**PROTOCOL TITLE**

**The Efficacy and Acceptability of a Remotely Delivered Transdiagnostic CBT Treatment for Perinatal Anxiety: A Case Series**

HREC Ref: HE20-218

Version Number: 2.2

Date of Protocol: 30/07/2021

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**STUDENT INVESTIGATOR**

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**Ethics Statement:**

The study will be conducted in accordance with the National Statement on Ethical Conduct in Human Research (2007), the CPMP/ICH Note for Guidance on Good Clinical Practice and consistent with the principles that have their origin in the Declaration of Helsinki. Compliance with these standards provides assurance that the rights, safety and well-being of trial participants are respected.

**SUMMARY**

|  |  |
| --- | --- |
| **Protocol Title** | The Efficacy and Acceptability of a Remotely Delivered Transdiagnostic CBT Treatment for Perinatal Anxiety: A Case Series |
| **Protocol Version** | 1.0 |
| **Objectives** | The purpose of this project is to assess the efficacy and acceptability of a remotely delivered transdiagnostic cognitive behavioural treatment for perinatal anxiety in an Australian sample. All participants in this research trial will receive treatment. |
| **Research Design** | This study uses a case series design where all accepted participants will receive treatment. Participants will be asked to complete standardised measures at screening, pre-treatment (T1), post-treatment (T2), and 3-month (T3) follow up. Participants will also complete brief standardised measures of anxiety and depression symptoms weekly throughout treatment in order to enable the researchers to monitor participants’ symptoms and safety throughout treatment. |
| **Sample Size** | N = 6 |
| **Selection Criteria** | Women will be eligible to participate in the study if they are: (1) within 10 months post birth; (2) 18 years of age or over; (3) competent in written and spoken English; (4) meet DSM-5 diagnostic criteria for an anxiety or related disorder as primary (assessed using the DIAMOND); (5) have an Overall Anxiety Severity and Impairment Scale (OASIS) score of 8 or over; and (6) have an Edinburgh Postnatal Depression Scale (EPDS) of below 3 on item 10.  Women will be excluded if they are: (1) not on a stable dose of pharmacological or anxiolytic medication; (2) report suicidal ideation and intent (as identified through risk related questions); (3) recent (i.e., past 3 months) suicide attempts or deliberate self-harm; (4) report past or present psychosis (assessed using the DIAMOND); (5) not endorse one of the anxiety and related disorders on the DIAMOND screener; and (6) are at high risk of suicide as determined by a score of 3 on item 10 of the Edinburgh Postnatal Depression Scale (EPDS) or during the telephone interview. |
| **Study Procedure** | Interested and suitable women experiencing perinatal anxiety will be recruited into the research study via online social media platforms (i.e., pregnancy-related Facebook groups) and through noticeboard advertisements at General Practitioner (GPs), midwife and community nurse clinics. Following the completion of the standardised questionnaire measures at screening, consenting and eligible participants will be contacted via phone by the student researcher to arrange a suitable time to complete a diagnostic interview to determine final eligibility. After the completion of this assessment, eligible participants will complete a further standardised questionnaire (T1) and will be scheduled for five weekly sessions with the student researcher, who is also a registered psychologist. The treatment will then be conducted by the student researcher during these sessions and will provide information regarding perinatal anxiety and skills for treating and managing perinatal anxiety. |
| **Analytic Plan** | Data will be analysed using SPSS. The OASIS, EPDS, PHQ-9, and CSQ will be scored based on the method described in each individual questionnaires protocol. Data will be collected at pre-intervention (baseline, T1), post-intervention (T2), and 3-month follow-up (T3) and will be reported and examined using visual inspection of graphs. Clinically significant change will be calculated. Descriptive data (95% confidence intervals; means and standard deviations) will be used to describe the pooled participant outcomes at pre-treatment, post-treatment, and three month follow up). |
| **Study Duration** | 1 year |

# BACKGROUND

## Disease Background

Perinatal anxiety, which encompasses all anxiety symptoms experienced during the perinatal period, affects between 16% and 39% of women (Fairbrother, Janssen, Antony, Tucker, & Young, 2016; Rubertsson, Hellstrom, Cross, & Sydsjo, 2014; Signal, et al., 2017; Giardinelli, et al., 2012), and may be a continuation of a pre-existing condition, the reoccurrence of a previous episode, or a newly developed disorder. Perinatal anxiety is characterized by excessive fear and anxiety, and behavioural related disturbances such as disrupted sleep, irritability and poor concentration experienced during the perinatal period (Misri, Abizadeh, Sanders, & Swift, 2015).

## Rationale for the Present Study

Cognitive-behavioural therapy (CBT) is considered the psychological treatment of choice for anxiety disorders in the general population, however, few studies have examined the efficacy of CBT targeting perinatal anxiety (Green, Haber, Frey, & McCabe, 2015; Lemon, Vanderkruik, & Dimidjian, 2015). Given that the perinatal period is associated with significantly increased risks of onset or relapse of mental health conditions, higher than at any other time of a women’s life (Beyond Blue, 2011), due to hormonal changes, psychosocial risk factors, and life stressors (Austin & Kingston, 2016; Beyond Blue, 2011), it is imperative that research exploring the efficacy of CBT for perinatal anxiety is conducted. CBT can be disseminated more efficiently through transdiagnostic approaches. In recent years, transdiagnostic CBT approaches for anxiety disorders have been gaining increased attention due to growing literature suggesting more similarities among anxiety disorders than differences (Norton & Barrera, 2012). Additionally, rates of comorbidity of Axis 1 disorders are extremely high, with research indicating comorbidity amongst anxiety and depressive disorders is approximately 55% (Brown, Campbell, Lehman, Grisham, & Mancill, 2001). Transdiagnostic approaches are designed to treat underlying emotional processes across disorders and can treat multiple anxiety disorders concurrently.

There is a growing body of research demonstrating the efficacy of transdiagnostic treatments in the treatment of anxiety disorders in the general population (Barlow et al., 2017; Dear et al., 2016; Titov et al., 2015). For example, Dear et al. (2015) explored the efficacy of diagnosis specific (DS) and transdiagnostic CBT (TCBT). Participants with generalised anxiety disorder (GAD) were randomly allocated to either an internet-delivered TCBT or DS-CBT group. The study found that participants’ symptoms of GAD significantly decreased across both treatment groups and found large within group effect sizes from pre-treatment to post-treatment in the DS-CBT group (Cohen’s *d=*1.52; 95% CI = 1.25-1.79) and in the TCBT group (Cohen’s *d=*1.51; 95% CI = 1.24-1.76), indicating no significant differences between DS-CBT and TCBT. In both conditions, large reductions in symptoms for comorbid diagnoses, including major depressive disorder (Cohen’s *d* ≥1.48; average reduction ≥50%), social anxiety disorder (Cohen’s *d* ≥0.80; average reduction ≥29%), and panic disorder (Cohen’s *d* ≥0.55; average reduction ≥33%) were found.

Whilst there is evidence to suggest that effective psychological treatments for anxiety exist, research has highlighted many barriers to accessing treatment in various populations. For example, Marques et al. (2010) explored barriers to treatment in a sample of individuals with obsessive-compulsive disorder and found the primary barriers to accessing treatment were the cost of treatment, lack of private health insurance, shame, and doubt that the treatment would be effective (Marques, et al., 2010). Similarly, Spence et al. (2011) explored barriers to accessing treatment in a sample of individuals with posttraumatic stress disorder and found that the primary barriers to accessing treatment included cost, lack of treatment response from previous therapy, and not perceiving their difficulties as severe enough to warrant therapy. For women who recently had a baby there are likely to be additional barriers to accessing care. For example, accessibility of treatment, cost, stigma, and flexible treatment options.

Remotely delivered treatment is one strategy for improving access to evidence-based treatment for individuals with perinatal anxiety. Remotely delivered treatments for anxiety disorders in the general population have been extensively studied in recent years and the efficacy of these interventions are overwhelmingly supported (Stubbings, Rees, Roberts, & Kane, 2013). Furthermore, there is evidence to suggest that for many of the anxiety disorders, remotely delivered treatments are just as effective as face to face treatments (Andersson et al., 2014; Stubbings et al., 2013). For example, Stubbings et al. (2013) explored the efficacy of individual CBT compared to videoconference-based CBT for the treatment of mood and anxiety disorders. The findings of this study indicated that there was no significant differences between face to face CBT and videoconfernce-based CBT in symptom reduction across mood and anxiety disorders (Stubbings et al., 2013). Similarly, Carpenter, Pincus, Furr, and Comer (2018) explored the acceptability and preliminary efficacy of family-based CBT for child anxiety delivered via videoconferencing. The study found that the intervention was acceptable to families and showed preliminary efficacy, and treatment gains were largely maintained at 3-month follow-up (Carpenter et al., 2018). Whilst the results of the above studies are preliminary, high intensity remotely delivered transdiagnostic treatment options have the potential to overcome many of the barriers to treatment that women may experience. Therefore, the investigation of high intensity treatment options for women experiencing perinatal anxiety deserve further attention.

The aim of the current project is to examine the *efficacy* and *acceptability* of remotely delivered transdiagnostic CBT for perinatal anxiety using a case series design;

# RESEARCH HYPOTHESES

Based on previous research, the primary hypotheses are that:

1. Participants self-reported symptoms of perinatal anxiety will reduce from pre-treatment (T1) to post-treatment (T2);
2. Participants self-reported symptoms of perinatal anxiety will reduce and participants will no longer meet diagnostic criteria for anxiety (as assessed by the DIAMOND) from pre-treatment (T1) to 3 month follow up (T3);
3. Remotely delivered transdiagnostic CBT will be perceived as an acceptable form of therapy, with high levels of treatment satisfaction reported.

# RESEARCH OBJECTIVES

## Primary Objectives

The primary aim of this research project is to examine the efficacy and acceptability of remotely delivered transdiagnostic CBT in the treatment of perinatal anxiety.

# RESEARCH DESIGN

## Research Design

A case series design will be employed.

## Research Groups

This is a case series. All participants (*N* = 6) will receive 5 x 50-mins weekly sessions of remotely delivered TCBT for the treatment of perinatal anxiety.

## Expected Participant Numbers

6 participants will be treated.

## Duration of the Research

This research project will run for 1 year.

## Research Endpoints

The primary endpoint for this research is the post-treatment time point (T2); that is, 5 weeks after participants start treatment. The secondary endpoint is the 3-month follow up time point (T3). The Diagnostic Interview for Anxiety, Mood, and OCD and Related Neuropsychiatric Disorders (DIAMOND), The Overall Anxiety Severity and Impairment Scale (OASIS) and The Edinburgh Postnatal Depression Scale (EPDS) will measure symptoms reduction at each endpoint.

## Name and Number of Centres

This research will be conducted remotely and through the following the following two centres:

1. The University of New England, Armidale, NSW 2351, Australia.
2. The University of Technology Sydney, Ultimo, NSW, Australia

Furthermore, this study will be registered with the Australian New Zealand Clinical Trials Registry (ANZCTR).

## Treatment

Treatment will consist of 5 x 50-minute weekly sessions, which will be conducted via the secure online platform, Zoom. Sessions will be recorded for quality and supervision purposes. The intervention will be delivered via the student researcher, Peta Maguire, who is a registered psychologist. The session outline for the treatment is below:

|  |  |
| --- | --- |
| **Session** | **Content** |
| 1 | *Introduction to the CBT Model*   * *Psychoeducation* * *Developing a CBT model* * *Homework: Symptom Monitoring Diary* |
| 2 | *Cognitive Restructuring*   * *Homework check-in* * *Introduction to automatic thoughts* * *Identifying and challenging unhelpful automatic thoughts* * *Homework: Unhelpful Thinking Worksheet* |
| 3 | *Arousal Reduction*   * *Homework check-in* * *Controlling physical symptoms using de-arousal strategies* * *Homework: Progressive Muscle Relaxation* |
| 4 | *Behaviour Modification*   * *Homework check-in* * *Identifying maladaptive behaviours* * *Education about graded exposure* * *Constructing an exposure stepladder* * *Homework: Graded exposure task* |
| 5 | *Challenges in Parenthood and Relapse Prevention*   * *Homework check in* * *Developing a relapse prevention plan* * *Extra resources* |

# RESEARCH PARTICIPANTS

## Inclusion Criteria

(a) Currently in the first 10 months postpartum (participants must be within 10 months postpartum to ensure treatment is delivered during the perinatal period);

(b) Proficient in English;

(c) 18 years of age or above;

(d) Have regular access to the internet;

(e) Meet DSM-5 diagnostic criteria for an anxiety or related disorder as primary (as determined by the DIAMOND);

(f) No history of psychotic illness or bipolar disorder;

(g) A score of at least 8 on the Overall Anxiety Severity and Impairment Scale (OASIS)

(h) If using medication, the medication is a stable dose

(i) Does not report suicidal ideation and intent (as identified through risk related questions during interview)

(j) Does not report recent (i.e., past 3 months) suicide attempts or deliberate self-harm

(k) Does not report past or present psychosis (assessed using the DIAMOND)

(l) A score of below 3 on item 10 of the Edinburgh Postnatal Depression Scale (EPDS)

## Exclusion Criteria

1. Currently not in the first 10 months postpartum
2. Not proficient in English
3. Under 18years of age
4. Do not have regular access to the internet
5. Does not endorse one of the anxiety and related disorders on the DIAMOND screener
6. History of a psychotic illness or bipolar disorder
7. Does not have a score of at least 8 on the Overall Anxiety Severity and Impairment Scale (OASIS)
8. Not on a stable dose of pharmacological medication
9. Report suicidal ideation and intent (as identified through risk related questions during interview).
10. Recent (i.e., past 3 months) suicide attempts or deliberate self-harm
11. Report past or present psychosis (assessed using the DIAMOND)
12. Are at high risk of suicide as determined by a score of 3 on item 10 of the Edinburgh Postnatal Depression Scale (EPDS).

