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Online cognitive behaviour therapy for maternal antenatal and postnatal anxiety and depression in routine care

Introduction

The World Health Organisation has identified maternal mental health during the perinatal period (i.e., the period encompassing pregnancy and childbirth through to 12 months postpartum) as a global health issue (Howard & Khalifeh, 2020). In Australia, it is estimated that up to one in five women are affected by perinatal mental health conditions (Austin et al., 2017; Buist & Bilsztra, 2006; Leach et al., 2017; Woolhouse et al., 2012). While some women experience severe mental illnesses (e.g., psychotic disorders and bipolar disorder), the most common conditions experienced during the perinatal period are anxiety and depressive disorders (Austin et al., 2017). Women most at risk of developing perinatal anxiety and depression appear to be those with a mental health history, indigenous and migrant women, women experiencing socio-economic disadvantage, and/or those who have undergone stressful life events (such as poor partner relationships, family violence and loss, adverse pregnancy/birth circumstances, or major relocations) (Austin et al., 2017; Leach et al., 2017; Schmied et al., 2013; Yelland, Sutherland & Brown, 2010). Perinatal depression and anxiety are associated with significant adverse effects on both mothers and infants. For mothers, these can include increased risk of obstetric complications and preterm labour, physical health comorbidities, and suicide; while for infants, adverse effects can include increased risk of neurodevelopmental issues, infectious illnesses, hospital admissions, and later emotional and behavioural difficulties (WHO, 2008; Grote et al., 2010; Grigoriadis et al., 2018).

Perinatal mental health screening is not universal in Australia and many women who screen positive for illness do not engage in treatment (Moss et al., 2020; Reay et al., 2011). Cognitive behaviour therapy (CBT) is the recommended first-line psychological treatment for mild to moderate perinatal anxiety and depression (Austin et al., 2017; National Institute for Health and Care Excellence, 2014). However, there are multiple barriers that limit the uptake

of traditional methods of CBT delivery, including out-of-pocket costs, logistical issues (e.g., the need for childcare), geographical isolation from services, and perceived stigma associated with seeking mental health treatment as a mother (Hermann, Fitelson, & Bergink, 2021; Kingston et al., 2015; Maguire et al., 2023; Woolhouse et al., 2009). Numerous systemic barriers also restrict the accessibility of psychological services within the community, such as the limited availability of care providers, funding inadequacies, and fragmented service provision (Smith et al., 2019), particularly in rural regions. In recent years, the COVID-19 pandemic may have further amplified these barriers to care by restricting access to face-to-face and group-based services (Hermann, Fitelson, & Bergink, 2021).

Delivering CBT via the internet (iCBT) may help to overcome some of the barriers to accessing perinatal mental health care. iCBT can be comparatively anonymous, convenient to access, and some programs can be delivered with limited or no clinician support (Andersson & Titov, 2014; Carlbring et al., 2018). In both clinician-guided and self-guided formats, iCBT has been shown to be effective in treating antenatal and postnatal depression and anxiety (e.g., Stentzel et al., 2023). In the antenatal period, studies have shown large effect size reductions in depression and anxiety symptoms following iCBT when delivered with clinician guidance, and these improvements were sustained for up to 3 months (Kim et al., 2014; Forsell et al., 2017). Significant but smaller effects have been shown for self-guided iCBT programs, where randomised controlled trials (RCTs) have demonstrated small to moderate effect size reductions in symptom severity, maintained for up to 1 month (Loughnan et al., 2019a). In the postnatal period, meta-analytic studies have shown moderate to large effect size reductions in depression, and small to moderate reductions in anxiety, following iCBT delivered in a clinician-guided format, with improvements sustained for between 1-6 months (Lau et al., 2017; Huang et al., 2018; Mu et al., 2021). Similar effects

have been shown for self-guided iCBT programs, where large effect size reductions in depression and anxiety are observed and sustained for 1 month (Loughnan et al., 2019b).

In addition to its clinical efficacy, iCBT also appears to be an acceptable method of treatment delivery in the perinatal period (Maguire et al., 2023). Controlled studies have shown high adherence to programs for antenatal depression and anxiety, with observed completion rates of 76% for self-guided and 82-83% for clinician-guided programs, respectively (Loughnan et al., 2019a; Kim et al., 2014; Forsell et al., 2017). Similarly, moderate to high adherence rates have been reported for postnatal depression and anxiety programs 75% completion for self-guided and 59.8%-97.1% for clinician-guided, respectively (Loughnan et al., 2019b; Lau et al., 2017).

