vythilingum, B., 2009. Validity of the Kessler 10 (K-10) in detecting DSM-IV defined mood and anxiety disorders among pregnant women. Arch Womens Ment Health 12, 69-74.

Spitzer, R.L., Kroenke, K., Williams, J.B., Löwe, B., 2006. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med 166, 1092-1097.

Sunderland, M., Wong, N., Hilvert-Bruce, Z., Andrews, G., 2012. Investigating trajectories of change in psychological distress amongst patients with depression and generalised anxiety disorder treated with internet cognitive behavioural therapy. Behav. Res. Ther. 50, 374-380.

Van den Bergh, B., Simons, A., 2009. A review of scales to measure the mother–foetus relationship. J Reprod Infant Psychol 27, 114-126.

Webster, J., Nicholas, C., Velacott, C., Cridland, N., Fawcett, L., 2010. Validation of the WHOQOL-BREF among women following childbirth. Aust NZ J Obstet Gynaecol 50, 132-137.

Woolhouse, H., Brown, S., Krastev, A., Perlen, S., Gunn, J., 2009. Seeking help for anxiety and depression after childbirth: results of the Maternal Health Study. Arch Womens Ment Health 12, 75-83.

Study 2: A randomized controlled trial of 'MUMentum Postnatal': Internet-delivered cognitive behavioural therapy for anxiety and depression in postpartum women – *Manuscript submitted for publication*

Introduction

Maternal anxiety and depression is common during the first 12 months after childbirth (i.e., postpartum period), with 10-15% of mothers likely to meet diagnostic criteria for an anxiety disorder or Major Depressive Disorder (MDD; Dennis, Falah-Hassani, & Shiri, 2017; Woody, Ferrari, Siskind, Whiteford, & Harris, 2017). If left untreated, anxiety and depression adversely affect both the mother and infant (e.g., reduced maternal self-care, poor childhood emotional and behavioural development; Stein et al., 2014). Despite the deleterious effects of postpartum mental health problems, effective treatments exist.

Cognitive behavioural therapy (CBT) is recommended for the treatment of mild to moderate anxiety and/or depression in postpartum women (Austin, Highet, & Expert Working Group, 2017; NICE, 2014). Yet, due to an absence of routine screening in primary care, postpartum anxiety and depression remain under-detected and undertreated (Biaggi, Conroy, Pawlby, & Pariante, 2016). Indeed, less than half of the women who are anxious or depressed seek help or receive evidence-based treatment such as CBT (Austin et al., 2008; Goodman & Tyer-Viola, 2010). This is due to a range of barriers that limit mothers' access and engagement with traditional face-to-face treatment services, including long waiting lists, out-of-pocket costs, geographical distance to services, logistical issues (e.g., childcare), and perceived stigma associated with seeking help (Woolhouse, Brown, Krastev, Perlen, & Gunn, 2009).

Delivering CBT via the Internet (iCBT) is one solution to overcoming known barriers to accessing treatment and improving treatment coverage. ICBT is private and convenient, affordable, and has high treatment fidelity (Andrews et al., 2018). In the general adult population, iCBT is well-established in the treatment of anxiety and depressive disorders and has been shown to be as effective as face-to-face CBT for some disorders (Carlbring, Andersson, Cuijpers, Riper, & Hedman-Lagerlöf, 2018). In postpartum populations, therapist-guided iCBT has been demonstrated to be effective in treating depression with moderate to large reductions in symptoms (pooled between-group effect size, Cohen's $d = 0.63$, Lau, Htun, Wong, Tam, & Klainin-Yobas, 2017). ICBT supported by low-intensity telephone coaching has been shown to be effective in six sessions (Milgrom et al, 2016). Of the women that received iCBT, 79% no longer met diagnostic criteria for depression compared to 18% in the TAU condition. Milgrom et al. (2016) showed a large effect favouring iCBT in reducing depression symptom severity ($d = 0.83$) and small to medium effects for anxiety and stress. However, the number of studies of iCBT for postpartum depression is small, and almost non-existent for the specific treatment of postpartum anxiety, resulting in several gaps in our understanding about treating postpartum anxiety and depression using iCBT.

Firstly, no studies have investigated the effects of iCBT on generalized anxiety disorder (GAD), or comorbid GAD and MDD in postpartum women. This is despite postpartum anxiety affecting a comparable number of women as depression, and resulting in similar adverse outcomes (Goodman, Watson, & Stubbs, 2016). Comorbid anxiety and depression is also common, and associated with greater symptom severity, poorer short- and long-term outcomes, and increased suicidality (Field et al., 2010; Ross, Evans, Sellers, & Romach, 2003). One recent study (Ashford, Olander, Rowe, Fisher, & Ayers, 2018) investigated the potential efficacy of delivering a self-help psychoeducational booklet online to women experiencing postpartum

anxiety. No group differences were evident between the treatment and control group at post-treatment, with the study suffering from high rates of dropout and non-usage attrition. Greater clinical attention to postpartum anxiety, including comorbidity with depression, is therefore warranted, particularly given depression-specific iCBT interventions appear to have only a small to moderate impact on anxiety symptom improvements compared to control conditions (d = 0.36; Lau et al., 2017).

Secondly, no studies have investigated the effects of unguided (i.e., no supervision or coaching) or very brief (i.e., less than six lessons) iCBT in treating postpartum anxiety or depression. In general adult populations, studies have demonstrated that unguided iCBT is comparable to guided iCBT in improving anxiety and depression (e.g., Titov et al., 2013), although in some studies, adherence is lower in unguided iCBT (Morgan et al., 2017). Brief unguided iCBT programs that can be accessed without reliance on specialist mental health clinicians for guidance may offer a more scalable, cost-effective way to teach new mothers how to manage anxiety and depression. In addition, very brief unguided programs may be more appealing to busy mothers who are time-poor and unable to commit to longer treatment, and for mothers residing in rural and remote geographical regions in which access to a supervising therapist may be limited. Lastly, few studies have investigated the impact of symptom change on maternal factors such as bonding (e.g., O'Mahen et al., 2014) and quality of life (QOL; Pugh, Hadjistavropoulos, & Dirkse, 2016). As a result, little is known about the effects of postpartum anxiety and depression on these outcomes and whether iCBT can offer additional benefits to the mother, infant, and family.

To address these limitations in the literature, we developed a brief unguided iCBT intervention, *'MUMentum Postnatal'*, to target symptoms of anxiety and depression in postpartum women (Loughnan, Newby et al., 2018). This program was created alongside our iCBT intervention for antenatal anxiety and depression, '*MUMentum Pregnancy'* (Loughnan, Sie et al., 2018). The *MUMentum Pregnancy* program was previously evaluated in depressed and anxious pregnant women, producing large and superior reductions in anxiety (between groups, Hedges g=0.76) and psychological distress (g=0.88) relative to treatment as usual (TAU). Adherence to iCBT was high (71%), as was patient satisfaction.

The current study aimed to evaluate the efficacy and acceptability of the three-lesson unguided *MUMentum Postnatal* program in postpartum women with elevated symptoms of depression and/or generalised anxiety compared to TAU. We hypothesized that the *MUMentum Postnatal* program would: (1) significantly reduce symptoms of anxiety, depression, and general psychological distress; (2) be significantly more effective at reducing these symptoms than TAU; (3) improve maternal feelings of emotional bonding to the infant, parenting confidence, and QOL; and (4) be acceptable to participants.

Method

Design

A CONSORT-revised 2010 compliant (Schulz, Altman, & Moher, 2010) randomised, controlled superiority trial (RCT) design was used to compare iCBT to TAU control. The trial protocol has been published (Loughnan, Newby et al., 2018), was approved by the Human Research Ethics Committee of St. Vincent's Hospital, Sydney (HREC/16/SVH/63) and is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12616000559415).