# STUDY PROCEDURES

## Study Flow Chart

|  |  |
| --- | --- |
|  | **Treatment Group**  **(N = 6)** |
| **SCREENING ASSESSMENT** | **Screenning Assessment**  (Complete screening questionnaires and administer the DIAMOND via phone interview) |
| **PRE- TREATMENT (T1)** | **Pre-treament Assessment**  (Complete pre-treatment self-report measures) |
| **TREATMENT** | **Receive Treatment**  (Five x 50-mins weekly sessions of TCBT to be delivered remotely by the student researcher) |
| **POST-TREATMENT**  **(T2)** | **Post-treatment Asessment**  **Endpoint**  (administer post-treatment self-report measures and DIAMOND) |
| **FOLLOW UP**  **(T3)** | **3-month Follow up Assessment**  **Endpoint**  (administer 3-month self-report follow up measures and DIAMOND) |

## Investigation Plan

At the screening stage, interested people will read the Participant Information and Consent Form online and after consenting will complete brief questionnaires (e.g., 30 minutes) that measure symptoms of anxiety and depression, as well as collecting demographic and contact details. Applicants who do not meet criteria will not be eligible to participate but will be referred back to their primary care physician. Applicants who do meet the criteria will be invited to participate in the next screening assessment.

Participants who meet criteria to participate will then take part in a telephone assessment. During this assessment participants will be assessed on their risk and a diagnostic interview will be conducted based on participants responses to the screener assessments. The telephone assessment will vary in length of time depending on participants symptoms and screener results (it is estimated that the telephone assessment will be 30 - 90minutes). Participants who meet criteria to participate will then complete T1 self-report measures.

Participants who meet all criteria will then commence treatment. Participants that do not meet the study criteria will be recommended to discuss their mental health with their GP and will be referred to alternative services as required. The treatment will consist of:

1. 5 x 50-minute sessions online videoconferencing sessions provided over 5 weeks by the student researcher (a registered psychologist), see Appendix C for an outline of the intervention.
2. Between session homework which will be emailed to participants at the end of the session, see Appendix C for homework tasks.

Participants will be given session times at the beginning of treatment and will receive email “invites” from the researcher with the session time and a link to access the online platform that sessions will be conducted via.

Participants are asked to complete online self-report questionnaires prior to starting treatment (i.e., pre-treatment), after completing the treatment (i.e., post-treatment), and 3 months post-treatment (i.e., follow up). Several brief questionnaires (i.e., taking 2 to 5 minutes) are administered each week of treatment to allow the researcher to monitor participants’ symptoms. These questionnaires will be on Qualtrics and a link to the questionnaires will be sent to the participant via email prior to their session each week for completion. The questionnaires administered in this study are all valid and reliable clinical and research measures.

## Study Procedure Risks

It is expected that participants will experience clinically significant improvements in perinatal anxiety symptoms from pre-treatment to post-treatment, and from pre-treatment to follow up. Furthermore, it is hoped that the techniques used in treatment will be applied by participants following the completion of treatment, resulting in the long term management of their symptoms. Treatment includes homework activities that will be emailed to participants at the end of each session that encourage participants to practice techniques and strategies discussed in treatment to manage their perinatal anxiety symptoms. Importantly, participating in psychological treatments may increase symptoms in the short term, however this increase is only temporary and alleviates as treatment progresses.

Our priority is to support participants in managing their anxiety symptoms and to maximise their emotional wellbeing. In the unlikely event that a participant becomes distressed, the student researcher is a registered psychologist who will be able to assess the situation and refer the person accordingly.

Risk management will occur at all stages of this project including:

*At Pre-Treatment:*

Applicants with significant depressive symptoms, current suicidal ideation with intent, or recent suicide attempts or deliberate self-harm will not be eligible to participate and will be encouraged to contact their primary care physician to access local support services. The participant information sheet will also provide contact details for support services to all applicants and participants. Participants will be provided with the researchers contact details and will be offered the opportunity to discuss any distress they’re feeling during each session. Participants will also continue their usual post-pregnancy care with the relevant health practitioners, and the importance of contacting their own General Practitioner and emergency services in a mental health emergency will be emphasised.

*During the Trial:*

The final page on the weekly questionnaires will contain contact details for emergency services and written details about staying safe in mental health emergencies. The Overall Anxiety Severity and Impairment Scale and Edinburgh Postnatal Depression Scale will also be administered each week to monitor participants’ emotional state throughout the treatment. Participants’ questionnaire responses will be checked following the completion of the questionnaire throughout treatment.

Symptoms of psychological distress will be discussed in session as part of treatment. Participants will be encouraged to discuss their symptoms with their General Practitioner, or to seek local mental health services if required. Significant thoughts of harming oneself (defined as a score of a or b on Question 10 of the EPDS) will prompt discussion between the researcher and the participant during the session regarding risk management with the recommendation of the participant contacting their primary physician or seeking support from their local community mental health service. Participants will also be offered mental health emergency contact numbers.

*During Completion of Questionnaires:*

Questionnaires assessing perinatal anxiety symptoms and depression will be completed at pre-treatment and post-treatment. Severe symptoms (i.e., a EPDS total score >13) and significant thoughts of suicide (i.e., a EPDS item 10 score >2) will be discussed with the participant in session and they will be encouraged to speak with their GP and their local community mental health service. Participants will also be given feedback regarding their symptoms during the final session and participants will be encouraged to follow-up with their local service providers if interested in further treatment. Post-treatment questionnaires will be sent to the participant for completion the week after treatment ends (week 6). A time will also be arranged the week following the completion of the treatment for the researcher to contact the participant to complete the DIAMOND. On completion of the post questionnaires participants will be emailed a $25 Coles/Myer Gift card for their participation. Like-wise, follow-up questionnaires will be sent to the participant 3-months post completion and a time will be arranged to complete a diagnostic interview with the researcher via phone. On completion of the follow up questionnaires participants will be emailed a $25 Coles/Myer Gift card for their participation.

The student researcher, whom is a registered psychologist, will monitor participants’ questionnaires throughout treatment and will deliver the treatment. All communications with participants will be documented in a re-identifiable clinical file, which will be retained as part of the study documents.

## Participant Recruitment and Screening

Recruitment involves the following steps:

1. The study will be described on online social media platforms (i.e., pregnancy-related Facebook groups) and hardcopy advertisements on community noticeboards. Interested people will read the study description and will be required to either click the link or look up the link that will open a Qualtrics page that contains the Participant Information and Consent information. Interested people will then elect to consent and proceed to the demographic questionnaire and the screening questionnaires, which will measure their symptoms and assess for the inclusion criteria.
2. Non-eligible persons will be automatically taken to the end of the questionnaire and will be strongly encouraged to speak to their primary care physician to identify local treatment options available.
3. Successful participants will be contacted by the researcher via phone to arrange a suitable time to complete further screening (DIAMOND, risk assessment). After the completion of this telephone assessment, successful participants will be scheduled five weekly sessions with the student researcher. Participants will then be required to a pre-treatment questionnaire. The treatment will then be conducted by the researcher during these sessions and will provide information regarding perinatal anxiety and skills for treating and managing perinatal anxiety.

**NOTE:** No active identification of potential participants will occur and the researchers will not directly or actively approach participants about the research; instead interested persons can read about the study via the Qualtrics link.

## Participant Enrolment

Eligible participants will be contacted via phone by the researcher regarding a suitable time for treatment to be conducted. Participants will then receive an email with detailed instructions for using the Zoom Software Platform which sessions will be conducted over. Participants will also receive weekly reminder emails prior to their session containing a link to open the Zoom platform for their session. Participants will also have the researchers contact details, which will be sent in session reminder emails, should they need to contact in the event of technical difficulties.

## Information and Consent

Interested individuals will read about this research on social media platforms or hardcopy advertisements on communitynoticeboards. Interested people are invited to look at the link attached to the research information advertisement. Interested people can then proceed to read the detailed Participant Information and Consent Form. Those that remain interested are required to consent to the research via the option on screen, which will then proceed to questionnaires relating to demographic information and screening questionnaires (i.e., 20 minutes). Eligible participants will then be contacted by phone to arrange a suitable time to complete a telephone interview with the researcher. Participants are invited throughout this process to contact the researcher with any questions or concerns and participants are informed that they can withdraw at any point without consequence. Completion of the screening questionnaires and ongoing participation in treatment are taken as ongoing consent.

**NOTE:** The Participant and Information Statement is attached as Appendix B.

## Randomisation Procedure

This is a case series with no participant randomisation.

## Participant Withdrawal Procedure

If a participant wishes to withdraw from the study once it has started, the participant may do so at any time without having to give reason. Participants that withdraw will be discussed with the broader research team, and the participant will be provided the option to discuss their symptoms and alternative treatment options with the researcher and encouraged to discuss accessing additional services with their primary care professional.

# OUTCOMES AND DATA COLLECTION

All self-report data will be collected online via Qualtrics and the treatment will be conducted via the secure platform Zoom. The following self-report questionnaires will be administered to participants and the timeline for their administration is included in the Appendix.

1. *Demographic Questionnaire*: This is a standard demographic questionnaire collecting information on age, location (postcode will be requested to assess geographical location), marital, employment and education status, medication use, pregnancy details, previous treatment history, and type of symptoms. Participants who indicate that they do not have regular access to the internet, are not aged over 18, or who are not less than 10 months post-partum will be automatically excluded from the study and will be taken to an exit page of the survey that indicates that they are not eligible for the study.
2. *Diagnostic Interview for Anxiety, Mood, and OCD and Related Neuropsychiatric Disorders (DIAMOND)* (Screener): The DIAMOND screener is a self-report questionnaire that indicates to the clinician which of the DIAMOND modules need to be administered during the telephone interview. Participants who do not endorse one of the anxiety and related disorders will be automatically excluded from the study and will be taken to an exit page of the survey that indicates that they are not eligible for the study
3. *Diagnostic Interview for Anxiety, Mood, and OCD and Related Neuropsychiatric Disorders (DIAMOND)*: The DIAMOND is a structured clinician administered interview with strong psychometric properties that is consonant with the diagnostic criteria for DSM-5. The relevant DIAMOND modules will be completed during the telephone interview based on the participant’s responses to the DIAMOND self-report screener. Risk related questions regarding suicidal ideation, plans and previous attempts in the past 12 months, as well as information relating to deliberate self-harm behaviours and licit and illicit drug use will be also be assessed.
4. *The Overall Anxiety Severity and Impairment Scale (OASIS)* (Norman, Cissell, Means‐Christensen, & Stein, 2006): This 5-item self-report measure is designed to assess the severity and impairment associated with anxiety disorders. The OASIS total scores range from 0 to 20 and a cut-off score of ≥ 8 has been determined as indicative of a probable anxiety disorder. The scale has high alpha reliability coefficients ranging from 0.80 to 0.84 (Campbell-Sills, et al., 2009; Norman, Cissell, Means‐Christensen, & Stein, 2006;). Participants who score less than 8 and will be taken to an exit page of the survey that indicates that they are not eligible for the study

1. *The Kessler 10-Item Psychological Distress Scale (K-10) (*Kessler, et al., 2002): The K-10 is a 10 item scale designed to measure non-specific psychological distress over the past two weeks. Total score range from 10 to 50, with scores over 10 indicating mild mental disorder. The scale shows strong psychometric properties is antenatal samples, with an alpha coefficient of 0.83 (Spie, et al., 2009).
2. *The Edinburgh Postnatal Depression Scale (EPDS*) (Cox, Saxbe, Holden, & Sagovsky, 1987): This 10-item measure is one of the most widely used screening instruments for assessing symptoms of perinatal anxiety and depression. Item 10 of the scale assesses for suicide risk, thus participants who score 3 on item 10 of the scale will be taken to an exit page of the survey that indicates that they are not eligible for the study.
3. *The Maternal Postnatal Attachment Scale (MPAS) (*Condon & Corkindale, 1993)*:* This is 19 item scale designed to measure maternal feelings of emotional bonding to their baby. Whilst this is not a diagnostic assessment, higher scores indicate more adaptive mother-baby bonding style. The scale has demonstrated acceptable psychometric properties, with an alpha coefficient of 0.85 (Loghnan, et al., 2019).
4. *The Karitane Parenting Confidence Scale (KPCS) (*Črnčec, Barnett, & Matthey, 2008)*:* This 15-item measure is designed to assess perceived parental self-efficacy, with higher scores indicating higher parenting confidence. Whilst not a diagnostic tool, score below 40 are indicative of lower than average parenting confidence. The KPCS has strong psychometric properties in postpartum samples, with an alpha coefficient of 0.84 (Loghnan, et al., 2019).
5. *The Client Satisfaction Questionnaire (CSQ*) (Larsen, Attkisson, Hargreaves, & Nguyen, 1979): This is an 8-item self-report measure designed to assess participant’s satisfaction and acceptability of the treatment. This questionnaire is administered at post-treatment only.
6. *Adherence Questionnaire:* Adherence will be measured by participants self-reported time spent practising the skills discussed in session each day.