Whilst iCBT for perinatal anxiety and depression is effective under research conditions, to our knowledge, iCBT is yet to be evaluated in naturalistic or real-world settings; that is, where most women access perinatal care. Considering iCBT research in the general population where program adherence can be reduced in routine care compared to research settings, it is essential to evaluate the effectiveness of perinatal iCBT programs when delivered in routine care. For instance, Newby and colleagues (2013) found that adherence for their anxiety and depression iCBT program dropped from 89% under RCT conditions to 41% adherence in routine primary care, while Mahoney et al. (2021b) reported 33% adherence in the general community for the self-guided format of this program. Community consumption of iCBT appears to have increased during the COVID-19 pandemic period (Li et al., 2021; Mahoney et al., 2021a; Mahoney et al., 2021c; Sharrock et al., 2021), indicating the potential scalability and utility of iCBT. However, the generalisability of iCBT outcomes from research to routine care settings requires investigation for women experiencing anxiety and depression in the perinatal period.

Accordingly, this study examined the outcomes of two perinatal iCBT programs delivered in the general community via THIS WAY UP, an Australian digital mental health service. One program targeted maternal symptoms of antenatal anxiety and depression, while the other addressed postnatal symptoms. Both programs were accessed by women either with the support of a clinician (clinician-guided) or independently (self-guided). Based on the above-mentioned research, we predicted that both programs would be associated with medium effect size reductions in depression, anxiety, and psychological distress, when delivered in both clinician-guided and self-guided formats, with adherence rates of 30-40%.

Method

Design

This study employed an observational, un-matched, pre-post treatment design. Treatment outcomes namely pre- to post-treatment reductions in symptom severity were examined for the pregnancy and postnatal programs separately.

Setting

THIS WAY UP is a not-for-profit provider of iCBT programs and an initiative of St Vincent's Hospital (Sydney, Australia) and the University of New South Wales (see thiswayup.org.au). Australian residents can complete program in a self-guided format, or guided by their own clinician (typically, the user's general practitioner [GP] or psychologist). Individuals residing outside of Australia can complete programs in the clinician-guided format only. Current analyses were restricted to Australian users.

Participants

Participants were women aged ≥ 18 years. To access the iCBT programs, participants created an account at THIS WAY UP and reported their first name, age, email address, postcode (optional) and how they found the THIS WAY UP service (optional). Participants' rural status (i.e., whether they resided in major cities, regional, rural, or remote communities) was inferred from their postcode and the Australian Statistical Geography Standards (Australian Bureau of Statistics, 2016). Participants and their clinicians were advised that the perinatal programs may not be beneficial if the participant: 1) was being treated with benzodiazepines or atypical anti-psychotics; 2) had an alcohol or substance use disorder; 3) had schizophrenia or bipolar affective disorder; or 4) was actively suicidal, because neither program had been evaluated in these populations in clinical trials (see Loughnan et al., 2019a; 2019b). However, adhering to this advice was at the discretion of the participant and their clinician, and these factors were not applied as exclusion criteria.

This study was conducted as part of the routine quality assurance activities of THIS WAY UP. By agreeing to THIS WAY UP's Terms of Use and Privacy Policy during program registration, all participants provided electronic informed consent that their pooled de-identified data could be collected, collated, analysed, and published for quality assurance and research purposes (St Vincent's Hospital Human Research Ethics Committee, 2020/ETH03027).

Pregnancy sample. 675 women registered for the Pregnancy program between 4th December 2018 and 19th November 2022. Of these 675 registrants, 529 commenced their program and completed baseline measures of clinical and demographic characteristics. We did not observe significant age differences between registrants who did not commence their program ($M(SD)= 34.09(5.67)$) and program commencers ($M(SD)= 33.57(5.30)$, $t(673)=$

1.02, $p=.31$). For the registrants who provided postcode information ($n=505$), we did not observe significant differences in rurality between non-commencers ($n= 27/102$, 26.5% regional/remote rurality) and program commencers ($n= 144/403$, 35.7% regional/remote rurality) ($\chi^2(1)= 3.12$, $p= .08$). However, program commencers were more likely to be supervised by a clinician compared to non-commencers (commencers supervised $n=330/529$, 62.4%; non-commencers supervised $n=61/146$, 41.8%; $\chi^2(1)= 29.92$, $p< .001$). The sample characteristics reported herein and the current estimates of iCBT outcomes are based on this sub-sample of program commencers, as these individuals completed baseline study measures. On average, participants were in their early 30s, most lived in major cities in Australia, accessed the clinician-guided format of the program, and were recommended the program by a health professional (see Table 1).