Participants

Participants were women recruited in Australia by advertisements posted on social media websites, online forums and flyers distributed in maternity hospitals in Sydney, Australia. All participants voluntarily applied and provided informed consent online.

Inclusion criteria. All participants met the following eligibility criteria: (i) within 12 months postpartum; (ii) aged over 18 years; (iii) fluent in written and spoken English; (iv) Australian resident; (v) computer and internet access; (vi) self-report symptoms of anxiety and/or depression above clinical threshold (e.g., GAD-7 and/or PHQ-9 total score ≥ 10); (vii) and willing to provide personal contact details and details of their general practitioner (GP).

Exclusion criteria. Applicants were excluded if they reported any of the following: (i) current substance abuse or dependence; (ii) current use of benzodiazepines; (iii) self-reported diagnosis of schizophrenia or bipolar disorder; (iv) started psychological therapy <4 weeks ago or medication <8 weeks ago for anxiety/depression. Applicants that reported severe depression or current suicidality at screening were excluded and directed to appropriate services.

Procedure

All women applied online at www.virtualclinic.org.au, provided online informed consent, and completed the aforementioned screening questions to determine if they were eligible for the study[2]. Successful applicants were automatically randomised to either the iCBT or TAU arm of the RCT and notified on-screen and via email of their allocation. Our randomisation sequence (i.e., 1:1 ratio within blocks of 20) was uploaded to our server by personnel not involved in the study. Participants' general practitioners (GPs) received a written letter advising that their patient was participating in a research study for postpartum anxiety and depression.

After randomisation, participants were required to log in to their Virtual Clinic account within two weeks to complete baseline questionnaires. Those allocated to iCBT then started Lesson 1. All three lessons were required to be completed within the active treatment period of six weeks. Participants in both groups were withdrawn if they did not complete baseline questionnaires within two weeks of screening, or if they requested to be withdrawn. Post-treatment questionnaires were completed one week after the active treatment period ended (i.e., Week 7), with follow-up questionnaires completed four weeks post-treatment (i.e., Week 11). Clinical contact only occurred when a participant's distress score or suicidal ideation[3] was significantly elevated (see Loughnan, Newby et al., 2018 for safety protocol). Automated notifications and reminders (i.e., to complete lessons and questionnaires) were sent via email and SMS.

Measures

Primary outcomes. Anxiety and depression were assessed according to the *Generalized Anxiety Disorder 7-item scale* (GAD-7; Spitzer, Kroenke, Williams, & Löwe, 2006) and *Patient Health Questionnaire 9-item scale (*PHQ-9; Kroenke, Spitzer, & Williams, 2001). Both scales

[2]Applicants meeting criteria yet reporting occasional suicidal ideation were contacted by the study clinician by phone to determine suitability.

[3] For the purposes of trial risk monitoring only, Item 9 of the *Beck Depression Inventory, second edition* (BDI-II; Beck, Steer, & Brown, 1996) was administered to assess the presence and severity of suicidal ideation and suicide risk.

are validated self-report measures of GAD and MDD symptoms experienced over the past two weeks, with symptom frequency rated on a 4-point scale. Total scores over nine on the GAD-7 (*R*=0-21) and PHQ-9 (*R*=0-27) are indicative an increased likelihood of diagnosis of GAD or MDD. Both measures have been validated in adult (e.g., Löwe et al., 2008) and postpartum samples (e.g., Sidebottom, Harrison, Godecker, & Kim, 2012). Internal reliabilities for the current sample were acceptable (Cronbach's α: GAD-7=.85; PHQ-9 = .75). The *Edinburgh Postnatal Depression Scale* (EPDS; Cox, Holden, & Sagovsky, 1987) was also administered to assess postpartum-specific depressive symptoms. Participants rated the intensity of symptoms over the past seven days, with total scores (*R*=0-30) over 12 indicative of probable depression. The EPDS is well validated as a screening tool in postpartum samples (Bergink et al., 2011; current sample α=.77).

Secondary outcomes. The *Kessler 10-item Psychological Distress scale* (K-10; Kessler et al., 2002) measured non-specific psychological distress over the past two weeks. Total scores ranged from 10 to 50, with scores over 20 indicative of a mild mental disorder. The K-10 demonstrates strong psychometric properties in non-perinatal samples (Furukawa, Kessler, Slade, & Andrews, 2003), acceptable validity in antenatal samples (e.g., Spies et al., 2009; current sample α=0.83). The *Maternal Postnatal Attachment Scale* (MPAS; Condon, 1993) assessed maternal feelings of emotional bonding to the infant with higher total scores indicative of more adaptive mother-infant bonding style (Condon & Corkindale, 1998). The MPAS has demonstrated acceptable psychometric properties (Condon & Corkindale, 1997; current sample α=.85). The *Karitane Parenting Confidence Scale* (KPCS; Črnčec, Barnett, & Matthey, 2008) assessed perceived parental self-efficacy with higher scores indicating higher parenting confidence. Total scores below 40 are indicative of lower than average parenting confidence. The KPCS has been validated in postpartum samples (current sample α=.84). The *World Health Organisation Quality of Life scale* (WHOQOL-BREF; Skevington, Lotfy, & O'Connell, 2004) assessed QOL over the past four weeks and is measured across four domains: physical health, psychological health, social relationships and environment. Higher scores are indicative of higher QOL. The WHOQOL-BREF has been validated in postpartum samples (e.g., Webster, Nicholas, Velacott, Cridland, & Fawcett, 2010; current sample α's = .71, .72, .46, .72).

In the iCBT group, expectancy of treatment benefit was assessed before Lesson 1 and Lesson 2 according to the Treatment Credibility and Expectancy questionnaire (CEQ; Devilly & Borkovec, 2000); treatment adherence was reflected in the mean number of CBT sessions completed; and treatment satisfaction was measured at post-treatment using items derived from the Treatment Satisfaction Questionnaire (TSQ; Cox, Fergus, & Swinson, 1994).

Treatment conditions

Internet-based CBT. The *MUMentum* Postnatal program is a three lesson, unguided iCBT intervention for postpartum anxiety and depression. The program was adapted from our validated, six-lesson, clinician-guided transdiagnostic iCBT program for anxiety and depression in adults (Newby et al., 2013; 2014), and tailored specifically to mothers in the postnatal period. Given the barriers to treatment uptake in this population (e.g., time-poor), course content was condensed and presented over three rather than six lessons. Content focused on psychoeducation and key cognitive behavioural skills such as though challenging, problem-solving, and graded exposure (see Table 1). The program was delivered in an illustrated comic-style story, with two fictional women experiencing postpartum anxiety and depression symptoms. Participants followed the characters' experiences of learning how to self-manage their symptoms using CBT skills. Each lesson consisted of a set of lesson slides showing the characters' stories and describing specific CBT skills; a lesson summary and action plan to revise and implement skills (i.e. homework); and a range of additional resources.

Table 1. *MUMentum Postnatal* lesson plans

Lesson	Title	Skills
1	Learning about anxiety and depression, and tackling physical symptoms	✓ Psychoeducation: - About anxiety and depression - Identifying symptoms - Cognitive behavioural model - Prioritising self-care - Physical symptoms ✓ Controlled breathing ✓ Progressive muscle relaxation ✓ Extra resources: Sleep hygiene, medications, fight-or-flight response, pleasant activities, partners and supporters, FAQs
2	Identifying unhelpful thoughts and dealing with uncertainty	✓ Psychoeducation: - About thoughts - Identifying unhelpful thoughts - Shifting unhelpful thoughts - Accepting uncertainty ✓ Thought challenging ✓ Coping cards ✓ Structured problem-solving ✓ Extra resources: Understanding intrusive thoughts, further examples, FAQs
3	Tackling unhelpful behaviours and building confidence	✓ Psychoeducation: - Unhelpful behaviours (low activity; avoidance) - Facing your fears ✓ Activity planning and monitoring ✓ Graded exposure ✓ Assertive communication ✓ Relapse prevention ✓ Extra resources: further examples, self-care plan, FAQs

Participants were encouraged to complete one lesson every one-to-two weeks, for a total treatment period of up to six weeks. All lessons were accessed sequentially via the online Virtual Clinic system, with an automated 5-day lockout period between lessons. Assistance was only available for technical issues, with time spent recorded as the number of minutes spent in contact with the participant via email or telephone.