# STATISTICAL CONSIDERATIONS

## Power Calculations

Based on similar case studies and guidelines, a minimum sample size of six participants is required (Kooistra, Dijkman, & Einhorn, 2009; Challacombe & Salkovskis, 2011). Thus, this study will aim to recruit six participants.

## Analysis Plan

Data will be analysed using SPSS. The OASIS, EPDS, PHQ-9, K-10, and CSQ will be scored based on the method described in each individual questionnaire protocol. Data will be collected at pre-intervention (baseline, T1), post-intervention (T2), and 3-month follow-up (T3) and will be reported and examined using visual inspection of graphs. Clinically significant change will be calculated according to the method outlined by Jacobson and Truax (1991). Descriptive data (95% confidence intervals; means and standard deviations) will be used to describe the pooled participant outcomes at pre-treatment, post-treatment, and three month follow up).

# QUALITY ASSURANCE AND CONTROL

The research team is experienced in data storage and employs numerous quality control measures. A password protected and restricted-access secure Microsoft Excel database will be created and all trial data will be stored on this. Data will also be stored on a secure SPSS datafile which will only be accessible by the research team. The research team members have a copy of this Trial Protocol and have reviewed the document at the outset of the research. The Chief Investigator will audit the data regularly to ensure adherence to the Trial Protocol. Monthly meetings will be held to review research progress and all Human Research Ethics Committee (HREC) approved amendments to our research protocols are discussed and updated Trial Protocols provided to all staff.

# ETHICS

## Investigator Authorization Procedure

Authorization from the UNE HREC is required before the commencement of any research-related activity. No promotion or recruitment will commence before HREC approval. Any amendments with the Trial Protocol will only be enacted after written approval from the HREC of University of New England.

## Patient Protection

The investigators are all familiar with and act in accordance with the National Statement on Ethical Conduct of Human Research.

# SAFETY

## Adverse Event Reporting

Monthly meetings will be conducted with the Chief Investigator and researcher to discuss participant progress and symptoms. Participants will receive weekly therapeutic sessions with the researcher, who is also a registered psychologist, thus any concerns will be discussed during this time. Other meetings are conducted on an as needed basis.

## Serious Adverse Event Reporting

Serious adverse events will be discussed with the research team and reported to the HREC via SAE documentation and emails. Additional meetings with the research team will be scheduled to further discuss such events.

## Data safety and Monitoring Board

Data safety will comply with the National Statement on Ethical Conduct in Human Research. Initially all data will be stored in a password protected Microsoft Excel spreadsheet and in SPSS software on password protected and restricted-access computers. Following the completion of the study, data will be stored on a password protected file on Cloud.UNE. The Chief Investigator will have full responsibility for the Cloud.UNE file.

# BLINDING AND UNBLINDING

The study is not blinded.

# CONFIDENTIALITY AND STORAGE AND ARCHIVING

The research team will have access to the identified data to monitor participant progress and safety during the treatment. Individually identifiable data is also required in order to monitor participants progress throughout the research. No other investigators or external parties will be provided with individually identifiable participant data and no de-identified data will be made available to other investigators or external parties without the HREC's consideration and expressed approval.

To maintain participant privacy, the Zoom software platform that sessions will be conducted over is password protected, and recorded sessions will be saved to password protected files on password protected computers, prior to being saved on the UNE.Cloud. The Zoom platform does not save data to the Zoom server. The UNE.Cloud database is also firewall protected. All of the researchers associated with the project are aware of and will adhere to the National Statement on Ethical Conduct in Human Research.

# REFERENCES

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# APPENDICES

The following appendices appear on the following pages:

1. Timeline for the administration of questionnaires
2. The questionnaires to be administered
3. An outline of the session content
4. Social media blurb
5. Flyer
6. The initial and weekly emails that will be sent to participants
7. The interview that will be conducted for screening purposes and at post-intervention and follow up

Appendix A

**TIMELINE FOR ADMINISTRATION OF QUESTIONNAIRES**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **SCREENING** | **PRE-TREATMENT** | **WEEKLY DURING TREATMENT** | **POST-TREATMENT** | **3-MONTH FOLLOW UP** |
| Demographic questionnaire | X | X |  |  |  |
| DIAMOND screener | X |  |  |  |  |
| DIAMOND Interview |  | X |  | X | X |
| EPDS | X | X | X | X | X |
| OASIS | X | X | X | X | X |
| K-10 |  | X |  | X | X |
| MPAS |  | X |  | X | X |
| KPCS |  | X |  | X | X |
| Adherence questionnaire |  |  | X |  |  |
| CSQ |  |  |  | X |  |

Appendix B

Study 4\_Screening

Survey Flow

Standard: Study Information\_Study 4 (3 Questions)

Standard: Demographic\_Study 4 (13 Questions)

Standard: DIAMOND (31 Questions)

EmbeddedData

DIAMOND = ${gr://SC\_e4dBmFvd5wm1hI2/Score}

DIAMOND = ${gr://SC\_cw4iRoQmeu4sKtE/Score}

Branch: New Branch

If

If DIAMOND Is Less Than or Equal to 0

EndSurvey: Advanced

Standard: EPDS\_Study 4 (11 Questions)

EmbeddedData

EPDS = ${gr://SC\_e4dBmFvd5wm1hI2/Score}

Branch: New Branch

If

If The thought of harming myself has occurred to me Yes, quite often Is Selected

EndSurvey: Advanced

Standard: OASIS\_Study 4 (6 Questions)

EmbeddedData

OASIS = ${gr://SC\_e4dBmFvd5wm1hI2/Score}dBmFvd5wm1hI2/Score}

Branch: New Branch

If

If OASIS Is Less Than 8

EndSurvey: Advanced

Standard: End (3 Questions)

Standard: End of Survey (1 Question)

|  |  |
| --- | --- |
| Page Break |  |

![A screenshot of a cell phone

Description automatically generated]()

You are invited to participate in a research project conducted by Peta Maguire. The research is being conducted as part of Peta’s Doctorate in Clinical Psychology in the School of Psychology and Behavioural Sciences at the University of New England.  The research project is being supervised by Associate Professor Navjot Bhullar (University of New England), Dr Suzie Cosh (University of New England) and Associate Professor Bethany Wootton (University of Technology Sydney).

**Research Project:**

The Efficacy and Acceptability of a Remotely Delivered Transdiagnostic CBT Treatment for Perinatal Anxiety: A Case Series

**Aim of the Research:**

Perinatal anxiety relates to anxiety that is experienced during the perinatal period (pregnancy to 12 months post birth). Perinatal anxiety can look different for each person and can include: 1) experiencing persistent and uncontrollable worries; 2) feeling constantly nervous or 'on edge'; 3) experiencing frequent physical symptoms of anxiety or panic attacks (such as racing heart, heart palpitations, shortness of breath or changes in breathing, shaking or trembling); or 4) intrusive and distressing thoughts and images or compulsive behaviours (such as excessive checking or reassurance seeking).

This research aims to investigate the efficacy and acceptability of remotely delivered Cognitive Behavioural Therapy (CBT) in the treatment of perinatal anxiety. In order to explore this we are asking individuals who are currently experiencing perinatal anxiety, that are in the first 10 months post birth, who are aged 18 years and over, and who can read and speak English fluently to complete an online questionnaire that will explore your symptoms and assess whether you’re eligible to participate in a 5 session remotely delivered CBT treatment.

**What Does the Study Involve?**

Interested participants will first be required to complete an online questionnaire, which we estimate will take approximately 30 minutes. Following the completion of the questionnaire you will be contacted via phone by the researcher to arrange a time to complete further screening assessments, which we estimate will take between 1-2 hours. If eligible to participate following the assessments, you will be requested to nominate a time for weekly sessions, which will be delivered by the online platform Zoom (a link with information relating to Zoom will be sent following you nominating a time). Treatment will involve 5 modules completed over 5 weekly sessions (50-60 minutes per session). Immediately after completing the treatment you will be asked to complete another set of questionnaires online, which we estimate will take approximately 15 minutes and interview with the therapist, which will take approximately 30-60 minutes. You will be contacted by email 3-months after completion of treatment requesting that you complete a follow-up online questionnaire and interview over the phone. The treatment sessions will be recorded in order to ensure the treatment is being provided as it should. Only my supervisors will view these recordings. The data collected from this study will offer information relating to the efficacy and acceptability of CBT in the treatment of perinatal anxiety. The data collected may assist in the development and provision of remotely delivered services for the treatment of perinatal anxiety to optimise uptake of effective treatment.

**Confidentiality:**

Any personal details gathered in the course of the study will remain confidential. However, if during the research it becomes apparent that participants are at risk of harm to themselves or others, the clinician may breach confidentiality to ensure the safety of the participant or the other person. Furthermore, confidentiality may be breached if information is disclosed relating to abuse or neglect of a child, disabled, or elderly person, or if illegal activity is disclosed during the course of the intervention. Additionally, a breach of confidentiality may occur if a court order is issued by a judge, which would require a release of information. No individual will be identified by name in any publication of the results.

**Participation is Voluntary:** Participation in this study is entirely voluntary, and therefore it is your choice whether you decide to participate or not. If you would like to participate after reading this Information Sheet, please complete the remainder of the questionnaire, including your demographic information. If you choose to participate, you will be then be contacted by email and will be asked to nominate some times when you might be available for the telephone interview and weekly treatment sessions. Indicating your willingness to participate in the interview and treatment sessions will also be used as your consent to participate.

**Questions:**

The questions in the questionnaire relate to your current symptoms, and will enable me to assess your current worries and stressors and situation. The questionnaire will also be repeated at the end of therapy, and 3-months following completion of therapy to assess the efficacy of perinatal anxiety. A smaller questionnaire will also be repeated weekly to assess symptom change. The questionnaires assess symptoms of anxiety, depression, parenting confidence and attachment.

**Use of Information:**

The data obtained from the questionnaires will be used as part of my doctoral thesis, which I expect to complete in 2021. Information from the interview may also be used in academic journal articles and conference presentations before and after this date.  At all times, your identity will be safeguarded by presenting the information in a way that will not allow you to be identified.

**Upsetting Issues:**

Over the duration of the study you will be asked to discuss your symptoms and recall recent examples of certain situations. This may raise upsetting issues. If the research does cause you distress you can contact the researcher and discuss your distress in session. Alternatively, you may wish to contact your local Community Health Centre (consult the white pages of your regional telephone directory), your General Practitioner, or Lifeline on 13 11 14. If you are concerned about the health of your baby please contact your treating doctor.

**Storage of Information:**

Data gathered in this study will initially be securely stored on Qualtrics™ a private provider of survey/ research software. Once the study period has closed the data will be downloaded to cloud.une.edu.au, UNE’s centrally managed cloud server managed by the research team. It will also be kept on a password protected computer which only members of the research team will have access too.

D**isposal of Information:**

All the data collected in this research will be kept for a minimum of seven years post-treatment after which it will be disposed of by deleting relevant computer files, and destroying or shredding hardcopy materials. Data will be removed from Qualrics™ once the project is complete.   **Approval:**

This project has been approved by the Human Research Ethics Committee of the University of New England (Approval NoHE20-218, Valid to 20/01/2022).

**Researchers Contact Details:**

If you have any questions regarding the research, you can contact Associate Professor Navjot Bhullar by email at navjot.bhullar@une.edu.au, or by phone on 02 6773 3187; Associate Professor Bethany Wootton by email at Bethany.wootton@uts.edu.au, or Ms Peta Maguire by email at pmaguir2@myune.une.edu.au.

**Complaints:**

Should you have any complaints concerning the manner in which this research is conducted, please contact:

Mrs Jo-Ann Sozou

Research Ethics Officer

Research Services   
University of New England

Armidale, NSW  2351

Tel: (02) 6773 3449

Email: humanethics@une.edu.au     Thank you for considering this request and I look forward to further contact with you.

Regards,

Peta Maguire        

Q4   
I have read the information contained in the Information Sheet for Participants and any questions I have asked have been answered to my satisfaction.   
  
  
  
I agree to participate in this study, with the understanding that:   
  
- My participation is voluntary,  
- I may withdraw at any time without consequences and without follow-up,  
- I agree that the research data collected for the study will form part of a thesis and may be published, or presented at conferences at a later date,  
- I agree that my responses to questionnaire's may be quoted using a pseudonym,  
- I am 18 years or over.   
  
  
  
I understand that no name or signature is required of me to give consent. By activating the "**proceed"** button below I am agreeing to the above and also to participate in this study. 

* Proceed to Study (1)
* Do Not Proceed (2)

Skip To: End of Survey If Continuing tEdit Question Label = Do Not Proceed

End of Block: Study Information\_Study 4

Start of Block: Demographic\_Study 4

Q5 The following questions tell us more about you and will help us to assess whether you are suitable for the study

Q6 What is your main language?