Postnatal sample. 1144 women registered for the Postnatal program between 5th August 2018 and 19th November 2022. Of these 1144 registrants, 973 commenced their program and completed baseline measures of clinical and demographic characteristics. We did not observe significant age differences between registrants who did not commence their program ($M(SD)= 34.87(5.63)$) and program commencers ($M(SD)= 34.30(5.08)$), $t(1142)= 1.33$, $p= .18$). For the postnatal registrants who provided their postcode ($n=909$), we observed a significant difference in rurality between non-commencers ($n= 33/123$, 26.8% regional/remote rurality) and commencers ($n= 297/786$, 37.8% regional/remote rurality), with a higher proportion of commencers residing in regional/remote locations ($\chi^2(1)= 5.52$, $p= .02$). Program commencers were also more likely to be supervised by a clinician compared to non-commencers (commencers supervised $n=625/973$, 64.2%; non-commencers supervised $n=72/171$, 42.1%; $\chi^2(1)= 29.92$, $p< .001$). Like the pregnancy sample, participants who commenced the postnatal program were in their 30s on average and most lived in major Australian cities. Most were recommended the postnatal program by a clinician and accessed

the clinician-guided format of the program (Table 1). A small subset of the postnatal sample (50/973, 5.12%) had previously engaged with the Pregnancy program prior to enrolling in the postnatal program.

Intervention

The THIS WAY UP Pregnancy and Postnatal programs both consist of three online lessons that depict the story of two fictional women who learn CBT skills to manage symptoms of low mood and anxiety during pregnancy and the postnatal period. Each lesson consists of an illustrated character storyline, a lesson summary providing in-depth information on relevant topics and CBT skills, and a range of extra resources for additional learning. The lessons include practical exercises that participants are encouraged to use in their daily life. The perinatal programs complement each other in terms of content and style, and can be completed independently or in sequence. The content of both iCBT programs includes: (1) psychoeducation about the nature and maintenance of anxiety and depression, (2) strategies to reduce physical symptoms (e.g., controlled breathing and progressive muscle relaxation), (3) cognitive restructuring to shift unhelpful thoughts, (4) activity scheduling and graded exposure to reduce maladaptive avoidance and safety behaviours, and (5) relapse prevention. Detailed program content and evidence supporting efficacy has been provided previously (Loughnan et al., 2019a; 2019b).

In each program, participants completed the three lessons sequentially. To encourage engagement with the program, there was no waiting period between Lesson one and Lesson two. However, there was a five-day wait-period between lesson two and three to allow participants time to practise the skills covered in prior lessons. Participants were sent email notifications when new lessons became available. Reminder emails were sent 5, 10 and 20

days after a lesson became available if the lesson had not already been completed.

Participants were encouraged to undertake a lesson every 1-2 weeks (completing the program over 4-6 weeks). However, consistent with other THIS WAY UP programs, participants were given 90 days access to their program, and if completed within this timeframe, they received an additional 12-months of access to program materials.

Participants completed questionnaires during their program and were emailed referral information about crisis services if they self-reported severe psychological distress (Kessler-10 total score ≥ 30 ; Kessler et al., 2002) and/or thoughts of self-harm (Edinburgh Postnatal Depression Scale Question 10 > 0 ; Cox, Holden & Sagovsky, 1987). For participants who completed the program in the guided format, participants' supervising clinician also received automated emails notifying them of their patients' high score. Supervising clinicians retained clinical responsibility for their patients for the duration of the program.

Measurement of outcomes

The *Edinburgh Postnatal Depression Scale* (EPDS; Cox, Holden & Sagovsky, 1987) is a 10-item self-report measure of perinatal-specific depression symptoms experienced over the past seven days. Total scores ≥ 13 indicate probable major depressive disorder (Cox, Holden & Sagovsky, 1987; Levis et al., 2020). Evidence of test-retest reliability ($r = .92$ over 3 days), and validity (including convergent, divergent, and criterion validity, and treatment sensitivity) has been established (Kernot et al., 2015; Bunevicius, Kusminskas, & Bunevicius, 2009). Participants completed the EPDS prior to lesson one and lesson three of the perinatal programs. The internal consistency of the EPDS at baseline was $\alpha = 0.86$ (pregnancy program) and $\alpha = 0.84$ (postnatal program).