Control condition. Participants in TAU completed the same pre-, post- and follow-up assessments as those in iCBT, which were accessed via the online Virtual Clinic system. Participants in this group were not restricted from receiving any services or supports, and thus varied across participants as is common for RCTs (Watts, Turnell, Kladnitski, Newby, & Andrews, 2015).

Statistical Analyses

All analyses were undertaken in Statistical Package for the Social Sciences (SPSS) version 24 (IBM SPSS, IBM Corp., Armonk, NY, USA). Group differences in baseline variables were examined using cross-tabulations, independent *t*-tests, and regression analyses. A-priori power calculation to determine the minimum sample size was informed by published RCTs of iCBT for postpartum depression (e.g., Milgrom et al 2016), and iCBT for anxiety and depression in the general adult population (e.g., Newby et al., 2013). To detect a between-group effect corresponding to Hedges' *g* of 0.80, the minimum sample size for each group (alpha set at 0.05, power of 80%) was identified as 25 per group. We aimed to recruit a minimum sample of N=100 to allow for expected attrition (e.g., O'Mahen et al., 2013). To determine treatment efficacy, intention-to-treat linear mixed models were estimated for each outcome measure, with restricted maximum likelihood (REML) estimation used to account for missing data due to participant drop-outs. These models were used to yield more accurate estimates of effect compared to completer as they account for the unbalanced nature of the data (Salim, Mackinnon, Christensen, & Griffiths, 2008). Mixed models were estimated separately for each outcome variable, with time, treatment group, and time by group interaction entered as fixed factors. Planned contrasts were used to compare changes within and between groups from baseline to post-treatment and follow-up for each group. Between-group effect sizes were calculated using the pooled standard deviation of the estimated marginal means and adjusted for sample size (Hedges *g*). Effect sizes of 0.20, 0.50, and 0.80 considered small, moderate, and large respectively (Cohen, 1988).

Clinical and reliable change. Symptom remission rates and reliable change was examined among those who completed treatment. Participants were classified as remitted if they met clinical threshold for a likely diagnosis of MDD or GAD (i.e., total score ≥10) at baseline, and completed treatment with a total score below threshold for a likely diagnosis. Reliable change indices (RCI) were used to determine the proportion of each group who reliably improved or deteriorated between baseline and post-treatment. RCI values were calculated using test-retest reliability values of 0.83 for GAD-7 (Spitzer et al., 2006), and 0.84 for PHQ-9 (Kroenke et al., 2001) and the baseline standard deviation of the marginal means of the entire sample (GAD-7=3.61, PHQ-9=3.15). Based on these estimates, participants who reported changes of 4.13 points for the GAD-7 and 3.49 points for the PHQ-9 were classified as either experiencing reliable improvements or deterioration with 95% confidence (Jacobson & Truax, 1991). Multinomial logistic regressions were then estimated to evaluate whether the groups differed in the extent to which they remitted, and/or experienced a reliable change in anxiety and depression symptom severity.

Results

Baseline characteristics

Participant flow is depicted in Figure 1. A total of 383 adult women applied to the study, with 131 randomised to iCBT (*n*=69) or TAU (*n*=62). Of those, 120 (iCBT: *n*=65, TAU: *n*=55) completed baseline questionnaires and were included in analyses.

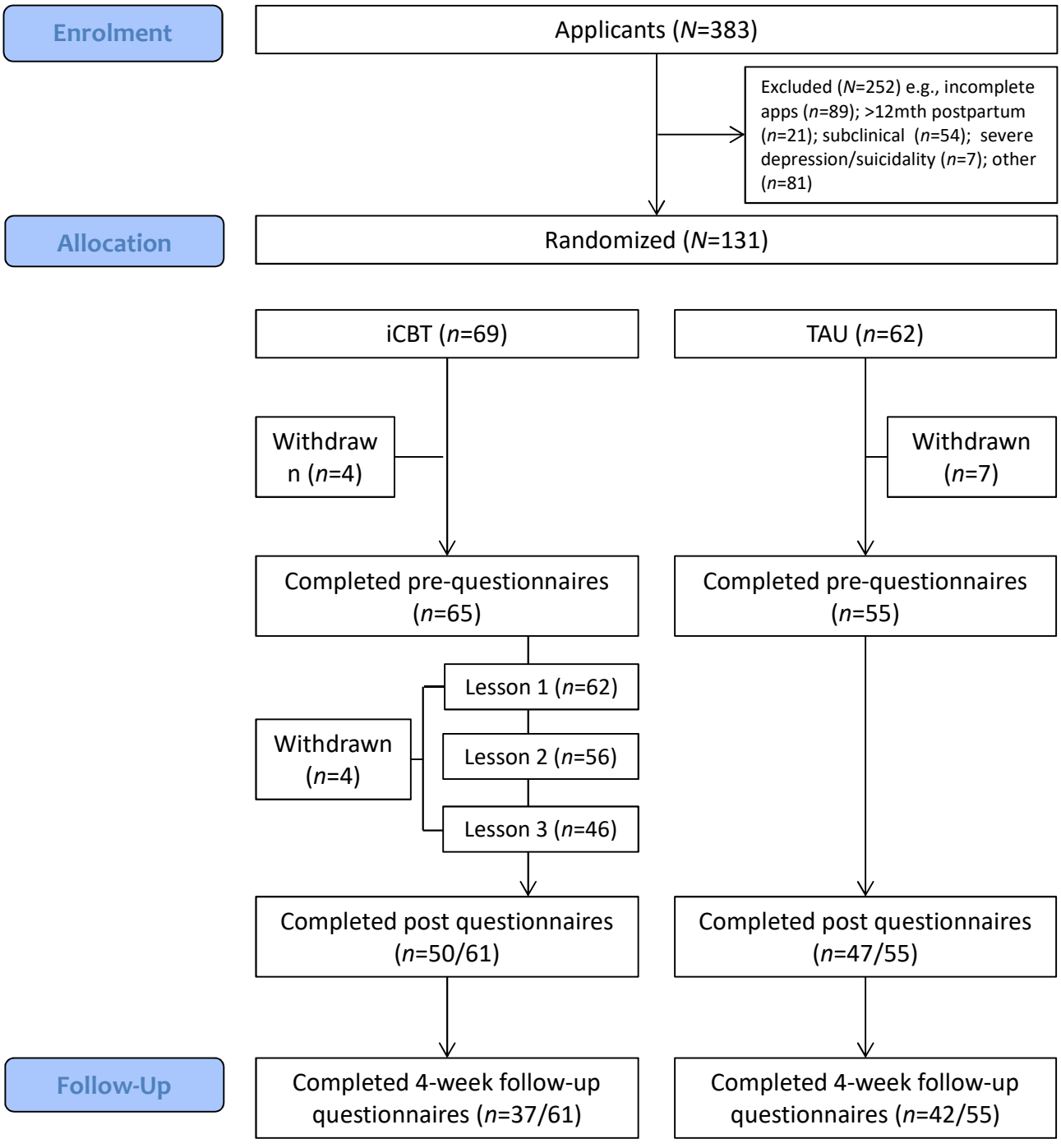

Figure 1. Participant flow diagram

Participants' demographics are shown in Table 2. Overall, participants were aged 32.56 years (*SD*=4.53; *R*=21-47), slightly higher than the Australian national average (30 years; AIHW, 2017), with a mean infant age of 4.55 months (*SD*=3.05; *R*=0.25-11). Most women were primiparous (i.e., first childbirth; 58%), married (88%), had a University degree (66%), and were on maternity leave or a stay-at-home parent (60%). Most women were also born in Australia (78%) and resided in major Australian cities (63%). Only 13% of women reported currently taking medication or receiving psychological treatment for depression and anxiety.

