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Evaluating effectiveness of antenatal cognitive behavioural based treatment for anxiety and stress

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Doctorate in Clinical Psychology

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Table of Contents

List of Table and Figures

Research Portfolio Abstract

Psychological distress is common during pregnancy. The objective of this thesis was to evaluate the effectiveness of antenatal cognitive behavioural based treatments in reducing psychological distress in pregnant women.

A systematic review was undertaken of randomised controlled studies utilizing antenatal cognitive behavioural based treatment in reducing anxiety and stress compared to treatment as usual. Eleven papers were identified through a systematic search of databases using predefined criteria comparing intervention groups to treatment as usual in pregnant women with anxiety or stress. The systematic review revealed preliminary evidence for the effectiveness of cognitive behavioural based treatment with several studies noting changes over time in anxiety and stress; however, only a few studies reported intervention effects when compared to control. While the systematic review results suggest that a small number of cognitive behavioural based interventions may be effective in reducing anxiety and stress during pregnancy compared to treatment as usual, confidence in these findings is limited due to methodological limitations such as lack of follow-up, high attrition rates and difficulties with generalisability. The evidence base is currently insufficient and further research which utilises a robust methodology is needed before any reliable conclusions can be drawn.

An empirical study was conducted to examine the effectiveness of a brief, single-session stress reduction programme introducing cognitive behavioural techniques aimed at reducing general anxiety, other pregnancy related distress and improving general well-being and pregnancy outcomes. Twenty-nine participants with clinically significant levels of anxiety were recruited to the empirical study from the local maternity hospital. Participants completed measures of general anxiety, pregnancy related anxiety, general well-being and childbirth experience. The control was derived from a historical dataset where 37 participants were matched for baseline anxiety levels. The empirical study demonstrated significant reductions in general anxiety; however, similar findings were also observed in the control group. Significant reductions were observed with pregnancy related anxiety and women also reported their childbirth experience similarly regardless of delivery type. Although our findings were not significant when compared to control, our recruitment design resulted in good return rates following birth. Further studies using sophisticated study design with use of robust control group are required.

Keywords: pregnancy, anxiety, stress, cognitive-behavioural therapy, antenatal

Doctorate Clinical Psychology Declaration of Own Work

Name: Victoria Ross

Title of Work: Treatment of Perinatal Psychological Distress

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- Composed and undertaken the work myself √
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  Received ethical approval from an approved external body and registered this application and confirmation of approval with the School of Health in Social Science's Ethical Committee. √

Signature **Date** 24.10.19

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1. Clinical effectiveness of antenatal cognitive behavioural based treatment in reducing anxiety and stress: a systematic review of randomised controlled trials.

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Abstract

Purpose: Psychological distress is common during pregnancy and is associated with poor pregnancy outcomes and reduced quality of life for women, children and families. In recent years, there has been an increased focus on psychological interventions delivered in the antenatal period and recent systematic reviews make limited observations of psychological interventions during pregnancy. However, these do not focus on specific interventions or utilise robust study design incorporating randomisation or control.

Methods: A systematic review was thus undertaken to draw together the evidence base regarding the effectiveness of cognitive behavioural based therapies delivered fully in the antenatal period in reducing maternal anxiety and stress. This focussed on studies which utilize randomised controlled trial methodology. Methodological quality of included studies was assessed using an adapted version of the Cochrane risk of bias tool.

Results: Eleven studies met the review's inclusion criteria, five of which found a significant benefit of intervention over control conditions on anxiety/stress. It would be recommended that future interventions include both cognitive and behavioural strategies to reduce anxiety during pregnancy. However, methodological limitations including lack of follow-up, high attrition rates, poorly representative sample and small sample size lead to difficulties when making generalisations from these findings.

Conclusion: Further robust studies utilising representative samples, larger sample size and inclusion of follow-ups are warranted.

Keywords: anxiety; distress; pregnancy; antenatal; cognitive-behavioural therapy

1.2 Introduction

1.2.1 Psychological distress and Pregnancy

Perinatal mental health has become a significant public health concern (Confidential Enquiry into Maternal and Child Health (CEMACH 2007). Psychological distress is common during pregnancy and can significantly reduce quality of life for mothers, children and families (Dunkel-Schetter and Tanner 2012; Guardino et al. 2014; Marchesi et al. 2016). Globally, 10-41% of women will experience anxiety during pregnancy (Giardinelli et al. 2012; Fairbrother et al. 2016). Perhaps surprisingly, depression is less common than anxiety with prevalence estimated at 3-17% (Rubertsson et al. 2014; Yazdanimehr et al. 2016). Despite high incidence and debilitating impact, anxiety disorders in pregnancy have failed to capture the research focus of other disorders including post-natal depression and post-partum psychosis.