The *Generalized Anxiety Disorder 7-item scale* (GAD-7; Spitzer et al., 2006) is a self-report measure of generalised anxiety disorder symptoms that have been experienced over the past two weeks, where total scores ≥ 10 indicate probable GAD (Spitzer et al., 2006).

Evidence supports the temporal stability ($r=.83$ over one week) and validity of the GAD-7 (e.g., convergent/divergent validity, criterion validity with respect to diagnosis via structured interview, treatment sensitivity) (Newby et al., 2013; Spitzer et al., 2006). The GAD-7 has been validated for use in perinatal samples (e.g., Simpson et al., 2014). Participants completed the GAD-7 prior to lessons one and three of both programs. The internal consistency of the GAD-7 prior to treatment was $\alpha=0.89$ (pregnancy program) and $\alpha=0.88$ (postnatal program).

The *Kessler 10-item Psychological Distress scale* (K-10; Kessler et al., 2002) is a self-reported measure of psychological distress experienced over the past two weeks. Total scores ≥ 20 indicate probable mental disorder(s) (Andrews & Slade, 2001). Evidence of test re-test reliability ($r=.80$ over 1-2 weeks), convergent and discriminant validity, and treatment sensitivity has been reported (Furukawa et al., 2003; Merson et al., 2021; Slade, Grove & Burgess, 2011; Sunderland et al., 2012). Participants completed the K-10 prior to each lesson in both perinatal programs. The internal consistency of the K-10 prior to treatment was $\alpha=0.91$ (pregnancy program) and $\alpha=0.90$ (postnatal program).

Analyses

Participant characteristics and adherence: Analyses were performed in SPSS v26.0. Consistent with Loughnan et al. (2019a; 2019b), participants who completed all 3 lessons of their perinatal program were classified as ‘completers’ and those who did not were classified as ‘non-completers’. To explore the characteristics of course completers compared to non-

completers, logistic regressions were run to examine whether baseline demographic and clinical variables (age, program format [self-guided vs. clinician-guided], GAD-7, K10 and EPDS score) predicted program completion. These regressions simultaneously examined whether missing post-treatment symptom data (i.e., K10, GAD7, and EPDS scores) was systematically related to predictor variables.

Treatment outcomes: To reduce bias in estimating treatment effects, multiple imputation was used to impute missing data at mid- and post-treatment for outcome measures using fully conditional specification as the imputation method (with 30 iterations, resulting in 10 imputed datasets). Linear mixed models analyses with random intercepts for participants were then used to estimate the effects of each program on EPDS, GAD-7 and K-10 scores across time in the imputed datasets. Models for each outcome measure were estimated separately for each program using a restricted maximum likelihood estimator, time was treated as a categorical variable, and a variance components structure was specified to model the covariance structure of the random intercept. The relative fit of the residual covariance structure of the random effects were evaluated using the Bayesian information criterion. For both program samples, specifying an identity covariance structure for the residuals of each outcome provided the closest model fit. Within-group Hedges' *g* effect sizes were calculated between pre-and post-treatment and corrected for the correlation between repeated measures. The fixed effect of the clinician assistance (clinician-guided vs. self-guided) by time interaction was added to each model. This enabled us to examine whether there was a difference in symptom improvement across treatment in the self-guided versus clinician-guided participants according to EPDS, GAD-7 and K10 scores.

Clinically significant change: Clinically significant change from pre- to post-treatment was evaluated in two ways for participants who completed post-treatment assessments. First, for women reporting above threshold symptoms at baseline, depression

and anxiety symptom severity were considered to have normalised from pre- to post-treatment if participants reported total EPDS scores <13 (Levis et al., 2020) and GAD-7 scores <10 at post-treatment (Spitzer et al., 2006), respectively. Second, based on Jacobson and Truax (1991), participants achieved reliable change if their EPDS and GAD score reduced (reliable improvement) or increased (reliable deterioration) by ≥ 5 and ≥ 6 points (respectively) from pre-to post-treatment (EPDS reliable change index [RCI] calculated with $SD_{Pregnancy}=5.64$, $SD_{Postnatal}=5.20$ and test-retest $r= .92$ from Kernot et al., 2015; GAD RCI calculated with $SD_{Pregnancy}=5.17$, $SD_{Postnatal}=5.21$, and test-retest $r= .83$ from Spitzer et al., 2006). To avoid artificially restricting the classification of RCI, RCI improvement estimates were based on treatment completers with baseline EPDS total scores ≥ 5 and GAD-7 total score ≥ 6 (i.e., where RCI improvement was possible to measure). Similarly, RCI deterioration was calculated among all completers with baseline GAD-7 ≤ 16 and EPDS ≤ 24 (i.e., where it was possible to detect reliable deterioration).