Participants' baseline clinical characteristics are provided in Table 2. The mean EPDS at baseline was 15.06, similar to the mean observed in other Australian samples of depressed postpartum women (e.g., Milgrom et al., 2016). Approximately 11% met clinical threshold (total score ≥10) for a likely diagnosis of GAD only, 12.5% for MDD only, and just over half for comorbid GAD and MDD (59%); 17.5% had remitted to subclinical range by baseline assessment. Less than 33% of participants were classified as experiencing severe symptoms of anxiety (GAD-7 total score=15-21) and distress (K-10 total score=30-50), and 6% for depression (PHQ-9 total score=20-27). There were no significant group differences on baseline outcome measures, except the K-10 (t(df)=2.27(118), p=0.03) which was controlled for in further analyses.

Table 2. Participant baseline characteristics and proportion of clinical reliable change at post-treatment.

	Total ***N*** **= 120**	**iCBT** ***n*** **= 65**	**TAU** ***n*** **= 55**	**iCBT vs TAU**
Mean age (years), mean (SD)	32.56 (4.53)	32.77 (4.21)	32.31 (4.90)	t(118) = 0.55, p = 0.58
Age of infant (months), mean (SD)	4.55 (3.05)	4.42 (3.02)	4.71 (3.10)	t(118) = -0.52, p = 0.60
Gestation at birth (weeks), mean (SD)	38.79 (1.67)	38.84 (1.46)	38.7 (1.89)	t(101) = 0.35, p = 0.73
Number of children, *n* (%)				
1	70 (58)	34 (52)	36 (65)	
2	35 (29)	24 (37)	11 (20)	
3+	15 (13)	7 (11)	8 (15)	
Rurality, *n* (%)				
Major cities	75 (63)	44 (68)	31 (56)	
Regional or rural areas	45 (38)	21 (32)	24 (44)	
Country of birth, *n* (%)				
Australia	94 (78)	49 (75)	45 (82)	
Other	26 (22)	16 (25)	10 (18)	
Relationship status, *n* (%)				
Single	3 (3)	2 (3)	1 (2)	
In a relationship	10 (8)	6 (9)	4 (7)	
Married/de facto	106 (88)	56 (86)	50 (91)	
Separated/Divorced	1 (1)	1 (2)	0 (0)	
Level of education, *n* (%)				
No qualification	1 (1)	0 (0)	1 (2)	
School-level	14 (12)	7 (11)	7 (13)	
Trade/certificate	17 (14)	11 (17)	6 (11)	
Diploma	9 (8)	7 (11)	2 (4)	
Undergraduate	57 (48)	29 (45)	28 (51)	
Post-graduate	22 (18)	11 (17)	11 (20)	
Employment status, *n* (%)				
Full-time paid work/study	13 (11)	7 (11)	6 (11)	

Part-time paid work/study	17 (14)	10 (15)	7 (13)	
At home parent	45 (38)	18 (28)	27 (49)	
Maternity leave	27 (23)	19 (29)	8 (15)	
Other	18 (15)	11 (17)	7 (13)	
Recruitment, *n* (%)				
Facebook	88 (73)	47 (72)	41 (75)	
Word of mouth	7 (6)	5 (8)	2 (4)	
Health professional	7 (6)	6 (9)	1 (2)	
Other	18 (15)	7 (11)	11 (20)	
Probable baseline diagnosis, *n* (%)				
Anxiety	13 (11)	9 (14)	4 (7)	
Depression	15 (13)	5 (8)	10 (18)	
Comorbid	71 (59)	40 (62)	31 (56)	
Subclinical[a]	21 (18)	11 (17)	10 (18)	
Symptom start, *n* (%)				
Antenatal	69 (58)	33 (51)	36 (65)	
Postnatal	41 (34)	24 (37)	17 (31)	
Don't know	10 (8)	8 (12)	2(4)	
Current medications, *n* (%)				
Yes	16 (13)	7 (11)	9 (16)	
No	103 (86)	57 (88)	46 (84)	
Prefer not to say	1 (1)	1 (2)	0 (0)	
Current psychotherapy[b], *n* (%)				
Yes	15 (13)	6 (10)	9 (16)	
No	103 (87)	57 (90)	46 (84)	
Baseline variables, mean (SD)				
GAD-7	12.21 (4.48)	12.57 (4.60)	11.78 (4.34)	t(118) = 0.96, $p = 0.34$
PHQ-9	12.14 (4.37)	12.43 (4.37)	11.80 (4.37)	$t(118) = 0.79$, $p = 0.43$
EPDS	15.15 (4.30)	15.62 (4.37)	14.60 (4.16)	$t(118) = 1.30$, $p = 0.20$
K-10	27.58 (6.32)	28.77 (6.57)	26.18 (5.77)	$t(118) = 2.27$, $p = 0.03$
MPAS	70 (11.14)	68.83 (11.05)	71.62 (11.17)	$t(110) = -1.31$, $p = 0.19$
KPCS	34.28 (5.66)	33.74 (5.91)	34.93 (5.32)	$t(118) = -1.15$, $p = 0.25$
WHOQOL-BREF				
(1) Physical health	56.01 (15.28)	54.95 (14.54)	57.27 (16.15)	$t(118) = -0.83$, $p = 0.41$
(2) Psychological	45 (14.60)	42.82 (14.24)	47.58 (14.74)	$t(118) = -1.79$, $p = 0.08$
(3) Social relationships	49.93 (18.19)	51.79 (17.77)	47.73 (18.60)	$t(118) = 1.22$, $p = 0.22$
(4) Environment	70.03 (13.30)	68.80 (13.49)	71.48 (13.05)	$t(118) = -1.10$, $p = 0.27$
Clinical and reliable change at post-treatment, *n* (%)				
GAD-7				
Remitted[c]	32/99 (32)	22/35 (63)	10/28 (36)	$\chi^2(1) = 6.47$, $p<.01$
Improved[d]	40/97 (41)	28/50 (56)	12/47 (26)	$\chi^2(1) = 9.48$, $p<.01$
Deteriorated[d]	2/97 (0.02)	0/50 (0)	2/47 (0.04)	$\chi^2(1) = 2.97$, $p = .09$
PHQ-9				
Remitted[c]	40/66 (61)	26/33 (79)	14/33 (42)	$\chi^2(1) = 9.75$, $p<.01$
Improved[d]	44/97 (45)	30/50 (60)	14/47 (30)	$\chi^2(1) = 9.08$, $p<.01$
Deteriorated[d]	4/97 (0.04)	0/50 (0)	4/47 (0.09)	$\chi^2(1) = 5.98$, $p<.01$

Note. [a]All participants, including those whose scores had reduced to subthreshold (<9) between screening and baseline assessment (i.e., ≤2 weeks), were included in analyses; [b]Variable data not available for two participants: total $N = 118$; iCBT $n = 63$; TAU $n = 55$; [c]Remission at post-treatment is defined as scores below clinical threshold for a likely diagnosis of GAD or MDD, only participants who met clinical

threshold at baseline were included in analyses; [d]Only those who completed post-treatment assessment were included in analyses.

Treatment adherence and data return

A total of 131 women who were randomised, 11 were withdrawn for not completing baseline measures. Four women in iCBT were no longer interested in participating, and were withdrawn from the study after starting treatment. A total of 46 women completed all three lessons of treatment (75% completion rate, n=46/61). Of those in iCBT, 82% completed post-treatment questionnaires and 61% completed follow-up questionnaires. Of those in TAU, 85% and 76% provided post-treatment and follow-up data, respectively. Groups did not differ in the extent to which they completed their post-treatment ($\chi^2(1)=0.26$, $p=0.61$; OR(95% CI)=1.29(0.48, 3.49)) or follow-up questionnaires ($\chi^2(1)=3.33$, $p=0.07$; OR(95% CI)=2.10(0.94, 4.70)).