* English (1)
* Other (2)

Skip To: End of Survey If What is your main language? = Other

Q7 What is your age (in years)?

* 0 - 17 (1)
* 18 - 24 (2)
* 25 - 34 (3)
* 35 - 45 (4)
* 46 - 55 (5)

Skip To: End of Survey If What is your age (in years)? = 0 - 17

Q8 Do you have regular access to the internet?

* Yes (1)
* No (2)

Skip To: End of Survey If Do you have regular access to the internet? = No

Q9 Age of infant from most recent pregnancy:

* 0-3months old (1)
* 4-6 months old (2)
* 7-10 months old (3)
* Over 10 months (4)

Skip To: End of Survey If Age of infant from most recent pregnancy: = Over 10 months

Q10 Are you currently accessing support/ counselling/ therapy from a mental health professional?

* Yes (1)
* No (2)

Skip To: Q12 If Are you currently accessing support/ counselling/ therapy from a mental health professional? = No

Q11 Is this support accessed due to anxiety or another difficulty?

* Anxiety (1)
* Depression (2)
* Other (3)

Q12 Have you previously accessed support/ counselling/ therapy from a mental health professional?

* Yes (1)
* No (2)

Skip To: Q15 If Have you previously accessed support/ counselling/ therapy from a mental health professional? = No

Q13 Was this support accessed due to anxiety or another difficulty?

* Anxiety (1)
* Depression (2)
* Other (3)

Q14 When did you access this support?

* Current (1)
* < 3 months (2)
* < 6 months (3)
* < 12 months (4)
* > 12 months (5)

Q15 Are you currently taking prescription medications for your mental health?

* Yes (1)
* No (2)

Skip To: End of Block If Are you currently taking prescription medications for your mental health? = No

Q16 If so, what is the name and dose of this medication?

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Q17 Have you been on the same dose of this medication for at least 3 months?

* Yes (1)
* No (2)

End of Block: Demographic\_Study 4

Start of Block: DIAMOND

Q18 The following questions ask about symptoms of various mental health problems. Please read the following statements and select YES or NO to indicate whether each statement applies to you.

Q19 I have frequent thoughts, urges, or images that I don't want to have (for example, thoughts about being contaminated even though I may not be, or that I may hurt someone else even though I don’t want to).

* Yes (1)
* No (2)

Q20 I do repetitive behaviours (for example, hand washing or cleaning, ordering or arranging, checking things, or repeating behaviours over and over), or I repeatedly do things in my mind (for example, counting, saying certain words or phrases) in order to feel better or to prevent something bad from happening.

* Yes (1)
* No (2)

Q21 I spend a lot of time worrying about my physical appearance

* Yes (1)
* No (2)

Q22 My house is excessively cluttered

* Yes (1)
* No (2)

Q23 I frequently pull out hair from my scalp or my body

* Yes (1)
* No (2)

Q24 I frequently pick at my skin

* Yes (1)
* No (2)

Q25 I get very anxious or fearful in social situations or when I am being observed

* Yes (1)
* No (2)

Q26 I have had a panic attack, where I experienced a lot of fear and physical sensations that came out of the blue

* Yes (1)
* No (2)

Q27 I feel very fearful or anxious in situations where it's difficult to escape quickly or get help (for example, using public transportation, being in open or enclosed spaces, standing in line or being in a crowded place or being alone away from home)

* Yes (1)
* No (2)

Q28 I feel excessively anxious or worried about many things, a lot of the time (for example, worry about finances, responsibilities at work/school, my health or the health of others).

* Yes (1)
* No (2)

Q29 There are certain objects, situations, or activities that I am very afraid of (for example, like animals, insects, blood, needles, heights, storms, flying, choking, vomiting, or enclosed spaces).

* Yes (1)
* No (2)

Q30 I feel very afraid to be away from a certain person or people

* Yes (1)
* No (2)

Q31 I have had a period of four days or more when my mood was so good or elevated, like I was on top of the world, that it caused problems for me, or people thought I wasn't my usual self

* Yes (1)
* No (2)

Q32 I have been feeling down, blue, or depressed frequently over the past two years

* Yes (1)
* No (2)

Q33 I have had a time when I felt very sad, blue, down, or depressed, or lost interest or pleasure in my usual activities, for two weeks or more

* Yes (1)
* No (2)

Q34 I get really depressed, irritable, anxious, or have mood swings in the week prior to menstruation (my period)

* Yes (1)
* No (2)

Q35 I am distressed about a really bad event (like seeing something that was life-threatening or caused someone to die, being seriously injured or seeing someone be seriously injured, or being sexually assaulted or molested) that I have experienced or witnessed

* Yes (1)
* No (2)

Q36 I'm having a hard time dealing with a stressful or unpleasant experience, or a major change in my life

* Yes (1)
* No (2)

Q37 I have had very strong beliefs in something that other people thought were strange, such as any of the following: a.     That people were conspiring against me, spying on me, or harassing me b.    That a governmental or religious organization was following me or harassing me c.    That someone I didn’t know, such as a celebrity, was in love with me d.    That I had special talents or powers, or that I was famous e.    That there was something very strange going on with my body f.     That someone had removed thoughts from my mind, placed thoughts in my mind, or read my mind g.    That someone or something was controlling my movements and actions h.    That someone was sending me special messages through the TV, radio, or books i.      That I did not exist, that the world did not exist, or that the world was ending j.      That a partner was being unfaithful to mek.   That I was responsible for a disaster or serious crime and needed to be punished

* Yes (1)
* No (2)

Q38   
I have had sensory experiences that others could not understand, such as:   
  
a.   Hearing sounds that others couldn’t hear, such as voices or music   
  
b.   Seeing things that others couldn’t see, such as colours, animals, people, or spirits   
  
c.   Having unusual sensations in my body, such as a feeling of electric shocks or bugs on me   
  
d.   Smelling odours that others could not smell, such as vomit, faeces, or something rotting

* Yes (1)
* No (2)

Q40 I avoid eating food because I think I am overweight

* Yes (1)
* No (2)

Q41 I often have eating "binges," in which I eat more than most people would eat, and it feels like my eating is out of control

* Yes (1)
* No (2)

Q42 I eat very little, have difficulty eating enough, or avoid certain foods

* Yes (1)
* No (2)

Q43 I have a physical health problem that makes me very worried or anxious, or requires me to do a lot to diagnose or monitor it

* Yes (1)
* No (2)

Q44 I often worry that I have a serious medical illness or injury, or that I am going to develop a serious medical illness or injury

* Yes (1)
* No (2)

Q45 I have had 3 or more alcoholic drinks within a 3 hour period on 3 or more occasions

* Yes (1)
* No (2)

Q46 I have used illegal drugs, or I have used prescription medications other than how they were prescribed more than three times

* Yes (1)
* No (2)

Q47 I have difficulty paying attention or concentrating when I need to

* Yes (1)
* No (2)

Q48 It often seems that I have difficulty sitting still or waiting for things

* Yes (1)
* No (2)

Q92 I have a lot of sudden movements (tics) that are hard to control, or make sounds that are hard to control

* Yes (1)
* No (2)

End of Block: DIAMOND

Start of Block: EPDS\_Study 4

Q93 We would like to know how you have been feeling in the past week. Please indicate which of the following comes closest to how you have been feeling over the past seven days, not just how you feel today. Please select one option for each question that comes closest to how you have felt in the last seven days.

Q94 I have been able to laugh and see the funny side of things

* As much as I always could (1)
* Not quite as much now (2)
* Definitely not so much now (3)
* Not at all (4)

Q95 I have looked forward with enjoyment to things

* As much as I always could (1)
* Not quite as much now (2)
* Definitely not so much now (3)
* Hardly at all (4)

Q96 I have blamed myself unnecessarily when things went wrong

* Yes, most of the time (1)
* Yes, some of the time (2)
* Not very often (3)
* No, never (4)

Q97 I have been anxious or worried for no good reason

* No, not at all (1)
* Hardly ever (2)
* Yes, sometimes (3)
* Yes, very often (4)

Q98 I have felt scared or panicky for no very good reason

* Yes, quite a lot (1)
* Yes, sometimes (2)
* No, not much (3)
* No, not at all (4)

Q99 Things have been getting on top of me

* Yes, most of the time I haven’t been able to cope at all (1)
* Yes, sometimes I haven’t been coping as well as usual (2)
* No, most of the time I have coped quite well (3)
* No, I have been coping as well as ever (4)

Q100 I have been so unhappy that I have had difficulty sleeping

* Yes, most of the time (1)
* Yes, sometimes (2)
* Not very often (3)
* No, not at all (4)

Q101 I have felt sad or miserable

* Yes, most of the time (1)
* Yes, sometimes (2)
* Not very often (3)
* No, not at all (4)

Q102 I have been so unhappy that I have been crying

* Yes, most of the time (1)
* Yes, quite often (2)
* Only occasionally (3)
* No, never (4)

Q103 The thought of harming myself has occurred to me

* Yes, quite often (1)
* Sometimes (2)
* Hardly ever (3)
* Never (4)

End of Block: EPDS\_Study 4

Start of Block: OASIS\_Study 4

Q104 The following items ask about anxiety and fear.  For each item, choose the answer that best describes your experience over the past week.

Q105 In the past week, how often have you felt anxious?

* No anxiety in the past week (1)
* Infrequent anxiety. Felt anxious a few times (2)
* Occasional anxiety. Felt anxious as much of the time as not. It was hard to relax. (3)
* Frequent anxiety. Felt anxious most of the time. It was very difficult to relax (4)
* Constant anxiety. Felt anxious all of the time and never really relaxed (5)

Q106 In the past week, when you have felt anxious, how intense or severe was your anxiety?

* Little or None: Anxiety was absent or barely noticeable (1)
* Mild: Anxiety was at a low level. It was possible to relax when I tried. Physical symptoms were only slightly uncomfortable (2)
* Moderate: Anxiety was distressing at times. It was hard to relax or concentrate, but I could do it if I tried. Physical symptoms were uncomfortable (3)
* Severe: Anxiety was intense much of the time. It was very difficult to relax or focus on anything else. Physical symptoms were extremely uncomfortable (4)
* Extreme: Anxiety was overwhelming. It was impossible to relax at all. Physical symptoms were unbearable (5)

Q107 In the past week, how often did you avoid situations, places, objects, or activities because of anxiety or fear?

* None: I do not avoid places, situations, activities, or things because of fear (1)
* Infrequent: I avoid something once in a while, but will usually face the situation or confront the object. My lifestyle is not affected (2)
* Occasional: I have some fear of certain situations, places, or objects, but it is still manageable. My lifestyle has only changed in minor ways. I always or almost always avoid the things I fear when I’m alone, but can handle them if someone comes with me (3)
* Frequent: I have considerable fear and really try to avoid the things that frighten me. I have made significant changes in my life style to avoid the object, situation, activity, or place (4)
* All the Time: Avoiding objects, situations, activities, or places has taken over my life. My lifestyle has been extensively affected and I no longer do things that I used to enjoy (5)

Q108 In the past week, how much did your anxiety interfere with your ability to do the things you needed to do at work, at school, or at home?

* None: No interference at work/home/school from anxiety (1)
* Mild: My anxiety has caused some interference at work/home/school. Things are more difficult, but everything that needs to be done is still getting done (2)
* Moderate: My anxiety definitely interferes with tasks. Most things are still getting done, but few things are being done as well as in the past (3)
* Severe: My anxiety has really changed my ability to get things done. Some tasks are still being done, but many things are not. My performance has definitely suffered (4)
* Extreme: My anxiety has become incapacitating. I am unable to complete tasks and have had to leave school, have quit or been fired from my job, or have been unable to complete tasks at home and have faced consequences like bill collectors, eviction, etc (5)

Q108 In the past week, how much has anxiety interfered with your social life and relationships?

* None: My anxiety doesn’t affect my relationships (1)
* Mild: My anxiety slightly interferes with my relationships. Some of my friendships and other relationships have suffered, but, overall, my social life is still fulfilling (2)
* Moderate: I have experienced some interference with my social life, but I still have a few close relationships. I don’t spend as much time with others as in the past, but I still socialise sometimes (3)
* Severe: My friendships and other relationships have suffered a lot because of anxiety. I do not enjoy social activities. I socialize very little (4)
* Extreme: My anxiety has completely disrupted my social activities. All of my relationships have suffered or ended. My family life is extremely strained (5)

End of Block: OASIS\_Study 4

Start of Block: End

Q109 Based on the initial screening you may meet criteria for the study. We will now need to conduct a telephone interview to confirm your eligibility. Please leave your name and telephone number below so that we can contact you to organise this.

Q110 What is your name?

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Q111 What is your phone number (you will be contacted by the researcher on this number)?

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End of Block: End

Start of Block: End of Survey

Q112   
Thank you for completing the above questionnaire  
  
If any of the above questions have caused you distress you may wish to contact Lifeline on 13 11 14 or you may wish to contact your local Community Health Centre (consult the white pages of your regional telephone directory). Alternatively you may wish to contact your doctor regarding your mental health concerns. If you are having thoughts of ending your own life or if you do not feel safe, please call 000 or present to your local hospital. If you are concerned about the health of your baby please contact your treating doctor.