Results

Participant characteristics

Table 1 provides the demographic and clinical characteristics of participants who commenced their iCBT program. Participants were characterised by moderate rates of probable GAD (i.e., GAD-7 ≥ 10) and/or MDD (EPDS ≥ 13), with $>70\%$ of participants reporting clinically significant psychological distress (K10 ≥ 20).

Adherence and program completion

Table 2 provides a summary of lesson completion for the clinician-guided vs. self-guided participants of each program. The mean number of lessons completed was similar for

both programs (Pregnancy: $M(SD)= 1.93(0.88)$; Postnatal: $M(SD)= 2.07(0.87)$), as was the proportion of participants completing all three lessons of their program (Pregnancy: 35.0%; Postnatal: 41.6%). To characterise course completers, logistic regressions with course completion status as the dependent variable were run separately for the postnatal and pregnancy samples. In the postnatal sample, baseline EPDS scores ($OR[95\% CI]= .984[.973-.996]$, $p= .008$) and clinician guidance ($OR[95\% CI]= .920 [.849-.998]$, $p= .043$) were significant predictors of program completion (the model was statistically significant compared to the constant-only model, $\chi^2= 30.70$, $p< 0.001$). Specifically, women with lower baseline depression severity and those undertaking the self-guided format were more likely to complete the postnatal program. In the pregnancy sample, women with lower baseline EPDS scores ($OR[95\% CI]= .993[.985- 1.00]$, $p= .049$) were more likely to complete their program, but no other predictors of completion were significant (compared to the constant-only model, the model was statistically significant, $\chi^2= 7.71$, $p= .021$). When logistic regressions were re-run with completion defined as completing 2/3 lessons (rather than 3/3 lessons), baseline EPDS scores remained the only significant predictor of perinatal program completion.

Treatment outcomes

Table 3 shows the estimated marginal means and linear mixed model results for each program. On average, participants from both programs experienced significant ($ps< .001$) reductions on all outcome measures, with medium effect size reductions from pre- to post-treatment in generalised anxiety, depression, and psychological distress. The fixed effect interaction between time and program format (i.e., clinician-guided vs. self-guided) was significant for all outcomes in both perinatal programs (with the exception of the EPDS in the pregnancy course), indicating that compared to the self-guided participants, the clinician-guided participants typically reported slightly greater improvement from pre- to post-treatment (Pregnancy: Mean GAD-7 pre-post treatment difference clinician-guided= 3.08 vs.

self-guided= 2.65, GAD-7 time*clinician assistance $F(2, 527.00)=4.47, p= .01$; Mean EPDS pre-post treatment difference clinician-guided= 2.92 vs. self-guided= 2.94, EPDS time*clinician assistance $F(2, 527.00)=1.10, p= .35$; Mean K10 pre-post treatment difference clinician-guided=4.81 vs. self-guided= 4.00, K10 time*clinician assistance $F(3, 790.25)=4.31, p= .004$. Postnatal Mean GAD-7 pre-post treatment difference clinician-guided= 3.64 vs. self-guided= 3.06, GAD-7 time*clinician assistance $F(2, 971.00)=4.50, p= .01$; Mean EPDS pre-post treatment difference clinician-guided=3.41 vs. self-guided=2.86, EPDS time*clinician assistance $F(2, 971.00)=3.20, p= .04$; Mean K10 pre-post treatment difference clinician-guided= 5.63 vs. self-guided= 4.65, K10 time*clinician assistance $F(3, 1456.25)=7.02, p< .001$).

Clinically significant change

Symptom normalisation. The proportion of participants whose anxiety (GAD < 10) and depression (EPDS \leq 12) symptom severity normalised was examined in the subsamples of women who (1) completed post-treatment questionnaires and (2) reported suprathreshold symptom severity at baseline. In the pregnancy program, 60.0% (45/75) of women had normalised GAD-7 scores, while 57.1% (52/91) reported normalised EPDS scores at post-treatment. In the postnatal program, 58.7% (125/213) of women reported normalised GAD-7 scores, while 46.8% (116/248) women reported normalised EPDS scores at post-treatment.