Treatment effects of the *MUMentum Postnatal* program

Table 3 presents the estimated marginal means and linear mixed model results of participants' symptom severity at baseline, post-treatment and follow-up assessments, and effect sizes for each of the outcome measures. There were significant group by time interactions (controlling for baseline K-10 scores) for PHQ-9 ($F_{2, 93.80}$=9.06, p<.001) and EPDS ($F_{2, 87.50}$=10.25, p<.001), and GAD-7 ($F_{2, 94.04}$=9.13, p<.001). There were also significant interactions for most secondary outcomes including K-10 ($F_{2, 216.22}$= 30.80, p<.001), MPAS ($F_{2, 87.77}$=16.71, p<.001), and the physical health ($F_{2, 53.65}$= 1.93, p<.001), psychological ($F_{2, 89.92}$=3.23, p<.05), and environment ($F_{2, 90.16}$=4.97, p<.01) QOL domains. In contrast, there were no significant group by time interactions noted for social relationships QOL (F(2, 87.12)=1.21, p=0.30), or KPCS (F(2, 88.81)=2.10, p=0.13).

Within-group effect sizes from baseline to post-treatment, and follow-up. From pre- to post-treatment, participants in iCBT demonstrated large and significant effect size reductions (gs=0.84-2.02) for GAD-7, PHQ-9, K-10, MPAS, and psychological QOL. Moderate reductions (gs=0.43-0.65) were demonstrated for KPCS, physical health, social, and environment QOL. For those in iCBT, effect sizes observed between pre-treatment and follow-up were also large and significant for all outcomes, except psychological and social QOL.

For those in TAU, small effect size reductions were observed between pre- and post-treatment for GAD-7 only, yet moderate symptom reductions were observed for GAD-7, PHQ-9, K-10, and EPDS (gs=0.47-0.62) between pre- and follow-up.

Between-group effect sizes at post-treatment and follow-up assessment. Participant symptom severity scores at post-treatment were significantly lower in the iCBT group relative to TAU, with large and significant between-group differences for GAD-7, PHQ-9, and K-10 (gs=0.78-1.69) and moderate effect size differences for MPAS, and psychological and social relationships QOL (gs=0.48-0.70).

At follow-up, participants in iCBT maintained superiority over TAU, for PHQ-9, K-10, and psychological QOL (gs=0.53-1.32). Notably, participants in iCBT demonstrated larger effect size differences for GAD-7 at follow-up (g=1.14) than at post-treatment (g=0.78). There were no statistically significant between-group differences observed at post-treatment or follow-up for KPCS (gs<0.17), or physical health and environment QOL domains (gs<0.41).

Table 3. Estimated marginal means (standard deviations) for primary and secondary outcome measures, within-group effect sizes, and between-group effect sizes at post-treatment and follow-up.

	EMM (SD)			Within-group ES (95%CI)		Between-group ES (95%CI)	
	Pre-treatment	Post-treatment	Follow-up	Pre to Post-treatment	Pre to Follow-up	Post-treatment	Follow-up
GAD-7[a]							
iCBT	12.08 (3.69)	6.66 (4.23)	5.42 (3.75)	1.26 (0.77, 1.52)***	1.82 (1.34, 2.29)***	0.78 (0.36, 1.19)*	1.14 (0.66, 1.62)*
TAU	12.12 (3.57)	9.97 (4.22)	9.78 (3.82)	0.44 (0.03, 0.79)	0.58 (0.17, 0.99)**		
PHQ-9[a]							
iCBT	11.81 (3.22)	6.11 (4.34)	6.32 (3.60)	1.42 (0.91, 1.67)***	1.54 (1.09, 2.00)***	0.99 (0.57, 1.41)*	0.85 (0.39, 1.31)*
TAU	12.26 (3.11)	10.44 (4.35)	9.52 (3.81)	0.33 (-0.07, 0.68)	0.59 (0.18, 1.00)***		
K-10[a]							
iCBT	27.64 (4.47)	18.19 (4.31)	18.33 (4.14)	2.02 (1.41, 2.25)***	1.97 (1.49, 2.46)***	1.69 (1.23, 2.15)*	1.32 (0.84, 1.81)*
TAU	26.91 (4.33)	25.50 (4.27)	23.96 (4.27)	0.24 (-0.16, 0.59)	0.47 (0.07, 0.88)**		
EPDS[a]							
iCBT	14.91 (3.15)	8.82 (4.96)	8.01 (4.05)	1.41 (0.89, 1.66)***	1.84 (1.37, 2.32)***	0.90 (0.49, 1.32)*	0.99 (0.52, 1.45)*
TAU	15.04 (3.04)	13.34 (4.96)	12.13 (4.22)	0.31 (-0.09, 0.67)	0.62 (0.21, 1.03)***		
MPAS[b]							
iCBT	69.64 (11.10)	76.76 (9.21)	77.69 (9.25)	-0.89 (-1.28, -0.50)**	-1.07 (-1.50, -0.64)***	-0.70 (-1.11, -0.29)*	-0.45 (-0.90, -0.001)*
TAU	72.12 (11.13)	70.40 (8.90)	73.37 (9.75)	0.12 (-0.27, 0.51)	-0.07 (-0.47, 0.33)		
KPCS[b]							
iCBT	33.98 (5.80)	37.41 (5.45)	38.08 (4.84)	-0.62 (-0.99, -0.24)***	-0.80 (-1.22, -0.38)***	-0.17 (-0.57, 0.23)	-0.10 (-0.54, 0.34)

TAU	34.83 (5.60)	36.47 (5.48)	37.57 (5.13)	-0.30 (-0.69, 0.09)	-0.53 (-0.94, 0.12)		
QOL: Physical health[b]							
iCBT	55.65 (15.34)	65.03 (15.63)	66.36 (13.08)	-0.65 (-1.03, -0.28)***	-0.87 (-1.29, -0.45)***	-0.31 (-0.71, 0.09)	-0.41 (-0.86, 0.03)
TAU	56.67 (14.80)	60.12 (15.69)	60.75 (13.78)	-0.19 (-0.58, 0.20)	-0.26 (-0.66, 0.14)		
QOL: Psychological[b]							
iCBT	44.27 (13.42)	56.25 (14.33)	57.84 (14.26)	-0.84 (-1.23, -0.46)***	-0.12 (-0.52, 0.29)	-0.53 (-0.94, -0.13)*	-0.53 (-0.98, -0.08)*
TAU	46.58 (12.94)	48.58 (14.36)	50.03 (14.96)	-0.13 (-0.52, 0.26)	-0.08 (-0.48, 0.32)		
QOL: Social[b]							
iCBT	51.67 (19.17)	58.30 (18.03)	58.40 (18.22)	-0.43 (-0.80, -0.05)**	-0.37 (-0.78, 0.03)	-0.47 (-0.88, -0.07)*	-0.37 (-0.82, 0.07)
TAU	47.60 (18.48)	49.65 (18.12)	51.39 (19.02)	-0.10 (-0.48, 0.29)	-0.19 (-0.60, 0.21)		
QOL: Environment[b]							
iCBT	69.03 (13.67)	74.48 (13.94)	75.09 (11.45)	-0.45 (-0.83, -0.08)***	-0.63 (-1.04, -0.21)***	-0.27 (-0.67, 0.13)	-0.18 (-0.62, 0.26)
TAU	71.30 (13.19)	70.74 (14.05)	72.93 (12.29)	0.03 (-0.36, 0.42)	-0.10 (-0.50, 0.30)		

Note. [a]Positive scores indicate symptom reduction; [b]Negative scores indicate symptom improvement; *=p<.05; **=p<.01; ***=p<.001; EMM = Estimated marginal means; SD = Standard deviation; ES = Effect size according to Hedges' g; 95%CI = 95% confidence interval; PHQ-9 = Patient Health Questionnaire 9-item scale; GAD-7 = Generalized Anxiety Disorder 7-item scale; K-10 = Kessler Psychological Distress 10-item scale; EPDS = Edinburgh Postnatal Depression Scale; MPAS = Maternal Postnatal Attachment Scale; KPCS = Karitane Parenting Confidence Scale; QOL = Quality of life according to the World Health Organisation Quality of Life-BREF scale.