End of Block: End of Survey

Study 3\_T1

Start of Block: Demographics

Q1 The following questions tell us more about you and your birthing experience. These will help us better understand your current situation.

Q2 What is your name? (This will be used to match your initial information with this information)

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Q3 What is your postcode?

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Q4 How old are you? (In years)

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Q5 What is your marital status?

* Single (1)
* Married/ De facto relationship (2)
* Widowed (3)
* Divorced/ Separated (4)
* Other (5)

Q6 What is your highest level of educational or vocational qualifications?

* Year 10 (1)
* High school graduate (2)
* Trade certificate/ apprenticeship (3)
* Undergraduate diploma or associated diploma (4)
* Bachelor degree (5)
* Masters or doctoral degree (6)

Q7 What is your current employment status?

* Employed full time (1)
* Employed part time (2)
* Casual employment (3)
* Unemployed (4)
* Full-time student (5)
* Part time student (6)
* Home duties or paid maternity leave (7)

Q8 Do you have private health insurance?

* Yes (1)
* No (2)

Q9 Age of infant from most recent pregnancy (in months)?

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Q10 Gestation at birth (in weeks)?

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Q11 How was your baby delivered?

* Vaginal delivery (1)
* Planned cesarean section birth (2)
* Emergency cesarean section birth (3)
* Other (4)

Q12 How many times have you given birth?

* One (1)
* Two (2)
* Three or more times (3)

End of Block: Demographics

Start of Block: OASIS

Q13 The following items ask about anxiety and fear.  For each item, choose the answer that best describes your experience over the past week.

Q14 In the past week, how often have you felt anxious?

* No anxiety in the past week (1)
* Infrequent anxiety. Felt anxious a few times (2)
* Occasional anxiety. Felt anxious as much of the time as not. It was hard to relax. (3)
* Frequent anxiety. Felt anxious most of the time. It was very difficult to relax (4)
* Constant anxiety. Felt anxious all of the time and never really relaxed (5)

Skip To: Q63 If In the past week, how often have you felt anxious? = No anxiety in the past week

Q15 In the past week, when you have felt anxious, how intense or severe was your anxiety?

* Little or None: Anxiety was absent or barely noticeable (1)
* Mild: Anxiety was at a low level. It was possible to relax when I tried. Physical symptoms were only slightly uncomfortable (2)
* Moderate: Anxiety was distressing at times. It was hard to relax or concentrate, but I could do it if I tried. Physical symptoms were uncomfortable (3)
* Severe: Anxiety was intense much of the time. It was very difficult to relax or focus on anything else. Physical symptoms were extremely uncomfortable (4)
* Extreme: Anxiety was overwhelming. It was impossible to relax at all. Physical symptoms were unbearable (5)

Q16 In the past week, how often did you avoid situations, places, objects, or activities because of anxiety or fear?

* None: I do not avoid places, situations, activities, or things because of fear (1)
* Infrequent: I avoid something once in a while, but will usually face the situation or confront the object. My lifestyle is not affected (2)
* Occasional: I have some fear of certain situations, places, or objects, but it is still manageable. My lifestyle has only changed in minor ways. I always or almost always avoid the things I fear when I’m alone, but can handle them if someone comes with me (3)
* Frequent: I have considerable fear and really try to avoid the things that frighten me. I have made significant changes in my life style to avoid the object, situation, activity, or place (4)
* All the Time: Avoiding objects, situations, activities, or places has taken over my life. My lifestyle has been extensively affected and I no longer do things that I used to enjoy (5)

Q17 In the past week, how much did your anxiety interfere with your ability to do the things you needed to do at work, at school, or at home?

* None: No interference at work/home/school from anxiety (1)
* Mild: My anxiety has caused some interference at work/home/school. Things are more difficult, but everything that needs to be done is still getting done (2)
* Moderate: My anxiety definitely interferes with tasks. Most things are still getting done, but few things are being done as well as in the past (3)
* Severe: My anxiety has really changed my ability to get things done. Some tasks are still being done, but many things are not. My performance has definitely suffered (4)
* Extreme: My anxiety has become incapacitating. I am unable to complete tasks and have had to leave school, have quit or been fired from my job, or have been unable to complete tasks at home and have faced consequences like bill collectors, eviction, etc (5)

Q18 In the past week, how much has anxiety interfered with your social life and relationships?

* None: My anxiety doesn’t affect my relationships (1)
* Mild: My anxiety slightly interferes with my relationships. Some of my friendships and other relationships have suffered, but, overall, my social life is still fulfilling (2)
* Moderate: I have experienced some interference with my social life, but I still have a few close relationships. I don’t spend as much time with others as in the past, but I still socialise sometimes (3)
* Severe: My friendships and other relationships have suffered a lot because of anxiety. I do not enjoy social activities. I socialize very little (4)
* Extreme: My anxiety has completely disrupted my social activities. All of my relationships have suffered or ended. My family life is extremely strained (5)

End of Block: OASIS

Start of Block: K-10

Q19 For the following please select the appropriate response.

Q20 About how often did you feel tired out for no good reason?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q21 About how often did you feel nervous?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q22 About how often did you feel so nervous that nothing could calm you down?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q23 About how often did you feel hopeless?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q24 About how often did you feel restless or fidgety?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q25 About how often did you feel so restless you could not sit still?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q26 About how often did you feel depressed?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q27 About how often did you feel that everything was an effort?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q28 About how often did you feel so sad that nothing could cheer you up?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q29 About how often did you feel worthless?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

End of Block: K-10

Start of Block: EPDS

Q30 We would like to know how you have been feeling in the past week. Please indicate which of the following comes closest to how you have been feeling over the past seven days, not just how you feel today. Please select one option for each question that comes closest to how you have felt in the last seven days.

Q31 I have been able to laugh and see the funny side of things

* As much as I always could (1)
* Not quite as much now (2)
* Definitely not so much now (3)
* Not at all (4)

Q32 I have looked forward with enjoyment to things

* As much as I always could (1)
* Not quite as much now (2)
* Definitely not so much now (3)
* Hardly at all (4)

Q33 I have blamed myself unnecessarily when things went wrong

* Yes, most of the time (1)
* Yes, some of the time (2)
* Not very often (3)
* No, never (4)

Q34 I have been anxious or worried for no good reason

* No, not at all (1)
* Hardly ever (2)
* Yes, sometimes (3)
* Yes, very often (4)

Q35 I have felt scared or panicky for no very good reason

* Yes, quite a lot (1)
* Yes, sometimes (2)
* No, not much (3)
* No, not at all (4)

Q36 Things have been getting on top of me

* Yes, most of the time I haven’t been able to cope at all (1)
* Yes, sometimes I haven’t been coping as well as usual (2)
* No, most of the time I have coped quite well (3)
* No, I have been coping as well as ever (4)

Q37 I have been so unhappy that I have had difficulty sleeping

* Yes, most of the time (1)
* Yes, sometimes (2)
* Not very often (3)
* No, not at all (4)

Q38 I have felt sad or miserable

* Yes, most of the time (1)
* Yes, sometimes (2)
* Not very often (3)
* No, not at all (4)

Q39 I have been so unhappy that I have been crying

* Yes, most of the time (1)
* Yes, quite often (2)
* Only occasionally (3)
* No, never (4)

Q40 The thought of harming myself has occurred to me

* Yes, quite often (1)
* Sometimes (2)
* Hardly ever (3)
* Never (4)

End of Block: EPDS

Start of Block: MPAS1

Q41 These questions are about your thoughts and feelings about your baby. Please tick one box only in answer to each question

Q42 When I am caring for the baby, I get feelings of annoyance or irritation

* Very frequently (1)
* Frequently (2)
* Occasionally (3)
* Very rarely (4)
* Never (5)

Q43 When I am caring for the baby I get feelings that the child is deliberately being difficult or trying to upset me

* Very frequently (1)
* Frequently (2)
* Occasionally (3)
* Very rarely (4)
* Never (5)

Q44 Over the last two weeks I would describe my feelings for the baby as:

* Dislike (1)
* No strong feelings towards the baby (2)
* Slight affection (3)
* Moderate affection (4)
* Intense affection (5)

Q45 Regarding my overall level of interaction with the baby I:

* Feel very guilty that I am not more involved (1)
* Feel moderately guilty that I not more involved (2)
* Feel slightly guilty that I am not more involved (3)
* I don't have any guilty feelings regarding this (4)

Q46 When I interact with the baby I feel:

* Very incompetent and lacking in confidence (1)
* Moderately incompetent and lacking in confidence (2)
* Moderately competent and confident (3)
* Very competent and confident (4)

Q47 When I am with the baby I feel tense and anxious:

* Very frequently (1)
* Frequently (2)
* Occasionally (3)
* Almost never (4)

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Q48 When I am with the baby and other people are present, I feel proud of the baby:

* Very frequently (4)
* Frequently (3)
* Occasionally (2)
* Almost never (1)

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Q49 I try to involve myself as much as I possibly can PLAYING with the baby:

* This is true (2)
* This is untrue (1)

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Q50 When I have to leave the baby:

* I usually feel rather sad (or it's difficult to leave) (5)
* I often feel rather sad (or it's difficult to leave) (4)
* I have mixed feelings of sadness and relief (3)
* I often feel rather relieved (and it's easy to leave) (2)
* I usually feel rather relieved (and it's easy to leave) (1)

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Q51 When I am with the baby:

* I always get a lot of enjoyment/ satisfaction (4)
* I frequently get a lot of enjoyment/ satisfaction (3)
* I occasionally get a lot of enjoyment/ satisfaction (2)
* I very rarely get a lot of enjoyment/ satisfaction (1)

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Q52 When I am not with the baby, I find myself thinking about the baby:

* Almost all the time (5)
* Very frequently (4)
* Frequently (3)
* Occasionally (2)
* Not at all (1)

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Q53 When I am with the baby:

* I usually try to prolong the time I spend with him/ her (2)
* I usually try to shorten the time I spend with him/ her (1)

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Q54 When I have been away from the baby for a while and I am about to be with him/ her again, I usually feel:

* Intense pleasure at the idea (5)
* Moderate pleasure at the idea (4)
* Mild pleasure at the idea (3)
* No feelings at all about the idea (2)
* Negative feelings about the idea (1)

Q55 I now think of the baby as:

* Very much my own baby (1)
* A bit like my own baby (2)
* Not yet really my own baby (3)

Q56 Regarding the things that we have had to give up because of the baby:

* I find that I resent it quite a lot (1)
* I find that I resent it a moderate amount (2)
* I find that I resent it a moderate amount (3)
* I find that I resent it a bit (4)
* I don't resent it at all (5)

Q57 Over the past three months, I have felt that I do not have enough time for myself or to pursue my own interests:

* Almost all the time (1)
* Very frequently (2)
* Occasionally (3)
* Not at all (4)

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Q58 Taking care of this baby is a heavy burden of responsibility. I believe this is:

* Very much so (4)
* Somewhat so (3)
* Slightly so (2)
* Not at all (1)

Q59 I trust my own judgement in deciding what the baby needs:

* Almost never (1)
* Occasionally (2)
* Most of the time (3)
* Almost all the time (4)

Q60 Usually when I am with the baby:

* I am very impatient (1)
* I am a bit impatient (2)
* I am moderately patient (3)
* I am extremely patient (4)

End of Block: MPAS1

Start of Block: KPCS

Q61 Please choose the answer that comes closest to how you generally feel.

Q62 I am confident about feeding my baby

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q63 I can settle my baby

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q64 I am confident about helping my baby to establish a good sleep routine

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q65 I understand what my baby is trying to tell me

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q66 I can soothe my baby when he/ she is distressed

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q67 I am confident about playing with my baby

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q68 If my baby has a common cold or slight fever, I am confident about handling this

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q69 I feel sure that my partner will be there for me when I need support

* Not applicable, I don't have a partner (1)
* No, hardly ever (2)
* No, not very often (3)
* Yes, some of the time (4)
* Yes, most of the time (5)

Q70 I am confident that my baby is doing well

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q71 I can make decisions about the care of my baby

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q72 Being a mother/ father is very stressful for me

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q73 I feel I am doing a good job as a mother

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q74 Other people think I am doing a good job as a mother

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q75 I feel sure that people will be there for me when I need support

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

End of Block: KPCS

Start of Block: End of Survey

Q76

Thank you for completing the above questionnaire.

If any of the above questions have caused you distress you may wish to contact Lifeline on 13 11 14 or you may wish to contact your local Community Health Centre (consult the white pages of your regional telephone directory). Alternatively you may wish to contact your doctor regarding your mental health concerns. If you are having thoughts of ending your own life or if you do not feel safe, please call 000 or present to your local hospital. If you are concerned about the health of your baby please contact your treating doctor.

End of Block: End of Survey

Study 3\_T2

Start of Block: Default Question Block

Q1 What is your name? (This will be used to match your previous information with this information)

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End of Block: Default Question Block

Start of Block: OASIS

Q2 The following items ask about anxiety and fear.  For each item, choose the answer that best describes your experience over the past week.

Q3 In the past week, how often have you anxious?