It is suggested that anxiety during pregnancy arises from an interaction between pre-existing vulnerabilities and the adjustment to pregnancy which includes social, health and psychological changes (Van Bussel et al. 2009; Dunkel-Schetter and Tanner 2012; Marchesi et al. 2016). Only 1 in 12 will experience new onset of symptoms (Marchesi et al. 2016). Whilst recent studies suggest estimated rates of distress in pregnancy are no different from the general population, some older studies indicate incidences of mood symptoms during pregnancy are higher than during other points in women's lives (Halbreich 2004).

Anxiety and stress are strongly associated with poor pregnancy outcomes and comorbidities including post-natal depression (PND) (Alder et al. 2007). Anxiety is associated with slower emotional, cognitive, social and neuro development as well as increased risk of impulsivity and behavioural problems in childhood and adolescence (Dunkel-Schetter and Tanner 2012; Rubertsson et al. 2014; Rouhe 2015). Despite these findings, some studies argue that general anxiety has no connection to obstetric outcomes (Andersson et al. 2004).

General anxiety disorder (GAD) is the most common anxiety disorder during pregnancy (Ross and McLean 2006). GAD and pregnancy related anxiety (PRA) have been the focus of much debate where they are proposed to be distinct domains; however, inconsistencies in definitions and validation of outcome measures cast doubt over this (Saisto and Halmesmaki 2003; Huizink et al. 2004; Grant et al. 2008; Fairbrother et al. 2016). It has been suggested PRA has higher impact on obstetric outcomes than general anxiety (Reck et al. 2013).

1.2.2 Treatments for maternal stress

Recent systematic reviews identified the most effective treatments for GAD to be cognitive behavioural based therapies in the general population (Hunot et al. 2007; Kazcurkin and Foa 2016). Cognitive Behavioural Therapy (CBT), pioneered by Ellis (1962) and Beck (1970) is an evidence based psychological therapy used in the treatment of anxiety and depressive disorders in the general population (Butler et al. 2006). Due to the ongoing adaption of CBT, it is one of the most extensively researched psychotherapeutic approaches (Butler et al. 2006; Hofmann et al. 2012). CBT combines both behavioural and cognitive approaches and is based on the theory that psychological distress is maintained by maladaptive cognitions such as schemas about oneself, the world and future, as well as physiological processes, feelings and problematic behaviours (Beck 1970).

Meta-analyses have found CBT to be effective in the general population treating depression and anxiety (Butler et al. 2006; Hofmann et al. 2008; Hofmann et al. 2012). In the last decade studies exploring the effectiveness of CBT for anxious pregnant women have emerged; however, the preliminary evidence available has been limited by methodological flaws, such as small sample size, lack of control group, long term follow-up, random assignment and selection bias (Lavender et al. 2016; Marchesi et al. 2016; Matvienko-Sikar et al. 2016).

CBT has evolved over the last decade incorporating both mindfulness and acceptance based approaches (Kabat-Zinn 1982; Hayes 2006; Hofmann et al. 2012). Mindfulness is an awareness that arises through paying attention, on purpose, in the present moment, non-judgementally (Kabat-Zinn, 1982). This approach encourages anxious thoughts to be observed and accepted rather than to be changed. Recent trials have focussed on mindfulness based interventions during pregnancy (Vieten and Austin 2008; Beddoe et al. 2009; Duncan and Bardacke 2010, Dunn et al. 2012; Byrne et al. 2014; Goodman et al. 2014; Gaurdino et al. 2014; Matvienko-Sikar and Dockray 2016; Yazdanimehr 2016). Despite some positive findings, methodological limitations including high attrition rates, focus on short term results and poor generalisability are observed.