Clinical and reliable change at post-treatment

For completers, there were significant differences between groups in the proportion of participants who remitted, and evidenced reliable change for anxiety and depression primary outcomes (see Table 2). More than half of those in iCBT demonstrated reliable improvements in anxiety (56%) and depression symptom severity scores (60%), compared to less than 30% of those in TAU. No participants evidenced reliable deterioration for anxiety or depression, compared with a total of 6 participants in TAU.

Treatment satisfaction and time spent

Expectancy. Ninety-seven percent of participants in the iCBT group rated the program as 'somewhat' to 'very logical' at Lesson 1 and Lesson 2 (58.5/60.5; *M*(SD)=7.37(1.60); *R*=3-9). Most also reported that they expected the program to be 'somewhat' to 'very successful' in reducing symptoms (50.5/60.5; 83%; *M*(*SD*)=5.98(1.78); *R*=1-9).

Treatment satisfaction. After treatment, most participants reported feeling 'mostly' to 'very satisfied' with the program (39/49; 80%; *M*(*SD*)=4.02(0.90); *R*=1-5), judged the quality of the program as 'good' to 'excellent' (42/49; 86%; *M*(*SD*)=3.35(0.72); *R*=2-4). Most participants were confident (>5) that the program was successful in teaching them skills for managing symptoms (40/49, 82%; (*M*(SD)=7.31(2.33); *R*=1-10), and in recommending the program to a friend experiencing postpartum anxiety and/or depression (41/49, 84%; (*M*(SD)=7.90(2.22); *R*=2-10). More than half participants reported that they preferred to receive help for their symptoms via an online program rather than another type of treatment (61%, 30/49); approximately 18% would have preferred both face-to-face and iCBT (9/49).

Time spent. On average, participants in iCBT reported spending approximately one hour per week completing each lesson (*M*(SD)=1.13(0.80); *R*=0.15-4, *n*=40), and one and a half hours revising and practising the skills (*M*(SD)=1.46(1.73); *R*=0-9.33, *n*=39). Over the course of the 11-week trial period, average technician time spent per participant was approximately 14 minutes for those in iCBT (*M*(*SD*)=13.74(8.15), *R*=1- 36 mins) and approximately 8 minutes for TAU (*M*(*SD*)=7.78(5.79), *R*=1-31 mins).

Discussion

This study examined the efficacy and acceptability of a brief unguided iCBT intervention in reducing postpartum anxiety and depressive symptoms. In an Australian sample of adult postpartum women, we found that our *MUMentum Postnatal* program was highly effective, demonstrating significantly greater reductions in anxiety, depression, and psychological distress compared to women receiving usual care. Additionally, the program produced meaningful improvements in maternal bonding, parenting confidence, and quality of life, with high participant engagement, adherence, and treatment satisfaction. These findings have important clinical implications given that no other iCBT programs have specifically targeted the treatment of postpartum GAD, or comorbid GAD and MDD symptoms.

Primary findings

The MUMentum Postnatal program demonstrated large improvements for symptoms of anxiety, depression, and distress between baseline and post-treatment (within-group Hedges' $g \geq 1.41$). For depression and general psychological distress, iCBT produced large and superior effect size improvements compared to TAU at post-treatment (between-group $g \geq 0.90$), with

gains sustained at follow-up ($g \geq 0.85$). Moreover, compared to TAU, iCBT led to greater improvements in anxiety symptom severity at post-treatment ($g=0.78$), with an even larger between-group effect size observed at follow-up ($g=1.14$). Majority of women had a likely diagnosis of comorbid GAD and MDD (59%) and symptoms in the moderate to severe range for anxiety (70%), depression (72%) and distress (68%). Given the severity and comorbidity of our sample, it is promising that the program produced such large improvements. Our results also highlight the importance of assessing for both depression and anxiety symptoms in postpartum women, as conceptualising all distress as depression may mean anxiety symptoms and significant comorbidities are not recognised and appropriately treated (Matthey, 2008; McCabe-Beane, Stasik-O'Brien, & Segre, 2018).

Although we cannot directly compare the benefit of *MUMentum Postnatal* with longer iCBT programs, the effects found in this study are consistent with RCTs investigating longer six lessons iCBT programs for postpartum MDD supported by telephone coaching (e.g., between-group Cohen's $d=0.83$; Milgrom et al., 2016), as well as face-to-face CBT interventions for postpartum depression (between-group $g=0.69$; Sockol, 2015). Our findings are also comparable with those investigating brief unguided iCBT for anxiety and depression in general adult populations (within-group g range=0.65-1.29; Morgan et al., 2017). Together, these findings suggest that brief programs presented in an online and self-help format may be an effective alternative to more costly and time-intensive treatments. The literature would benefit from directly comparing the effects of iCBT and face-to-face psychotherapy for postnatal anxiety and depression. Doing so would highlight whether the limited differences that have been demonstrated between iCBT and face-to-face therapy for depression in the general adult population (Carlbring et al., 2018) generalize to vulnerable perinatal populations.

Secondary findings

We also demonstrated that *MUMentum Postnatal* produced large and superior improvements in maternal bonding with their infant at post-treatment ($g=0.70$), and moderate effect size improvements at follow-up ($g=0.45$) compared to TAU. These findings have key clinical implications as mother-infant bonding is critical to infant health and wellbeing (Rossen et al., 2017), and depression has been correlated with poor bonding postpartum (Ohoka et al., 2014). Further, we found small to moderate between-group differences in QOL favouring iCBT at post-treatment across two QOL domains (i.e. psychological, $g=0.53$; social, $g=0.47$). For parenting confidence, moderate to large within-group improvements were demonstrated at post-treatment (within-group $g=0.62$), which continued to improve over time ($g=0.80$). Whilst other iCBT studies for postpartum depression have either not measured, or have not found significant benefits on parenting or mother-infant outcomes (e.g., O'Mahen et al., 2014; Pugh et al., 2016), our results highlight QOL and parenting confidence as two important areas of future investigation, which may be essential if we are to maximise treatment benefits for the mother, infant, and family. Additionally, further research should seek to examine the changes in objective measures of bonding and connection between the mother and infant, as our results are reliant on only self-report measures.

The *MUMentum Postnatal* program also demonstrated high program adherence and participant satisfaction. Three quarters of participants (75%) completed all three lessons. These completion rates are consistent with those of longer, telephone-coached iCBT programs for postpartum depression (e.g., 86%, Milgrom et al 2016; 60%, Pugh et al 2016), and much higher than those found for an unguided, internet-delivered behavioural activation intervention for

postpartum depression (39%, O'Mahen et al., 2013) and brief unguided iCBT for anxiety and depression in the general adult population delivered outside of a research setting (14%, Morgan et al 2017). These completion rates are promising given that the research technician spent on average only 14 minutes per participant over the whole trial period, demonstrating the feasibility of the program in terms of time and resources. Participant credibility and satisfaction ratings were also positive, with majority reporting that they were confident that the program would provide techniques to effectively cope with their symptoms. Further research would benefit from exploring factors that promote program adherence and influence program completion, particularly given that unguided iCBT tends to have lower completion rates once disseminated in naturalistic vs. controlled research settings (Morgan et al., 2017). Our sample characteristics also suggest that unguided iCBT may be most acceptable for women who are likely to self-refer and seek help online. We found only 6% of participants came via clinician referral despite a diverse recruitment strategy. This may be reflective of low clinician uptake of iCBT programs in vulnerable populations. Future studies should therefore aim to evaluate iCBT in a more heterogeneous sample and increase the number of participants from clinician referrals and rural communities (where face-to-face services are limited) to examine groups likely to benefit from unguided iCBT.