Reliable change indices. In the pregnancy program, 30.7% (n=43/140) and 29.4% (n=50/170) experienced reliable improvement in their anxiety and depression symptom severity, respectively. In the postnatal program, 33.8% (n=112/331) and 37.1% (n=144/388) experienced reliable improvement in their anxiety and depression symptom, respectively. In the pregnancy program, 4.7% (n=8/170) and 5.5% (n=10/183) experienced reliable deterioration in their anxiety and depression symptom severity, respectively. In the postnatal

program, 3.2% (n=11/347) and 5.3% (n=21/397) experienced reliable deterioration in their anxiety and depression symptom severity, respectively.

Discussion

This study explored the outcomes of two iCBT programs for perinatal anxiety and depression when delivered in the community. First, we found that women who accessed the Pregnancy and Postnatal iCBT program in routine care were experiencing anxiety and depression symptoms across the full spectrum of severity. While most participants reported clinically elevated levels of anxiety or depression prior to starting their program, around 30-40% of the sample reported subthreshold symptom severity. This is an important difference from prior perinatal iCBT research cohorts where women with subthreshold symptom severity have typically been excluded from clinical trials (e.g., O'Mahen et al., 2014; Milgrom et al., 2016; Loughnan et al., 2019a; 2019b). Although this study did not assess the reasons for utilising iCBT, it is conceivable that some women undertook the programs prophylactically, to prevent exacerbation of anxiety or depression. While it is possible that the measures used underestimate the level of distress and symptom severity experienced by women perinatally, subclinical symptoms of mental health disorders nevertheless impact mother and infant wellbeing (Fallon et al., 2019; Matthies et al., 2017). Given the high prevalence of anxiety and depression symptoms in perinatal populations (Dennis et al., 2017) and the potential scalability of iCBT (particularly self-guided programs), further research is needed to examine the effectiveness and utility of iCBT in preventing the onset and/or reoccurrence of anxiety and depressive disorders for women in the perinatal period.

As predicted, we found that the pregnancy and postnatal iCBT programs were associated with medium pre- to post-treatment effect size reductions in symptoms of generalised anxiety, depression, and psychological distress. Consistent with prior research,

clinician-guided participants reported slightly greater improvements across treatment compared to self-guided participants. For women who completed their program, around half reported anxiety and/or depression symptom normalisation at post-treatment. Reliable and clinically significant improvement in anxiety and/or depression symptom severity was observed in approximately one third of treatment completers; whereas reliable deterioration was observed in a minority of completers (3-5% and 5-6% of completers for anxiety and depression, respectively).

In comparison to the present findings, iCBT administered under research conditions typically results in large effect size reductions in symptom severity and higher rates of reliable symptom improvement of ~60% (O'Mahen et al., 2013; Kim et al., 2014; Forsell et al., 2017; Loughnan et al., 2019b). While our findings require replication, it is possible that perinatal iCBT programs may be less effective in routine care settings or that sample variations across research and routine care settings may influence treatment outcomes. Indeed, the markedly lower symptom severity of the current sample compared to RCT samples likely contributed to the more modest symptom improvements observed in this study. Additional research is needed to clarify the impact of patient-related and contextual factors on therapy effectiveness, and to explore what factors may moderate or mediate treatment outcomes in different settings (e.g., patient motivation and readiness to engage with treatment). Approximately half the women in this study were recommended their perinatal program by a health professional. It is important for future research to examine the clinical reasoning and decision-making processes that clinicians employ when recommending or not recommending perinatal iCBT and how these practises may impact program uptake and outcomes. Future research should also evaluate the utility of perinatal iCBT programs within blended and stepped models of care; where greater clinical support can be provided to women with severe symptoms, functional impairments, psychosocial vulnerabilities, or limited

responsiveness to treatment. Nevertheless, our findings highlight the importance of examining therapy outcomes in ‘real world’ settings as distinct from clinical trials. They also suggest that iCBT programs may be beneficial for a portion of women in the community who experience perinatal anxiety and/or depression, of varying symptom severity.

Approximately 35% and 42% of women completed all lessons in their pregnancy and postnatal program, respectively. Rates of program completion were lower in this study compared to previous RCTs, though they were consistent with completion rates observed for other clinician-guided and self-guided iCBT programs disseminated in routine care, ranging from 14-47% (Hobbs et al., 2017; Hobbs et al., 2018; Morgan et al., 2017; Grierson et al., 2020). Women who reported lower baseline depression symptom severity were more likely to complete their iCBT program. It is possible that symptoms associated with depression (e.g., anhedonia, amotivation, fatigue) may have influenced iCBT lesson completion. Given the limited mental health service provision for women with subclinical symptom severity, this finding may offer some support for iCBT as a viable care pathway for those with lower-level symptom severity, particularly depression symptoms. However, perinatal program completion was not consistently associated with baseline levels of anxiety or distress, age, rural status, or the presence of a guiding clinician. The lack of association between the presence of a clinician and greater program adherence was surprising because this has been observed in other studies (e.g., Newby et al., 2013; Mahoney et al., 2021b). As women were not randomly assigned to self- versus clinician-guided programs in this study, it is possible that both groups had similar expectancy of benefit. Further, we did not collect information on the nature of the clinician guidance provided to the women in this study, and as such, the amount of support that women received may have been minimal. Further studies are needed to assess the amount and type of clinician support provided to women undertaking iCBT, and

to identify what support(s) can optimise treatment adherence whilst remaining feasible in routine care settings.