1.2.3 Rationale for current review

There has been increased focus on psychological interventions delivered in the antenatal period and recent systematic reviews make limited observations of psychological interventions during pregnancy (Alderice et al. 2013; Hall et al. 2016; Lavender et al. 2016; Marchesi et al. 2016; Matvienko-Sikar et al. 2016; Taylor et al. 2016). However, these do not focus on specific interventions or utilise robust study design incorporating randomisation or control. Two Cochrane systematic reviews explore interventions during the perinatal period focussing on psychological interventions for post-natal depression (Dennis et al. 2007) and mind body interventions for anxiety (Marc et al. 2011). A systematic review was thus undertaken to draw together the evidence base regarding the effectiveness of CBT

based therapies delivered fully in the antenatal period in reducing maternal anxiety and stress which utilise randomised controlled trial methodology.

1.3 Objective

This review aims to assess the methodological quality of randomised controlled trials delivering antenatal CBT based interventions to determine whether these interventions reduce stress and anxiety symptoms when compared to a control.

1.4 Methods:

This review was conducted according to PRISMA guidelines (Moher et al. 2015).

1.4.1 Participants

Participants were pregnant women (≥18 years) and either had elevated levels of anxiety or stress, or were at risk of developing these. This was determined by completion of validated outcome measures or structured or semi-structured clinical interviews (First et al. 1995). Studies that did not report baseline anxiety levels for each intervention group were excluded.

1.4.2 Interventions

Studies were eligible for inclusion if they utilised interventions based on cognitive behavioural theories. The definition of a CBT intervention used in a recent Cochrane systematic review was used as guidance: "a treatment that assists the individual in identifying erroneous beliefs and systematic distortions in information processing with the hopes of reducing distress and enhancing coping efforts" (Dennis et al. 2007). Previous research indicates that high rates of co-morbid anxiety are associated with depression (Alder et al. 2007); therefore, interventions which were not actively targeting anxiety but measured the effectiveness of the intervention on anxiety or stress were also included.

Studies that included only one component of CBT, such as relaxation, mind body, social support and educational interventions were not included in the review. Individuals participating in studies investigating the effect of interventions for high risk pregnancies (pre-eclampsia, severe and enduring mental health disorders) were excluded.

1.4.3 Comparators

No restrictions were placed in terms of the control groups used by studies. Any form of standard or usual care compared to a variety of CBT interventions were included.

1.4.4 Outcome Measures

Studies which assessed the clinical effectiveness of interventions using self-report validated outcome measures of stress or anxiety were eligible for inclusion. Outcome measures were required to be completed for both intervention and control group at baseline and at least once post-intervention within the antenatal period.

1.4.5 Study design

The study included solely randomised controlled trials (RCTs). RCTs limit the risk of bias and are considered as the most appropriate design to evaluate the effects of an intervention (Centre for reviews and dissemination 2009). This review did not restrict studies based on length of follow-up, size of sample or publication status. Only studies published in English were included. Different methods of synthesis were considered including meta-analysis and systematic review. Several factors meant that completing a systematic review synthesis would be most appropriate. This included lack of data available in at least one study (Austin, 2008), meaning effect sizes could not be calculated and lack of intention to treat analysis in several studies. In addition, due to heterogeneity between studies including intervention format (individual/group/online), timing of intervention and gestational age, a statistical meta-analysis was not appropriate.

1.4.6 Literature Search Strategy

To confirm that a similar systematic review had not been completed or was planned, the Cochrane Library was searched and a protocol was published online on PROSPERO (Appendix A); summarizing key details of the methodology, to promote transparency and reduce bias. An expert librarian was consulted regarding the search terms.

The Cochrane Pregnancy and Childbirth Group's Trials Register was searched. In addition, Medline (1966 to December, 2016), EMBASE, CINAHL, PsychINFO and MIDIRS. Searches were performed using search terms: [Pregnan* or birth or prenatal or antenatal or perinatal or "pre-natal" or "peri-natal" or "ante-natal" or birth] AND [Anxi* or birth anxiety or Anxiety disorders or depress* or depressive disorder or mental disorder] or [stress or distress] AND *cognitive therap* or cognitive behavio* or CBT or *acceptance and commitment therapy* or mindful* or intervention]. The searches were limited to studies on female pregnant humans and written in English.

'Grey Literature' was also searched by exploring databases of theses, google scholar and searching conference abstracts.

1.4.7 Study and data collection process

The literature searches identified 1,971 potentially relevant abstracts. Title and abstracts were screened and duplicates removed. Articles that made no reference to randomisation or CBT based therapies were excluded. This resulted in 88 studies which were read in full, 11 of which met inclusion criteria for this review. Reference lists of articles that meet inclusion criteria were scanned for additional papers and searches made for any papers that subsequently cited those papers (Fig. 1).