Our findings provide preliminary evidence that clinician guidance or coaching may not be required to achieve large treatment benefits and high adherence. Brief unguided iCBT programs that do not rely on the operation of staff with specialist training or coaching represent a highly scalable and cost-effective way to offer cognitive behavioural interventions to women in the postpartum period. Within a stepped-care approach, *MUMentum Postnatal* can offer mothers the option to self-refer and self-manage their symptoms. Such programs can be implemented as part of the population-wide screening process recommended in the Australian Clinical Practice Guidelines (Austin et al 2017).This is particularly important if we are to reduce help-seeking barriers and improve treatment coverage in this population. Only 13% of our sample reported currently receiving treatment, despite most women experiencing moderate to severe symptoms of anxiety and/or depression. Moreover, limited clinician resources can then be directed (i.e., via existing clinician-intensive iCBT programs and face-to-face treatment) towards more high-risk mothers and those experiencing severe anxiety and depressive disorders, or those who do not respond to unguided iCBT. Future research should seek to determine whether *MUMentum Postnatal* is cost-effective in a naturalistic setting, and if the program can be transferred to routine care with maintained effects and treatment adherence.

Limitations

Our findings should be interpreted in the context of the following study limitations. Some caution in generalising our findings is warranted as our sample was self-selected, and we did not assess participants using clinician-administered diagnostic outcome measures. We also utilised a TAU control condition and did not impose limitations on access to other healthcare services. Therefore, we cannot exclude the possible effects of other variables or treatments on clinical outcomes. Lastly, given that our follow-up period was short it is difficult to determine whether symptom improvements were sustained long-term.

Conclusions

This study provides preliminary evidence for the efficacy and acceptability of *MUMentum Postnatal,* a brief unguided iCBT intervention for the treatment of anxiety and/or

depression in postpartum women. Our findings contribute to the existing evidence base for the efficacy of iCBT for postpartum depression, and establishes preliminary efficacy of iCBT for postpartum GAD, and comorbid MDD and GAD symptoms. This is particularly important for the treatment of postpartum anxiety, which has received little attention to date. Further RCTs are required to replicate our findings and investigate whether treatment effects are sustained long-term. The potential clinical value of unguided iCBT for postpartum women is substantial. *MUMentum Postnatal* can overcome barriers to accessing treatment and improve treatment coverage as a scalable and low cost 'first step' intervention for all women screening positive for distress, anxiety and/or depression in routine care.

References

Andrews, G., Basu, A., Cuijpers, P., Craske, M. G., McEvoy, P., English, C., & Newby, J. M. (2018). Computer therapy for the anxiety and depressive disorders is effective, acceptable and practical health care: an updated meta-analysis (in press). *Journal of Anxiety Disorders*.

Ashford, M. T., Olander, E. K., Rowe, H., Fisher, J. R., & Ayers, S. (2018). Feasibility and Acceptability of a Web-Based Treatment with Telephone Support for Postpartum Women With Anxiety: Randomized Controlled Trial. *JMIR Mental Health, 5*(2).

Austin, M.-P., Frilingos, M., Lumley, J., Hadzi-Pavlovic, D., Roncolato, W., Acland, S., . . . Parker, G. (2008). Brief antenatal cognitive behaviour therapy group intervention for the prevention of postnatal depression and anxiety: a randomised controlled trial. *Journal of Affective Disorders, 105*(1), 35-44.

Austin, M.-P., Highet, N., & Group, a. t. E. W. (2017). *Mental healthcare in the perinatal period: Australian Clinical Practice Guideline*. Melbourne: Centre for Perinatal Excellence.

Beck, A. T., Steer, R. A., & Brown, G. K. (1996). *Beck depression inventory (2nd edition) - manual*. San Antonio, TX: The Psychological Corporation

Bergink, V., Kooistra, L., Lambregtse-van den Berg, M. P., Wijnen, H., Bunevicius, R., van Baar, A., & Pop, V. (2011). Validation of the Edinburgh Depression Scale during pregnancy. *Journal of Psychosomatic Research, 70*(4), 385-389.

Biaggi, A., Conroy, S., Pawlby, S., & Pariante, C. M. (2016). Identifying the women at risk of antenatal anxiety and depression: A systematic review. *Journal of Affective Disorders, 191*, 62-77.

Carlbring, P., Andersson, G., Cuijpers, P., Riper, H., & Hedman-Lagerlöf, E. (2018). Internet-based vs. face-to-face cognitive behavior therapy for psychiatric and somatic disorders: an updated systematic review and meta-analysis. *Cognitive behaviour therapy, 47*(1), 1-18.

Cohen, J. (1988). *Statistical power analysis for the behavioral sciences (2nd ed.)*. Hillsdale, NJ: Lawrence Earlbaum Associates.

Condon, J. T. (1993). The assessment of antenatal emotional attachment: development of a questionnaire instrument. *Psychology and Psychotherapy: Theory, Research and Practice, 66*(2), 167-183.

Condon, J. T., & Corkindale, C. (1997). The correlates of antenatal attachment in pregnant women. *Psychology and Psychotherapy: Theory, Research and Practice, 70*(4), 359-372.

Cox, B. J., Fergus, K. D., & Swinson, R. P. (1994). Patient satisfaction with behavioral treatments for panic disorder with agoraphobia. *Journal of Anxiety Disorders, 8*(3), 193-206.

Cox, J. L., Holden, J. M., & Sagovsky, R. (1987). Detection of postnatal depression: Development of the 10-item Edinburgh Postnatal Depression Scale *British Journal of Psychiatry, 150*, 782-786.

Črnčec, R., Barnett, B., & Matthey, S. (2008). Development of an instrument to assess perceived self-efficacy in the parents of infants. *Research in Nursing & Health, 31*(5), 442-453.

Dennis, C. L., Falah-Hassani, K., & Shiri, R. (2017). Prevalence of antenatal and postnatal anxiety: Systematic review and meta-analysis. *The British Journal of Psychiatry, 210*, 315-323. doi:10.1192/bjp.bp.116.187179

Devilly, G. J., & Borkovec, T. D. (2000). Psychometric properties of the credibility/expectancy questionnaire. *Journal of behavior therapy and experimental psychiatry, 31*(2), 73-86.

Field, T., Diego, M., Hernandez-Reif, M., Figueiredo, B., Deeds, O., Ascencio, A., . . . Kuhn, C. (2010). Comorbid depression and anxiety effects on pregnancy and neonatal outcome. *Infant Behavior and Development, 33*(1), 23-29.

Furukawa, T. A., Kessler, R. C., Slade, T., & Andrews, G. (2003). The performance of the K6 and K10 screening scales for psychological distress in the Australian National Survey of Mental Health and Well-Being. *Psychological Medicine, 33*(02), 357-362.

Goodman, J. H., & Tyer-Viola, L. (2010). Detection, treatment, and referral of perinatal depression and anxiety by obstetrical providers. *Journal of Women's Health, 19*(3), 477-490.

Goodman, J. H., Watson, G. R., & Stubbs, B. (2016). Anxiety disorders in postpartum women: A systematic review and meta-analysis. *Journal of Affective Disorders, 203*, 292-331.

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*(1), 12.

Kessler, R. C., Andrews, G., Colpe, L. J., Hiripi, E., Mroczek, D. K., Normand, S.-L., . . . Zaslavsky, A. M. (2002). Short screening scales to monitor population prevalences and trends in non-specific psychological distress. *Psychological Medicine, 32*(06), 959-976.

Kroenke, K., Spitzer, R., & Williams, J. (2001). The PHQ-9: validity of a brief depression severity measure [Electronic version]. *Journal of General Internal Medicine, 16*(9), 606-613.