Our findings should be considered in light of a number of limitations. All data were self-reported, and we did not conduct structured diagnostic assessments. Detailed information was not collected (e.g., to characterise the treatment history, health status, gestational age/months postpartum, employment status, or relationship status of participants). As such, it is unclear how our findings would generalise to populations with specific sociodemographic characteristics. Our sample was limited to adult women living in Australia. THIS WAY UP is internationally available and future research needs to investigate the generalisability of current findings to international populations and women aged under 18 years. Research to explore the cultural relevance of the current programs and to identify program adaptations that may enhance their suitability for more diverse cohorts is also warranted.

Participant attrition and missing data are limitations of study design which may have led to biased estimates of treatment effect, though imputation methods were used to minimise bias. Furthermore, we could not examine the treatment outcomes of the portion of women who registered but did not commence their program (~20%), and as such, our analyses are not truly intention-to-treat. Interestingly, women residing in regional/remote areas and those supervised by a clinician were more likely to start their program. Future research should replicate these findings, as well as further characterise which women are less likely to start or complete perinatal iCBT programs and the reasons for this. While current indices of program adherence (i.e, counts of registration, commencements and lesson completion) provide some estimate of user engagement, they do not provide a comprehensive reflection of how women utilise and interact with iCBT, which may need to be explored.

It is possible that current rates of adherence and treatment response may have been influenced by factors not directly measured or considered in this study. Existing literature suggests that social factors can impact adherence to perinatal iCBT programs, whereby women with less perceived social support, those undertaking work or study, and those who report greater work and social impairment have poorer adherence (O'Mahen et al., 2014). We also did not collect follow-up data which precludes conclusions regarding the durability of treatment outcomes. Lastly, to evaluate the perinatal iCBT programs in a real-world setting, the study design did not include a control group. The observed reductions in symptom severity from pre- to post-treatment may have been related to other factors beyond the programs, although the pattern of symptom reduction mirrors that seen in RCTs of the same programs (Loughnan et al., 2019a; 2019b).

Conclusions

In this study, self-guided and clinician-guided iCBT for perinatal anxiety and depression was associated with significant reductions in symptom severity and psychological distress when delivered in routine care. While further studies are needed to evaluate the effectiveness of iCBT in routine care settings, iCBT represents a scalable treatment option that can be integrated into existing healthcare systems to help increase the accessibility and availability of evidence-based mental health care for women during the perinatal period.

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Table 1. Participant demographic and clinical characteristics

	Pregnancy program		Postnatal program	
	<i>N</i> = 529		<i>N</i> = 973	
	M (<i>SD</i>)	Range	M (<i>SD</i>)	Range
Age	33.57 (5.30)	18 – 48	34.30 (5.08)	19 – 50
GAD-7				
Lesson 1	9.76 (5.17)	0 – 21	10.73 (5.21)	0 – 21
Lesson 3 ^a	6.50 (4.94)	0 – 21	7.03 (4.86)	0 – 21
EPDS				
Lesson 1	12.96 (5.64)	0 – 29	14.20 (5.20)	0 – 28
Lesson 3 ^a	9.57 (5.52)	0 – 24	10.60 (5.37)	0 – 26
K-10				
Lesson 1	25.21 (7.84)	10 – 50	26.22 (7.51)	10 – 48
Lesson 3 ^a	20.21 (7.05)	10 – 47	20.54 (7.10)	10 – 50
	<i>N</i>	%	<i>n</i>	%
Rural status ^b				
Major city	259	64.3	489	62.2
Regional or remote	144	27.2	297	37.8
Program format				
Self-guided	199	37.6	348	35.8
Clinician-guided	330	62.4	625	64.2
Clinician profession ^c				
GP	141	42.7	379	60.6
Allied health	128	38.8	180	28.8
Other	61	18.5	66	10.6
How found THIS WAY UP ^d				
Recommended by a health professional	365	78.8	712	80.4
Word of mouth	27	5.8	68	7.7
Internet search	33	7.1	59	6.7
Link from another website	20	4.3	21	2.4
From media or advertisement	5	1.1	8	0.9
Private health fund	11	2.4	15	1.7