Extracted information included: participant demographics; details of the intervention and controls; study completion rates; outcomes and times of measurement; information for assessment of the risk of bias. Study characteristics and results of interest are presented in Table 1. Risk of bias ratings for RCTs and quality ratings are outlined in Table 2.

1.4.8 Quality Assessment

There is no single approach for addressing methodological quality in systematic reviews; it is therefore important to review possible criteria and guidance in the area and tailor the criteria to the review question. Methodological quality was assessed using an adapted version of The Cochrane Collaboration's risk of bias tool for bias in each study (Higgins et al. 2011). This process was also informed by guidance and literature regarding systematic appraisal of risk of bias in randomised controlled trials (Centre for reviews and dissemination 2007).

Dimensions of methodological quality were assessed including selection bias, performance bias, detection bias, attrition and reporting bias. Ratings on each dimension included low risk, high risk or unclear risk.

The papers were rated by first author (VR) and a randomly selected 50% proportion of papers were independently rated by JF using a random number generator where there was 89% agreement in ratings.

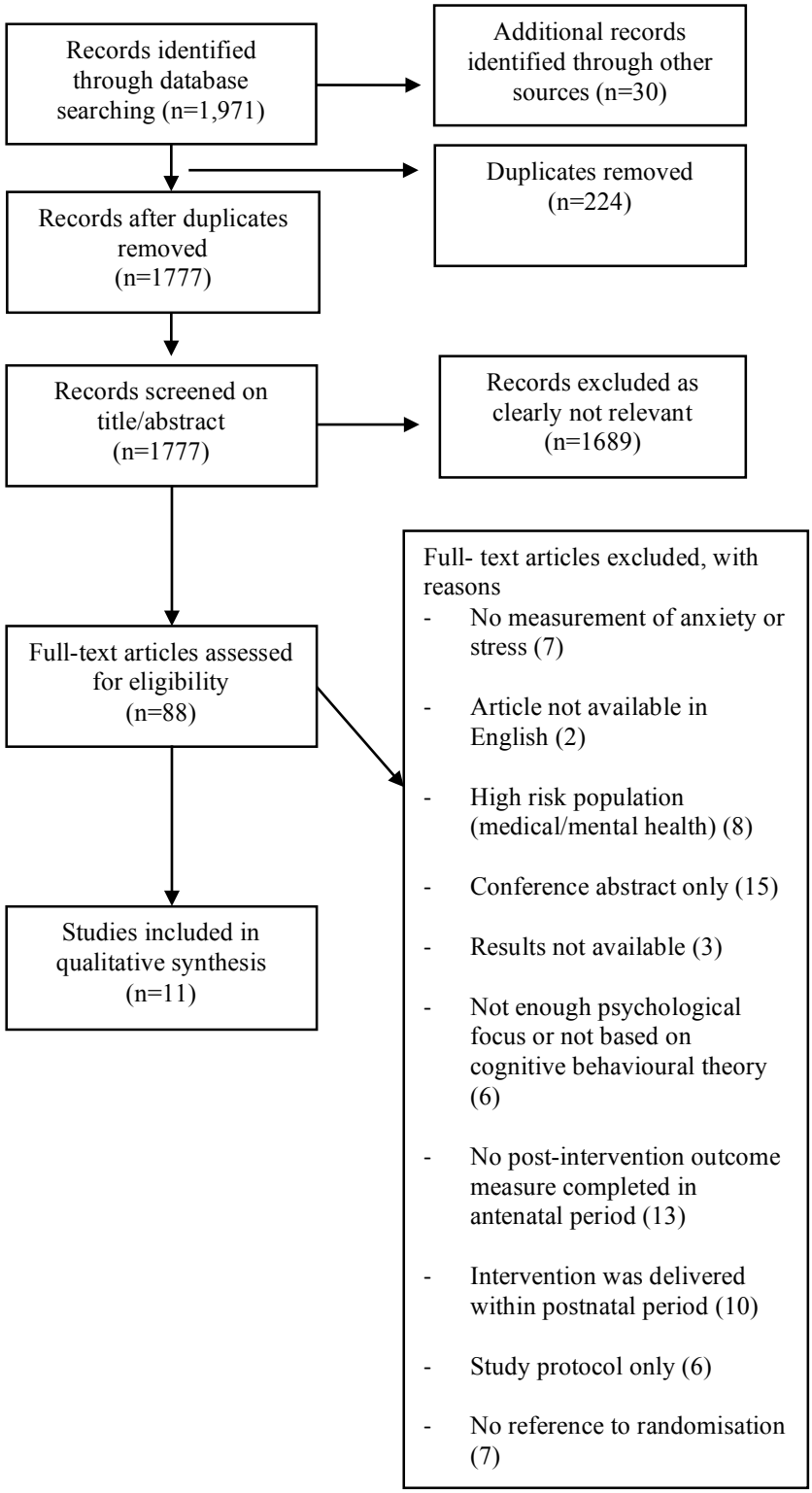

Fig. 1 PRISMA flow chart

1.4.9 Characteristics of Studies

Key characteristics of included studies are presented in Table 1.

Table 1: Characteristics of Studies											
Study	Group	N	Mean age (years)	Gestati-on age (weeks)	Outcome Measures	Baseline Anxiety/ Stress Mean (SD)	Post Anxiety/ Stress	Compl-eters	F/U (Y/N)	ES 95% CI (Cohen's d*)*	Key findings
Austin et al. (2008) Australia RCT	CBT Group Therapy 6 x 120 minute weekly sessions + follow-up	191	31.4	25.7 (5.3)	STAI	35.1	89	89	2M PP 4M PP	Not enough informa-tion provided.	Anxiety diagnosis reduced at post-intervention and follow-up, though did not reach statistical significance (P>0.05). Similar improvements found in control group. No significant difference between groups (p>0.05).