* No anxiety in the past week (1)
* Infrequent anxiety. Felt anxious a few times (2)
* Occasional anxiety. Felt anxious as much of the time as not. It was hard to relax. (3)
* Frequent anxiety. Felt anxious most of the time. It was very difficult to relax (4)
* Constant anxiety. Felt anxious all of the time and never really relaxed (5)

Q4 In the past week, when you have felt anxious, how intense or severe was your anxiety?

* Little or None: Anxiety was absent or barely noticeable (1)
* Mild: Anxiety was at a low level. It was possible to relax when I tried. Physical symptoms were only slightly uncomfortable (2)
* Moderate: Anxiety was distressing at times. It was hard to relax or concentrate, but I could do it if I tried. Physical symptoms were uncomfortable (3)
* Severe: Anxiety was intense much of the time. It was very difficult to relax or focus on anything else. Physical symptoms were extremely uncomfortable (4)
* Extreme: Anxiety was overwhelming. It was impossible to relax at all. Physical symptoms were unbearable (5)

Q5 In the past week, how often did you avoid situations, places, objects, or activities because of anxiety or fear?

* None: I do not avoid places, situations, activities, or things because of fear (1)
* Infrequent: I avoid something once in a while, but will usually face the situation or confront the object. My lifestyle is not affected (2)
* Occasional: I have some fear of certain situations, places, or objects, but it is still manageable. My lifestyle has only changed in minor ways. I always or almost always avoid the things I fear when I’m alone, but can handle them if someone comes with me (3)
* Frequent: I have considerable fear and really try to avoid the things that frighten me. I have made significant changes in my life style to avoid the object, situation, activity, or place (4)
* All the Time: Avoiding objects, situations, activities, or places has taken over my life. My lifestyle has been extensively affected and I no longer do things that I used to enjoy (5)

Q6 In the past week, how much did your anxiety interfere with your ability to do the things you needed to do at work, at school, or at home?

* None: No interference at work/home/school from anxiety (1)
* Mild: My anxiety has caused some interference at work/home/school. Things are more difficult, but everything that needs to be done is still getting done (2)
* Moderate: My anxiety definitely interferes with tasks. Most things are still getting done, but few things are being done as well as in the past (3)
* Severe: My anxiety has really changed my ability to get things done. Some tasks are still being done, but many things are not. My performance has definitely suffered (4)
* Extreme: My anxiety has become incapacitating. I am unable to complete tasks and have had to leave school, have quit or been fired from my job, or have been unable to complete tasks at home and have faced consequences like bill collectors, eviction, etc (5)

Q7 In the past week, how much has anxiety interfered with your social life and relationships?

* None: My anxiety doesn’t affect my relationships (1)
* Mild: My anxiety slightly interferes with my relationships. Some of my friendships and other relationships have suffered, but, overall, my social life is still fulfilling (2)
* Moderate: I have experienced some interference with my social life, but I still have a few close relationships. I don’t spend as much time with others as in the past, but I still socialise sometimes (3)
* Severe: My friendships and other relationships have suffered a lot because of anxiety. I do not enjoy social activities. I socialize very little (4)
* Extreme: My anxiety has completely disrupted my social activities. All of my relationships have suffered or ended. My family life is extremely strained (5)

End of Block: OASIS

Start of Block: K-10

Q8 For the following please select the appropriate response.

Q9 About how often did you feel tired out for no good reason?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q10 About how often did you feel nervous?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q11 About how often did you feel so nervous that nothing could calm you down?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q12 About how often did you feel hopeless?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q13 About how often did you feel restless or fidgety?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q14 About how often did you feel so restless you could not sit still?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q15 About how often did you feel depressed?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q16 About how often did you feel that everything was an effort?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q17 About how often did you feel so sad that nothing could cheer you up?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q18 About how often did you feel worthless?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

End of Block: K-10

Start of Block: EPDS

Q19 We would like to know how you have been feeling in the past week. Please indicate which of the following comes closest to how you have been feeling over the past seven days, not just how you feel today. Please select one option for each question that comes closest to how you have felt in the last seven days.

Q20 I have been able to laugh and see the funny side of things

* As much as I always could (1)
* Not quite as much now (2)
* Definitely not so much now (3)
* Not at all (4)

Q21 I have looked forward with enjoyment to things

* As much as I always could (1)
* Not quite as much now (2)
* Definitely not so much now (3)
* Hardly at all (4)

Q22 I have blamed myself unnecessarily when things went wrong

* Yes, most of the time (1)
* Yes, some of the time (2)
* Not very often (3)
* No, never (4)

Q23 I have been anxious or worried for no good reason

* No, not at all (1)
* Hardly ever (2)
* Yes, sometimes (3)
* Yes, very often (4)

Q24 I have felt scared or panicky for no very good reason

* Yes, quite a lot (1)
* Yes, sometimes (2)
* No, not much (3)
* No, not at all (4)

Q25 Things have been getting on top of me

* Yes, most of the time I haven’t been able to cope at all (1)
* Yes, sometimes I haven’t been coping as well as usual (2)
* No, most of the time I have coped quite well (3)
* No, I have been coping as well as ever (4)

Q26 I have been so unhappy that I have had difficulty sleeping

* Yes, most of the time (1)
* Yes, sometimes (2)
* Not very often (3)
* No, not at all (4)

Q27 I have felt sad or miserable

* Yes, most of the time (1)
* Yes, sometimes (2)
* Not very often (3)
* No, not at all (4)

Q28 I have been so unhappy that I have been crying

* Yes, most of the time (1)
* Yes, quite often (2)
* Only occasionally (3)
* No, never (4)

Q29 The thought of harming myself has occurred to me

* Yes, quite often (1)
* Sometimes (2)
* Hardly ever (3)
* Never (4)

End of Block: EPDS

Start of Block: MPAS

Q30 These questions are about your thoughts and feelings about your baby. Please tick one box only in answer to each question

Q31 When I am caring for the baby, I get feelings of annoyance or irritation

* Very frequently (1)
* Frequently (2)
* Occasionally (3)
* Very rarely (4)
* Never (5)

Q32 When I am caring for the baby I get feelings that the child is deliberately being difficult or trying to upset me

* Very frequently (1)
* Frequently (2)
* Occasionally (3)
* Very rarely (4)
* Never (5)

Q33 Over the last two weeks I would describe my feelings for the baby as:

* Dislike (1)
* No strong feelings towards the baby (2)
* Slight affection (3)
* Moderate affection (4)
* Intense affection (5)

Q34 Regarding my overall level of interaction with the baby I:

* Feel very guilty that I am not more involved (1)
* Feel moderately guilty that I not more involved (2)
* Feel slightly guilty that I am not more involved (3)
* I don't have any guilty feelings regarding this (4)

End of Block: MPAS

Start of Block: KPCS

Q35 Please choose the answer that comes closest to how you generally feel.

Q36 I am confident about feeding my baby

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q37 I can settle my baby

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q38 I am confident about helping my baby to establish a good sleep routine

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q39 I understand what my baby is trying to tell me

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q40 I can soothe my baby when he/ she is distressed

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q41 I am confident about playing with my baby

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q42 If my baby has a common cold or slight fever, I am confident about handling this

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q43 I feel sure that my partner will be there for me when I need support

* Not applicable, I don't have a partner (1)
* No, hardly ever (2)
* No, not very often (3)
* Yes, some of the time (4)
* Yes, most of the time (5)

Q44 I am confident that my baby is doing well

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q45 I can make decisions about the care of my baby

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q46 Being a mother/ father is very stressful for me

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q47 I feel I am doing a good job as a mother

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q48 Other people think I am doing a good job as a mother

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q49 I feel sure that people will be there for me when I need support

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

End of Block: KPCS

Start of Block: CSQ

Q50 Listed below are a number of questions regarding the treatment. Please read each item carefully, and circle one of the four options that best reflect how you feel about the question

Q51 How would you rate the quality of service you received?

* Excellent (1)
* Good (2)
* Fair (3)
* Poor (4)

Q52 Did you get the kind of service you wanted?

* No, definitely not (1)
* No, not really (2)
* Yes, generally (3)
* Yes, definitely (4)

Q53 To what extent has our program met your needs?

* Almost all of my needs have been met (1)
* Most of my needs have been met (2)
* Only a few of my needs have been met (3)
* None of my needs have been met (4)

Q54 If a friend were in need of similar help, would you recommend our service to her?

* No definitely not (1)
* No, not really (2)
* Yes, generally (3)
* Yes, definitely (4)

Q55 How satisfied are you with the amount of help you have received?

* Quite satisfied (1)
* Indifferent or mildly dissatisfied (2)
* Mostly satisfied (3)
* Very satisfied (4)

Q56 Have the services you received helped you to deal more effectively with your problems?

* Yes, they helped a great deal (1)
* Yes, they helped somewhat (2)
* No, they really did not help (3)
* No, they seemed to make things worse (4)

Q57 In an overall, general sense, how satisfied are you with the service you have received?

* Very satisfied (1)
* Mostly satisfied (2)
* Indifferent or mildly dissatisfied (3)
* Quite dissatisfied (4)

Q58 If you were to seek help again, would you come back to our program?

* No, definitely not (1)
* No, I don't think so (2)
* Yes, I think so (3)
* Yes, definitely (4)

Q59 What did you LIKE about the treatment?

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Q60 What did you NOT LIKE about the treatment?

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Q61 Finally, do you have any other feedback or information you would like to share with us?

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

End of Block: CSQ

Start of Block: Block 7

Start of Block: End of Survey

Q62

Thank you for completing the above questionnaire.

If any of the above questions have caused you distress you may wish to contact Lifeline on 13 11 14 or you may wish to contact your local Community Health Centre (consult the white pages of your regional telephone directory). Alternatively you may wish to contact your doctor regarding your mental health concerns. If you are having thoughts of ending your own life or if you do not feel safe, please call 000 or present to your local hospital. If you are concerned about the health of your baby please contact your treating doctor.

End of Block: End of Survey

Study 3\_T3

Start of Block: Default Question Block

Q1 What is your name? (This will be used to match your previous information with this information)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

End of Block: Default Question Block

Start of Block: OASIS

Q2 The following items ask about anxiety and fear.  For each item, choose the answer that best describes your experience over the past week.

Q3 In the past week, how often have you felt anxious? 

* No anxiety in the past week (1)
* Infrequent anxiety. Felt anxious a few times (2)
* Occasional anxiety. Felt anxious as much of the time as not. It was hard to relax. (3)
* Frequent anxiety. Felt anxious most of the time. It was very difficult to relax (4)
* Constant anxiety. Felt anxious all of the time and never really relaxed (5)

Q4 In the past week, when you have felt anxious, how intense or severe was your anxiety?

* Little or None: Anxiety was absent or barely noticeable (1)
* Mild: Anxiety was at a low level. It was possible to relax when I tried. Physical symptoms were only slightly uncomfortable (2)
* Moderate: Anxiety was distressing at times. It was hard to relax or concentrate, but I could do it if I tried. Physical symptoms were uncomfortable (3)
* Severe: Anxiety was intense much of the time. It was very difficult to relax or focus on anything else. Physical symptoms were extremely uncomfortable (4)
* Extreme: Anxiety was overwhelming. It was impossible to relax at all. Physical symptoms were unbearable (5)

Q5 In the past week, how often did you avoid situations, places, objects, or activities because of anxiety or fear?

* None: I do not avoid places, situations, activities, or things because of fear (1)
* Infrequent: I avoid something once in a while, but will usually face the situation or confront the object. My lifestyle is not affected (2)
* Occasional: I have some fear of certain situations, places, or objects, but it is still manageable. My lifestyle has only changed in minor ways. I always or almost always avoid the things I fear when I’m alone, but can handle them if someone comes with me (3)
* Frequent: I have considerable fear and really try to avoid the things that frighten me. I have made significant changes in my life style to avoid the object, situation, activity, or place (4)
* All the Time: Avoiding objects, situations, activities, or places has taken over my life. My lifestyle has been extensively affected and I no longer do things that I used to enjoy (5)

Q6 In the past week, how much did your anxiety interfere with your ability to do the things you needed to do at work, at school, or at home?

* None: No interference at work/home/school from anxiety (1)
* Mild: My anxiety has caused some interference at work/home/school. Things are more difficult, but everything that needs to be done is still getting done (2)
* Moderate: My anxiety definitely interferes with tasks. Most things are still getting done, but few things are being done as well as in the past (3)
* Severe: My anxiety has really changed my ability to get things done. Some tasks are still being done, but many things are not. My performance has definitely suffered (4)
* Extreme: My anxiety has become incapacitating. I am unable to complete tasks and have had to leave school, have quit or been fired from my job, or have been unable to complete tasks at home and have faced consequences like bill collectors, eviction, etc (5)

Q7 In the past week, how much has anxiety interfered with your social life and relationships?

* None: My anxiety doesn’t affect my relationships (1)
* Mild: My anxiety slightly interferes with my relationships. Some of my friendships and other relationships have suffered, but, overall, my social life is still fulfilling (2)
* Moderate: I have experienced some interference with my social life, but I still have a few close relationships. I don’t spend as much time with others as in the past, but I still socialise sometimes (3)
* Severe: My friendships and other relationships have suffered a lot because of anxiety. I do not enjoy social activities. I socialize very little (4)
* Extreme: My anxiety has completely disrupted my social activities. All of my relationships have suffered or ended. My family life is extremely strained (5)

End of Block: OASIS

Start of Block: K-10

Q8 For the following please select the appropriate response.