Don't know	2	0.4	2	0.2
Clinical characteristics				
GAD-7 > 10 and EPDS < 13	48	9.1	91	9.4
EPDS ≥ 13 and GAD < 10	92	17.4	168	17.3
GAD-7 > 10 and EPDS ≥ 13	195	36.9	447	45.9
GAD-7 < 10 and EPDS < 13	194	36.7	267	27.4
K10 > 20	386	73.0	780	80.2

Note. GAD-7 = Generalized Anxiety Disorder 7-item scale; EPDS = Edinburgh Postnatal Depression Scale; K-10 = Kessler 10-item Psychological Distress scale.

^a sample size for GAD-7, EPDS and K-10 lesson 3 completers ($n_{\text{Pregnancy}} = 185$, $n_{\text{Postnatal}} = 405$). ^b sample size for rural status based on optional provision of postcodes ($n_{\text{Pregnancy}} = 403$, $n_{\text{Postnatal}} = 786$).

^c profession of clinicians supervising participants enrolled into the clinician-guided format.

^d sample size based on optional provision of response ($n_{\text{Pregnancy}} = 463$, $n_{\text{Postnatal}} = 886$).

Table 2. Lesson-by-lesson completion rates for clinician-guided and self-guided participants commencing the perinatal iCBT programs

Lessons completed	Pregnancy (<i>N</i> = 529)			Postnatal (<i>N</i> = 973)		
	Self-guided	Clinician-guided	Total	Self-guided	Clinician-guided	Total
	<i>n</i> (%)	<i>n</i> (%)	<i>N</i> (%)	<i>n</i> (%)	<i>n</i> (%)	<i>N</i> (%)
1+	199 (100)	330 (100)	529 (100)	348 (100)	625 (100)	973 (100)
2+	117 (58.8)	190 (57.6)	307 (58.0)	221 (63.5)	411 (65.8)	632 (65.0)
3	73 (36.7)	112 (34.0)	185 (35.0)	159 (45.7)	246 (39.4)	405 (41.6)
	<i>M</i> (<i>SD</i>)	<i>M</i> (<i>SD</i>)	<i>M</i> (<i>SD</i>)	<i>M</i> (<i>SD</i>)	<i>M</i> (<i>SD</i>)	<i>M</i> (<i>SD</i>)
Mean lessons completed	1.95 (0.88)	1.92 (0.87)	1.93 (0.88)	2.09 (0.90)	2.05 (0.86)	2.07 (0.87)

Table 3. Estimated marginal means, linear mixed models results, and effect sizes for the THIS WAY UP perinatal programs

	Pre-treatment	Mid-treatment	Post-treatment	<i>df</i> for the time	<i>F</i>	<i>r</i>	Hedge's <i>g</i> (95% CI)
	EMM (<i>SD</i>)	EMM (<i>SD</i>)	EMM (<i>SD</i>)	effect			
Pregnancy							
GAD-7	9.62 (4.49)	-	6.76 (5.24)	(1, 527)	160.15*	0.31	0.63 (0.50; 0.75)
EPDS	12.90 (4.97)	-	9.97 (5.24)	(1, 527)	124.95*	0.29	0.58 (0.46; 0.70)
K-10	24.98 (6.53)	22.45 (6.65)	20.57 (6.81)	(2, 1054)	103.59*	0.31	0.52 (0.40; 0.64)
Postnatal							
GAD-7	10.60 (4.65)	-	7.25 (4.96)	(1, 971)	356.20*	0.31	0.71 (0.62; 0.80)
EPDS	14.09 (4.80)	-	10.95 (5.37)	(1, 971)	306.14*	0.34	0.64 (0.55; 0.74)
K-10	26.00 (6.64)	23.58 (6.77)	20.86 (6.80)	(2, 1942)	274.11*	0.37	0.60 (0.51; 0.69)

Note. GAD-7= Generalized Anxiety Disorder 7-item scale; EPDS= Edinburgh Postnatal Depression Scale; K-10= Kessler 10-item Psychological Distress scale; *F*= average value across imputed datasets; *r*= Pearson correlation between Lesson 1 and Lesson 3 scores for calculation of within-group effect sizes; EMM= estimated marginal mean; *SD*= standard deviation; **p* = < .001