	Reading control	86	N/A	N/A	STAI	32.0	32.0	43			
Bittner et al. 2014 Germany RCT	CBT group Therapy 8 x 90 minute weekly sessions	80	29.5 (3.6)	16.1 (3.1)	STAI ASI GAS	38.0 (6.1) 31.8 (22.6) 81.5 (33.0)	35.0 (7.0) 25.1 (14.1) 73.6 (39.3)	21	3M PP	Between groups STAI – 0.258 ASI – 0.189 GAS – 0.145	Decline in anxiety over time post intervention/post-partum although did not reach significant difference (P>0.05). No between groups statistically significant difference on anxiety or stress (p>0.05).
	TAU	80	29.7 (4.7)	16.6 (3.9)	STAI ASI GAS	38.0 (6.2) 32.5 (18.8) 90.4 (41.8)	36.9 (7.7) 28.6 (22.2) 79.3 (39.3)	53			

Guardino et al. 2014 USA RCT	Mindfulness 6 x 120-minute weekly group sessions	24	33.1 (4.8)	17.8 (5.1)	STAI PSS PRA PSA	45.7 (7.6) 41.8 (6.0) 24.4 (3.8) 11.6 (3.0)	39.5 (6.3) 37.3 (5.3) 22.7 (3.8) 7.7 (1.7)	4	6W PI	Between groups: STAI – 0.221 PSS – 0.522 PRA – 0.0000 PSA – 0.512	Significantly larger decreases over time in PSA post intervention and when compared to control (p=<0.05) not sustained F/U. PRA scores reduced significantly post intervention within groups (p<0.05), no intervention effect or sustained at F/U. PSS/STAI scores improved over time (P<0.05) and at follow-up, but no intervention effect (p>0.05).
	Reading control group (You and your Baby: Pregnancy, 2006)	23	33.1	17.8	STAI PSS PRA PSA	44.4 (11.0) 39.9 (8.6) 23.2 (5.0) 10.7 (2.8)	37.4 (11.5) 35.8 (8.0) 22.7 (5.9) 8.95 (3.00)	23		
Milgrom et al. 2015 Australia RCT	CBT – Beating the blues before birth. 8 x 60 minute weekly individual sessions	27	32.8 (5.9)	19.9 (7.7)	BAI	22.4 (10.1)	10.4 (7.6)	23	9 M PP	Between groups BAI-0.903	Statistically significant reductions in anxiety post intervention within groups (p=<0.001) and between groups (p=0.006). Maintained at follow up.
	TAU	27	30.8 (5.9)	21.0 (5.7)	BAI	20.6 (10.7)	17.4 (7.9)	21			
Muthukrishnan et al. 2016	Mindfulness 2 x individual sessions per	37	21 (2.56)	16.2 (2.9)	PSS	30.59 (1.9)	19.05 (1.4)	N/A	No	Between groups	Significant difference in perceived stress post intervention within