Q9 About how often did you feel tired out for no good reason?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q10 About how often did you feel nervous?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q11 About how often did you feel so nervous that nothing could calm you down?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q12 About how often did you feel hopeless?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q13 About how often did you feel restless or fidgety?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q14 About how often did you feel so restless you could not sit still?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q15 About how often did you feel depressed?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q16 About how often did you feel that everything was an effort?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q17 About how often did you feel so sad that nothing could cheer you up?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

Q18 About how often did you feel worthless?

* None of the time (1)
* A little of the time (2)
* Some of the time (3)
* Most of the time (4)
* All of the time (5)

End of Block: K-10

Start of Block: EPDS

Q19 We would like to know how you have been feeling in the past week. Please indicate which of the following comes closest to how you have been feeling over the past seven days, not just how you feel today. Please select one option for each question that comes closest to how you have felt in the last seven days.

Q20 I have been able to laugh and see the funny side of things

* As much as I always could (1)
* Not quite as much now (2)
* Definitely not so much now (3)
* Not at all (4)

Q21 I have looked forward with enjoyment to things

* As much as I always could (1)
* Not quite as much now (2)
* Definitely not so much now (3)
* Hardly at all (4)

Q22 I have blamed myself unnecessarily when things went wrong

* Yes, most of the time (1)
* Yes, some of the time (2)
* Not very often (3)
* No, never (4)

Q23 I have been anxious or worried for no good reason

* No, not at all (1)
* Hardly ever (2)
* Yes, sometimes (3)
* Yes, very often (4)

Q24 I have felt scared or panicky for no very good reason

* Yes, quite a lot (1)
* Yes, sometimes (2)
* No, not much (3)
* No, not at all (4)

Q25 Things have been getting on top of me

* Yes, most of the time I haven’t been able to cope at all (1)
* Yes, sometimes I haven’t been coping as well as usual (2)
* No, most of the time I have coped quite well (3)
* No, I have been coping as well as ever (4)

Q26 I have been so unhappy that I have had difficulty sleeping

* Yes, most of the time (1)
* Yes, sometimes (2)
* Not very often (3)
* No, not at all (4)

Q27 I have felt sad or miserable

* Yes, most of the time (1)
* Yes, sometimes (2)
* Not very often (3)
* No, not at all (4)

Q28 I have been so unhappy that I have been crying

* Yes, most of the time (1)
* Yes, quite often (2)
* Only occasionally (3)
* No, never (4)

Q29 The thought of harming myself has occurred to me

* Yes, quite often (1)
* Sometimes (2)
* Hardly ever (3)
* Never (4)

End of Block: EPDS

Start of Block: MPAS

Q30 Click to write the question text

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Q31 When I am caring for the baby, I get feelings of annoyance or irritation

* Very frequently (1)
* Frequently (2)
* Occasionally (3)
* Very rarely (4)
* Never (5)

Q32 When I am caring for the baby I get feelings that the child is deliberately being difficult or trying to upset me

* Very frequently (1)
* Frequently (2)
* Occasionally (3)
* Very rarely (4)
* Never (5)

Q33 Over the last two weeks I would describe my feelings for the baby as:

* Dislike (1)
* No strong feelings towards the baby (2)
* Slight affection (3)
* Moderate affection (4)
* Intense affection (5)

Q34 Regarding my overall level of interaction with the baby I:

* Feel very guilty that I am not more involved (1)
* Feel moderately guilty that I not more involved (2)
* Feel slightly guilty that I am not more involved (3)
* I don't have any guilty feelings regarding this (4)

End of Block: MPAS

Start of Block: KPCS

Q35 Please choose the answer that comes closest to how you generally feel.

Q36 I am confident about feeding my baby

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q37 I can settle my baby

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q38 I am confident about helping my baby to establish a good sleep routine

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q39 I understand what my baby is trying to tell me

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q40 I can soothe my baby when he/ she is distressed

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q41 I am confident about playing with my baby

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q42 If my baby has a common cold or slight fever, I am confident about handing this

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q43 I feel sure that my partner will be there for me when I need support

* Not applicable, I don't have a partner (1)
* No, hardly ever (2)
* No, not very often (3)
* Yes, some of the time (4)
* Yes, most of the time (5)

Q44 I am confident that my baby is doing well

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q45 I can make decisions about the care of my baby

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q46 Being a mother/ father is very stressful for me

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q47 I feel I am doing a good job as a mother

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q48 Other people think I am doing a good job as a mother

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

Q49 I feel sure that people will be there for me when I need support

* No, hardly ever (1)
* No, not very often (2)
* Yes, some of the time (3)
* Yes, most of the time (4)

End of Block: KPCS

Start of Block: End of Survey

Q50   
If any of the above questions have caused you distress you may wish to contact Lifeline on 13 11 14 or you may wish to contact your local Community Health Centre (consult the white pages of your regional telephone directory). Alternatively you may wish to contact your doctor regarding your mental health concerns. If you are having thoughts of ending your own life or if you do not feel safe, please call 000 or present to your local hospital. If you are concerned about the health of your baby please contact your treating doctor.

End of Block: End of Survey

Study 3\_Weekly

Start of Block: Default Question Block

Q1 The following questions will help us assess your symptoms weekly. Please complete prior to your session.

Q2 What is your name? (This will be used to match your previous information with this information)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

End of Block: Default Question Block

Start of Block: OASIS

Q3 The following items ask about anxiety and fear.  For each item, choose the answer that best describes your experience over the past week.

Q4 In the past week, how often have you felt anxious?

* No anxiety in the past week (1)
* Infrequent anxiety. Felt anxious a few times (2)
* Occasional anxiety. Felt anxious as much of the time as not. It was hard to relax. (3)
* Frequent anxiety. Felt anxious most of the time. It was very difficult to relax (4)
* Constant anxiety. Felt anxious all of the time and never really relaxed (5)

Q5 In the past week, when you have felt anxious, how intense or severe was your anxiety?

* Little or None: Anxiety was absent or barely noticeable (1)
* Mild: Anxiety was at a low level. It was possible to relax when I tried. Physical symptoms were only slightly uncomfortable (2)
* Moderate: Anxiety was distressing at times. It was hard to relax or concentrate, but I could do it if I tried. Physical symptoms were uncomfortable (3)
* Severe: Anxiety was intense much of the time. It was very difficult to relax or focus on anything else. Physical symptoms were extremely uncomfortable (4)
* Extreme: Anxiety was overwhelming. It was impossible to relax at all. Physical symptoms were unbearable (5)

Q6 In the past week, how often did you avoid situations, places, objects, or activities because of anxiety or fear?

* None: I do not avoid places, situations, activities, or things because of fear (1)
* Infrequent: I avoid something once in a while, but will usually face the situation or confront the object. My lifestyle is not affected (2)
* Occasional: I have some fear of certain situations, places, or objects, but it is still manageable. My lifestyle has only changed in minor ways. I always or almost always avoid the things I fear when I’m alone, but can handle them if someone comes with me (3)
* Frequent: I have considerable fear and really try to avoid the things that frighten me. I have made significant changes in my life style to avoid the object, situation, activity, or place (4)
* All the Time: Avoiding objects, situations, activities, or places has taken over my life. My lifestyle has been extensively affected and I no longer do things that I used to enjoy (5)

Q7 In the past week, how much did your anxiety interfere with your ability to do the things you needed to do at work, at school, or at home?

* None: No interference at work/home/school from anxiety (1)
* Mild: My anxiety has caused some interference at work/home/school. Things are more difficult, but everything that needs to be done is still getting done (2)
* Moderate: My anxiety definitely interferes with tasks. Most things are still getting done, but few things are being done as well as in the past (3)
* Severe: My anxiety has really changed my ability to get things done. Some tasks are still being done, but many things are not. My performance has definitely suffered (4)
* Extreme: My anxiety has become incapacitating. I am unable to complete tasks and have had to leave school, have quit or been fired from my job, or have been unable to complete tasks at home and have faced consequences like bill collectors, eviction, etc (5)

Q8 In the past week, how much has anxiety interfered with your social life and relationships?

* None: My anxiety doesn’t affect my relationships (1)
* Mild: My anxiety slightly interferes with my relationships. Some of my friendships and other relationships have suffered, but, overall, my social life is still fulfilling (2)
* Moderate: I have experienced some interference with my social life, but I still have a few close relationships. I don’t spend as much time with others as in the past, but I still socialise sometimes (3)
* Severe: My friendships and other relationships have suffered a lot because of anxiety. I do not enjoy social activities. I socialize very little (4)
* Extreme: My anxiety has completely disrupted my social activities. All of my relationships have suffered or ended. My family life is extremely strained (5)

End of Block: OASIS

Start of Block: EPDS

Q9 We would like to know how you have been feeling in the past week. Please indicate which of the following comes closest to how you have been feeling over the past seven days, not just how you feel today. Please select one option for each question that comes closest to how you have felt in the last seven days..

Q10 I have been able to laugh and see the funny side of things

* As much as I always could (1)
* Not quite as much now (2)
* Definitely not so much now (3)
* Not at all (4)

Q11 I have looked forward with enjoyment to things

* As much as I always could (1)
* Not quite as much now (2)
* Definitely not so much now (3)
* Hardly at all (4)

Q12 I have blamed myself unnecessarily when things went wrong

* Yes, most of the time (1)
* Yes, some of the time (2)
* Not very often (3)
* No, never (4)

Q13 I have been anxious or worried for no good reason

* No, not at all (1)
* Hardly ever (2)
* Yes, sometimes (3)
* Yes, very often (4)

Q14 I have felt scared or panicky for no very good reason

* Yes, quite a lot (1)
* Yes, sometimes (2)
* No, not much (3)
* No, not at all (4)

Q15 Things have been getting on top of me

* Yes, most of the time I haven’t been able to cope at all (1)
* Yes, sometimes I haven’t been coping as well as usual (2)
* No, most of the time I have coped quite well (3)
* No, I have been coping as well as ever (4)

Q16 I have been so unhappy that I have had difficulty sleeping

* Yes, most of the time (1)
* Yes, sometimes (2)
* Not very often (3)
* No, not at all (4)

Q17 I have felt sad or miserable

* Yes, most of the time (1)
* Yes, sometimes (2)
* Not very often (3)
* No, not at all (4)

Q18 I have been so unhappy that I have been crying

* Yes, most of the time (1)
* Yes, quite often (2)
* Only occasionally (3)
* No, never (4)

Q19 The thought of harming myself has occurred to me

* Yes, quite often (1)
* Sometimes (2)
* Hardly ever (3)
* Never (4)

End of Block: EPDS

Start of Block: Block 4

Q20 We are interested to learn how much time you spent working on the skills described in the treatment so far. Your honesty is appreciated.

Q21 On average, how many minutes have you spent per day working on the skills described in the treatment in the last week?  (Please respond in minutes)

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End of Block: Block 4

Start of Block: End of Survey

Q22

Thank you for completing the above questionnaire.

If any of the above questions have caused you distress you may wish to contact Lifeline on 13 11 14 or you may wish to contact your local Community Health Centre (consult the white pages of your regional telephone directory). Alternatively you may wish to contact your doctor regarding your mental health concerns. If you are having thoughts of ending your own life or if you do not feel safe, please call 000 or present to your local hospital. If you are concerned about the health of your baby please contact your treating doctor.

End of Block: End of Survey

Appendix C

*Transdiagnostic CBT* *Intervention Plan*

|  |  |
| --- | --- |
| **Session** | **Content** |
| 1 | *Introduction to the CBT Model*   * *CBT Formulation – Discussion regarding formulation, perinatal specific symptoms, perpetuating factors* * *Homework: Thought Diary* |
| 2 | *Cognitive Restructuring*   * *Introduction to automatic thoughts* * *Identifying negative automatic thoughts, cognitive distortions, and core beliefs* * *Homework: Unhelpful Thinking Worksheet* |
| 3 | *Arousal Reduction*   * *Controlling physical symptoms including de-arousal strategies* * *Managing symptoms of anxiety* * *Homework: Progressive Muscle Relaxtion strategies* |
| 4 | *Behaviour Modification*   * *Identifying maladaptive behaviours* * *Education about graded exposure* * *Homework: Graded exposure task* |
| 5 | *Challenges in Parenthood and Relapse Prevention*   * *Parenthood worries and relapse prevention* |

**Session 1:**

*Introduction to the CBT Model*

* *CBT Formulation – Discussion regarding formulation, perinatal specific symptoms, perpetuating factors.*

The below model will be collaboratively filled in with the participant during the session. This will assist in formulating the participants triggers, automatic thoughts (which will be further explored in the subsequent session), and perpetuating factors for their anxiety. The researcher will guide and prompt the participant to explore their behaviours, emotions and bodily sensations.