Lau, Y., Htun, T. P., Wong, S. N., Tam, W. S. W., & Klainin-Yobas, P. (2017). Therapist-supported internet-based cognitive behavior therapy for stress, anxiety, and depressive symptoms among postpartum women: a systematic review and meta-analysis. *Journal of Medical Internet Research, 19*(4).

Loughnan, S. A., Newby, J. M., Haskelberg, H., Mahoney, A., Kladnitski, N., Smith, J., . . . Andrews, G. (2018). Internet-based cognitive behavioural therapy (iCBT) for perinatal anxiety and depression versus treatment as usual: study protocol for a randomized controlled trial. *Trials*.

Loughnan, S. A., Sie, A., Hobbs, M. J., Joubert, A. E., Smith, J., Haskelberg, H., … Newby, J. M. (2018). A randomized controlled trial of 'MUMentum Pregnancy': Internet-delivered cognitive behavioural therapy program for antenatal anxiety and depression. Manuscript submitted for publication.

Löwe, B., Decker, O., Müller, S., Brähler, E., Schellberg, D., Herzog, W., & Herzberg, P. Y. (2008). Validation and standardization of the Generalized Anxiety Disorder Screener (GAD-7) in the general population. *Medical Care, 46*(3), 266-274.

Matthey, S. (2008). Using the Edinburgh Postnatal Depression Scale to screen for anxiety disorders. *Depression and Anxiety, 25*(11), 926-931. doi:10.1002/da.20415

McCabe-Beane, J. E., Stasik-O'Brien, S. M., & Segre, L. S. (2018). Anxiety Screening During Assessment of Emotional Distress in Mothers of Hospitalized Newborns. *Journal of Obstetric, Gynecologic & Neonatal Nursing, 47*(1), 105-113.

Milgrom, J., Danaher, B. G., Gemmill, A. W., Holt, C., Holt, C. J., Seeley, J. R., . . . Ericksen, J. (2016). Internet cognitive behavioral therapy for women with postnatal depression: a randomized controlled trial of MumMoodBooster. *Journal of Medical Internet Research, 18*(3).

Morgan, C., Mason, E., Newby, J. M., Mahoney, A. E., Hobbs, M. J., McAloon, J., & Andrews, G. (2017). The effectiveness of unguided internet cognitive behavioural therapy for mixed anxiety and depression. *Internet Interventions, 10*, 47-53.

Newby, J. M., Mackenzie, A., Williams, A. D., McIntyre, K., Watts, S., Wong, N., & Andrews, G. (2013). Internet cognitive behavioural therapy for mixed anxiety and depression: a randomized controlled trial and evidence of effectiveness in primary care. *Psychological Medicine, 43*(12), 2635-2648.

NICE. (2014). Antenatal and postnatal mental health: Clinical management and service guidance. *NICE clinical guideline (CG192)*, 1-50.

O'Mahen, H., Richards, D., Woodford, J., Wilkinson, E., McGinley, J., Taylor, R. S., & Warren, F. (2014). Netmums: a phase II randomized controlled trial of a guided Internet behavioural activation treatment for postpartum depression. *Psychological Medicine, 44*(8), 1675-1689.

O'Mahen, H. A., Woodford, J., McGinley, J., Warren, F. C., Richards, D. A., Lynch, T. R., & Taylor, R. S. (2013). Internet-based behavioral activation—Treatment for postnatal depression (Netmums): A randomized controlled trial. *Journal of Affective Disorders, 150*(3), 814-822.

Ohoka, H., Koide, T., Goto, S., Murase, S., Kanai, A., Masuda, T., . . . Ozaki, N. (2014). Effects of maternal depressive symptomatology during pregnancy and the postpartum period on infant–mother attachment. *Psychiatry and Clinical Neurosciences, 68*(8), 631-639.

Pugh, N. E., Hadjistavropoulos, H. D., & Dirkse, D. (2016). A randomised controlled trial of therapist-assisted, internet-delivered cognitive behavior therapy for women with maternal depression. *PloS one, 11*(3), e0149186.

Ross, L. E., Evans, S. G., Sellers, E., & Romach, M. (2003). Measurement issues in postpartum depression part 1: anxiety as a feature of postpartum depression. *Arch Womens Ment Health, 6*(1), 51-57.

Rossen, L., Hutchinson, D., Wilson, J., Burns, L., Allsop, S., Elliott, E. J., . . . Mattick, R. P. (2017). Maternal bonding through pregnancy and postnatal: Findings from an Australian longitudinal study. *American journal of perinatology, 34*(08), 808-817.

Salim, A., Mackinnon, A., Christensen, H., & Griffiths, K. (2008). Comparison of data analysis strategies for intent-to-treat analysis in pre-test–post-test designs with substantial dropout rates. *Psychiatry Research, 160*(3), 335-345.

Schulz, K. F., Altman, D. G., & Moher, D. (2010). CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMC medicine, 8*(1), 18.

Sidebottom, A. C., Harrison, P. A., Godecker, A., & Kim, H. (2012). Validation of the Patient Health Questionnaire (PHQ)-9 for prenatal depression screening. *Archives of Women's Mental Health, 15*(5), 367-374.

Skevington, S. M., Lotfy, M., & O'Connell, K. A. (2004). The World Health Organization's WHOQOL-BREF quality of life assessment: psychometric properties and results of the international field trial. A report from the WHOQOL group. *Quality of Life Research, 13*(2), 299-310.

Sockol, L. E. (2015). A systematic review of the efficacy of cognitive behavioral therapy for treating and preventing perinatal depression. *Journal of Affective Disorders, 177*, 7-21.

Spies, G., Stein, D., Roos, A., Faure, S., Mostert, J., Seedat, S., & Vythilingum, B. (2009). Validity of the Kessler 10 (K-10) in detecting DSM-IV defined mood and anxiety disorders among pregnant women. *Arch Womens Ment Health, 12*(2), 69-74.

Spitzer, R. L., Kroenke, K., Williams, J. B., & Löwe, B. (2006). A brief measure for assessing generalized anxiety disorder: the GAD-7. *Archives of Internal Medicine, 166*(10), 1092-1097.

Stein, A., Pearson, R. M., Goodman, S. H., Rapa, E., Rahman, A., McCallum, M., . . . Pariante, C. M. (2014). Effects of perinatal mental disorders on the fetus and child. *The Lancet, 384*(9956), 1800-1819.

Titov, N., Dear, B. F., Johnston, L., Lorian, C., Zou, J., Wootton, B., . . . Rapee, R. M. (2013). Improving adherence and clinical outcomes in self-guided internet treatment for anxiety and depression: randomised controlled trial. *PloS one, 8*(7), e62873.

Watts, S. E., Turnell, A., Kladnitski, N., Newby, J. M., & Andrews, G. (2015). Treatment-as-usual (TAU) is anything but usual: a meta-analysis of CBT versus TAU for anxiety and depression. *Journal of Affective Disorders, 175*, 152-167.

Webster, J., Nicholas, C., Velacott, C., Cridland, N., & Fawcett, L. (2010). Validation of the WHOQOL-BREF among women following childbirth. *Australian and New Zealand Journal of Obstetrics and Gynaecology, 50*(2), 132-137.

Welfare, A. I. o. H. a. (2017). Australia's mothers and babies 2015 - in brief. . *Canberra: AIHW, Perinatal statistics series no. 33. Cat. no. PER 91*.

Woody, C., Ferrari, A., Siskind, D., Whiteford, H., & Harris, M. (2017). A systematic review and meta-regression of the prevalence and incidence of perinatal depression. *Journal of Affective Disorders*.

Woolhouse, H., Brown, S., Krastev, A., Perlen, S., & Gunn, J. (2009). Seeking help for anxiety and depression after childbirth: results of the Maternal Health Study. *Arch Womens Ment Health, 12*(2), 75-83.