Emotions



Thoughts



Body

Sensations



Situation



Behaviours



Trigger

*Homework: Thought Diary*

The researcher will introduce the below homework task and explain the purpose of the thought diary. The participant will then be emailed the thought diary to complete over the next week. This will be used to guide the following session.

|  |  |  |  |
| --- | --- | --- | --- |
| **Situation**  (Who, what, where, when) | **Thoughts**  (What was going through your mind when this happened) | **Feelings & Body Sensations**  (What did you feel? What did your body feel? Rate your emotion 0-100%) | **Behaviours**  (What did you do when this happened?) |
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**Session 2:**

*Cognitive Restructuring*

* *Introduction to automatic thoughts*
* *Identifying negative automatic thoughts, cognitive distortions, and core beliefs*

Prior to the session the researcher will examine the completed weekly questionnaires to assess for any changes. If there are any concerning changes these will be discussed in session. Automatic thoughts (i.e., what are automatic thoughts, types of automatic thoughts – neutral, positive and negative) and how/why automatic thoughts develop will then be discussed. Unhelpful thinking styles will be introduced and explored (see next page for handout that will be used on the share screen function to exemplify each unhelpful thinking style). Participants will be asked to identify which of the thinking styles they use and give specific examples of when they have used the thinking style. The previous weeks homework activity will be used to guide this and participants will be asked to identify which thinking style they were using in the situations noted in their homework activity.

Core beliefs and the development of core beliefs will then be introduced. Participants will be encouraged to identify their core beliefs, which the researcher will guide based on the above activity and the previous weeks formulation. The researcher will introduce thought challenging which will lead to introducing the homework activity.

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*Homework: Unhelpful Thinking Worksheet*

The researcher will introduce the below homework task and explain the purpose of the unhelpful thought worksheet. The participant will then be emailed the unhelpful thinking styles handout and the unhelpful thinking worksheet to complete over the next week. This will be used to guide the following session. ![A screenshot of a cell phone

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**Session 3:**

*Arousal Reduction*

* *Controlling physical symptoms including de-arousal strategies*
* *Managing symptoms of anxiety*

Prior to the session the researcher will examine the completed weekly questionnaires to assess for any changes. If there are any concerning changes these will be discussed in session. The previous weeks homework task will also be explored initially. Following this, the researcher will introduce arousal reduction strategies.

Arousal reduction strategies will be explored. These will include progressive muscle relaxation (PMR) that the participant can employ to relieve anxiety symptoms and will include practising PMR in session and as homework. Furthermore, participants will be asked to recall their breathing patterns when feeling anxious. For example, anxiety can cause an increase in our breathing rate as part of the fight or flight response to a perceived threat, and techniques to gain control over ones breathing will be explored.

In addition to PMR other strategies will be brainstormed that may assist in managing anxiety and that will enhance overall wellbeing and mental health. This will include getting enough sleep, limiting caffeine, avoiding alcohol and nicotine, choosing healthy eating options, and exercising.

*Homework: Arousal reduction strategies*

Participants will be asked to practice the PMR techniques from the session between sessions. Participants will be asked to continue using the homework worksheet from the previous session to continue monitoring and challenging their thoughts.

**Session 4:**

*Behaviour Modification*

* *Education about maladaptive behaviours*
* *Identifying maladaptive behaviours*
* *Addressing maladaptive behaviours*

Prior to the session the researcher will examine the completed weekly questionnaires to assess for any changes. If there are any concerning changes these will be discussed in session. The previous weeks homework task will also be explored initially. Following this, the researcher will provide education on maladaptive behaviours and the therapist and the participants will work together to identify the participants maladaptive behaviours (previous homework tasks and sessions will be drawn upon to identify the maladaptive behaviours) and exploring alternative behaviours the participant may employ. Participants will then be asked to describe the main triggers to their anxiety, as discussed in previous sessions, and to describe specific situations related to their anxiety that make them experience varying levels of discomfort (i.e., on a scale of 0 to 10 where 0 is no anxiety and 10 is extremely anxiety provoking where would each situation fit). A graded exposure hierarchy will then be introduced and completed collaboratively with the participant, as per the handout on the following page. Participants homework will then be to asked to gradually engage in the anxiety provoking situations for homework.

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*Homework: Graded exposure task*

Participants will be asked to engage in certain situations on their exposure hierarchy. The amount of situations the participant is to engage in will be discussed during the session and will be determined in collaboration with the participant depending of the participants anticipated levels of anxiety and their beliefs about being able to engage in the tasks. Participants will be asked to complete the below worksheet for each of the situations.

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| --- | --- | --- | --- | --- | --- | --- |
| **Exposure Homework Sheet** | | | | | | |
| **Feared Situation:** | | | **Exercise:** What will I do? How long for? | | | |
| **Day/ Time** | **Thoughts**  What might happen?  What is the worst thing about it?  How likely is this to happen? | **Anxiety Rating**  *0-10* **Before** | **Anxiety Rating**  *0-10* **During** | **Anxiety Rating**  *0-10* **After** | **Duration** | **Comments**  What happened? What did you do? How was your anxiety affected? What helped? What could you do differently? |
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**Session 5:**

* *Preparing for parenthood worries and relapse prevention*
* *Therapy blueprint to be completed*
* *Other worries that may arise*

Prior to the session the researcher will examine the completed weekly questionnaires to assess for any changes. If there are any concerning changes these will be discussed in session. The previous weeks homework task will also be explored initially. The researcher will ask the participant to discuss their thoughts, feelings and body sensations whilst completing the exposure tasks, or to discuss any setbacks that they experienced. The researcher will then introduce the therapy blueprint, please see the following page. The clinician will collaboratively complete this with the participant. The completion of the therapy blueprint also offers the participant an opportunity to discuss potential setbacks, how ready they feel to manage these setbacks, and their perceived ability to manage their symptoms of anxiety. A copy of the completed therapy blueprint will be emailed to the participant following the session. The participant will also be reminded about completing the post intervention questionnaires and a phone interview will be scheduled for the completion of the diagnostic assessment with the researcher. The clinician will encourage participants to seek a further referral to a mental health practitioner through their General Practitioner if clinically indicated.

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Appendix D

**Social Media Invite**

The following text will be posted on pregnancy related social media groups.

**Have you recently had a baby? Are you experiencing anxiety?**

We wish to invite you to participate in our research project exploring the acceptability and effectiveness of remotely delivered Cognitive Behaviour Therapy (CBT) for the treatment of perinatal anxiety.

If you are a woman within 10 months post birth, aged 18 years or older, and who is experiencing perinatal anxiety you may be eligible to participate in a 5 session remotely delivered CBT treatment.

The treatment is provided free of charge by a registered psychologist and is delivered via the videoconferencing platform Zoom. For more information please visit: **insert link xxx**

*This project has been approved by the Human Research Ethics Committee of the University of New England (approval number HE20-218; Valid to 20/01/2022)*

Appendix E

Text

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Appendix F

**Initial Email**

Dear ,

As discussed on the phone earlier your weekly Zoom sessions will be on **Day and Time.** Sessions will be conducted via the Zoom platform. You can access Zoom meetings via Skype for Business or via PC, Mac, Linux, iOS, or Android, or by downloading the Zoom application. For more information on how to connect to a Zoom meeting, see <https://about-zoom.uts.edu.au/connecting-zoom>.

Each week prior to your session you will receive an email with the link to the Zoom meeting. You will also receive a link to a Qualtrics questionnaire which will include questions relating to your symptoms over the past 7 days. This will help us better understand your current symptoms and will be used to guide sessions. Please complete this questionnaire (approximately 10 minutes) prior to your session.

If you have any concerns, technical difficulties, or need to reschedule your appointment please do not hesitate to contact me via email on [pmaguir2@myune.edu.au](mailto:pmaguir2@myune.edu.au).

Warm regards,

Peta Maguire

Psychologist

**Weekly Reminder Emails**

Dear ,

This is a friendly reminder you have a session with Peta today at **time** via Zoom.

You can access this session from PC, Mac, Linux, iOS or Android by clicking here: **link**

You may also access this session via Skype for Business (Lync) by clicking here: **Link**

For more information on how to connect to a Zoom meeting, see <https://about-zoom.uts.edu.au/connecting-zoom>.

Please also complete your weekly symptom measures (approximately 10 minutes) at least **1 hour prior** to your session. These can be accessed via **link**

If you have any concerns, technical difficulties, or need to reschedule your appointment please do not hesitate to contact me via email on [pmaguir2@myune.edu.au](mailto:pmaguir2@myune.edu.au).

Warm regards,

Peta Maguire

Psychologist

Appendix G

**Telephone Screening Interview**

Good morning/afternoon/evening, my name is Peta Maguire I am a researcher and psychologist from the University of New England and I’m conducting a study on perinatal anxiety. Thank you for completing the screening questionnaire and providing your details.

Before starting, can I check that you are 18 years or over? [If not, interview to be terminated]

Is now a convenient time to ask you some questions? This may up to two hours.

*[If the participant does not agree to continue at this time, either make a new time for the interview or thank them for their time and hang up.]*

Do I have your permission to make an audio recording of this interview to ensure that I accurately recall the information you provide? Any personal information you provide will be confidential and you will not be identified by name in any publication of the results. [*If permission is not given, interview to be terminated]*

The questions I will be asking relate to your self-reported symptoms and will be used to help us to better understand your current concerns. These will also be used to ensure you eligible to participate in this study. Do you have any questions about this?

I would like to firstly ask you questions relating to any thoughts you’ve had over the past 12 months relating to harming yourself. Is that ok?

Have you made a suicide attempt in the last 12 months? (*If answered yes this will be further explored in relation to when this was and supports accessed. If within the past 3 months, interview will be terminated and alternative supports such as the local mental health service, GP, or hospital will be discussed).*

Do you currently have a plan or intent to end your life? (*If answered yes this will be further explored in relation to when this was and supports accessed. If within the past 3 months, interview will be terminated and alternative supports such as the local mental health service, GP, or hospital will be discussed).*

Have you deliberately harmed yourself in the past 12 months? This includes cutting, burning, scratching yourself etc? (*If answered yes this will be further explored in relation to when the self-harming occurred, how the self-harm was inflicted and supports accessed. If the self-harming is current or within the previous 3 months the interview will be terminated and alternative supports such as the local mental health service, GP, or ospital will be discussed).*

Are you drinking alcohol or using illegal drugs on a daily basis? (*If answered yes this will be further explored in relation to the regularity, amount and type of substance used. If the substances are used daily the interview will be terminated and alternative supports such as the local mental health service, GP, or AOD service will be discussed).*

*The DIAMOND modules relevant to the persons self-reported symptoms on the DIAMOND Screener questionnaire.*

*[If they do not meet criteria]* Thank you for your time, unfortunately you do not meet eligibility criteria to participate in this study. We recommend that you attend your GP for a Mental Health Care Plan and to access further support. End interview

[*If they meet criteria]* Thank you for your time. Based on your self-report measures and the interview we have just completed, you are eligible to participate in this study. Participation includes completing self-report measures each week, which will take approximately 10 minutes, then attending 5 weekly sessions via an online platform Zoom. Sessions will be with myself. Following the completion of therapy, we will arrange a time that I can contact you via phone to go through the interview we just completed, this will used to measure your symptom severity. You will then be contacted by phone 3 months after you have completed therapy for another interview to assess symptom severity. Does this sound ok? Do you have any questions?

What time suits you for sessions each week?

I will send you an email now with the session details and with information on how to access sessions through the Zoom platform. Sessions will be recorded for quality reasons to ensure that session adhere to the research treatment protocol, however these will only be accessed by the research team if required, do I have your permission to record all sessions?

You will also receive reminder emails each week with the link to access the Zoom session and with a link to the weekly self-report measures. Please ensure you complete these at least 1 hour before the session, as they will be used to guide sessions. Could I please confirm your email address?

Do you have any questions?

Thank you again for your time and please do not hesitate to contact me via email on [pmaguir2@myune.edu](mailto:pmaguir2@myune.edu) if you have any questions, concerns or technical difficulties.

**Telephone Post Intervention Interview**

Good morning/afternoon/evening, it is Peta Maguire from the University of New England calling. Is this **Name.** As discussed in your final session last week, I am calling today to ask you questions similar to the ones you answered prior to commencing the intervention to assess your symptoms.

Is now a convenient time to ask you some questions? This should take about 30 minutes maximum. *[If the participant does not agree to continue at this time, either make a new time for the interview or thank them for their time and hang up.]*

Do I have your permission to make an audio recording of this interview to ensure that I accurately recall the information you provide? Any personal information you provide will be confidential and you will not be identified by name in any publication of the results*. [If permission is not given, interview to be terminated].*

You will have received a link with the post intervention questionnaires in the reminder email for today’s interview, could you please confirm that you received this link and have completed the questionnaires?

The questions I will be asking today relate to your self-reported symptoms pre-intervention and will be used to assess your symptom severity following therapy. Do you have any questions about this?

*The relevant modules of the DIAMOND interview will be administered to assess symptom severity.*

Thank you for your time today. Do you have any additional comments or questions regarding the intervention or todays interview?

I will contact you again in 3 months via email and then phone. The email will contain a link with questionnaires similar to ones you have already completed. I will then contact you via phone and ask similar questions to today which will be used to assess your symptoms. You will receive a $25 Gift Card via email today for your time and on completion of the follow-up interview in 3 months’ time, you will be sent another $25 Gift Card for your time. Do I have your permission to contact you in 3 months’ time?

Thank you again for your time and please do not hesitate to contact me via email on [pmaguir2@myune.edu](mailto:pmaguir2@myune.edu) if you have any questions, concerns or technical difficulties