India RCT	week for 5 weeks									PSS- 0.903	groups and between groups when compared with control (p=0.04).
	TAU	37	23 (2.4)	N/A	PSS	30.59 (2.1)	32.1 (2.4)	N/A			
Matvienko-Skiar & Dockray 2016 Ireland RCT (pilot)	Mindfulness/ Gratitude Accessed 4 x week over 3 weeks –online intervention	32	33.8	16.2	PDQ	29.3 (9.3)	27.9 (7.7)	24	No	Between groups: PDQ: 0.748	Significant within groups effect (p=0.04). No intervention effect (P>0.05).
	TAU	14	33.8	16.2	PDQ	23.4 (6.1)	22.8 (5.8)	12			
Richter et al. 2012 Germany RCT	CBT Group program 8x 90 minute weekly sessions	80	29.2	22.5	PDQ PSS	14.1 (5.0) 22.6 (6.5)	13.4 (5.5) 20.7 (6.5)	21	No	Within groups PDQ – 0.189 PSS 0.264	PDQ/PSS scores reduce post intervention, though not statistically (P=0.23, P=0.38). Between groups interactions did not show statistical significance.
	TAU	80	29.9	24.7	PDQ PSS	14.9 (5.6) 23.7 (7.1)	14.50 (6.1) 22.5 (7.1)	40			

Veiten & Astin 2008 Pilot RCT USA	Mindful Motherhood (Acceptance/ Mindfulness) 8 x 120 minute weekly sessions	15	33.9 (SD, 3.8)	25 (SD, 4.0)	PSS STAI	20.1 (5.1) 43.8 (12.4)	15.9 (5.7) 35.4 (9.1)	13	Yes 3M	Between groups PSS – 0.193 STAI – 0.091	At post intervention, statistically significant difference in state anxiety compared with wait-list (p=0.04), not sustained at follow-up. PSS changed over time although not statistically significant (p=0.35).
	Wait-list control	19	25	N/A	PSS STAI	17.1 (5.0) 35.6 (10.9)	16.9 (4.6) 35.6 (8.4)	18			
Zhang & Emory, 2015 USA (African-American) Pilot RCT	Mindful Motherhood (Mindfulness/ Acceptance based group therapy) 8 x 60 minute sessions twice weekly	34	25.3	21.5	PSS PES -uplift intensity -pregnancy related hassles	43.9 (10.2) 2.2 (0.5) 2.1 (0.5)	39.7 (7.46) 2.35 (0.4) 1.85 (0.4)	3	1M PI	Between groups – PSS-0.099 PES-0.686 'related hassles' and 0.141 on 'uplift intensity'	Stress reduced post intervention, though no associations between number of groups attended and stress levels with no significant results. (P>0.05). However, number of sessions was positively associated with pregnancy related distress at post intervention and follow up.
	TAU	31	N/A	N/A	PSS PES -uplift intensity -pregnancy related hassles	39.5 (8.2) 2.34 (0.5) 2.0	38.9 (8.62) 2.4 (0.3) 2.2 (0.6)	N/A			
Woolhouse et al. 2014	Mind Baby Body program	17	30.81	(Trimester 1st – 17.7%,	DASS STAI PSS	8.62 (7.72) 35.9 (14.1)	4.62 (3.95) 32.83 (7.1)	13	No	Within groups DASS	DASS anxiety significant differences (p=0.02)

Australia RCT	–Mindfulness group therapy 6 x weekly sessions			2nd – 70.6%, 3rd – 11.8)						0.087 Between groups: 0.016	within groups post intervention. No significant difference on STAI (p=0.52), PSS (P=0.6), DASS Stress (0.33) No significant difference between groups at post intervention for any measure.
	TAU	15	34.1	(Trimester 1st - 33.3%, 2nd – 53.3%, 3rd – 13.4%)	DASS STAI PSS	4.8 (5.9) 34.8 (11.5)	33.0 (12.8)	10			
Yazdanime-hr et al. 2016 Iran RCT	Intervention – 8 x 90 minute weekly sessions + one month follow-up	40	26.0 (5.8)	15.0 (1.1)	BAI	19.8 (6.3)	10.9 (4.5)	33	1M PI	Between groups 1.67	At post intervention anxiety reduced over time and reached significance within and between groups (p<0.001) and maintained at follow-up. .
	TAU	40	26.7 (4.5)	15.0 (1.2)	BAI	20.2 (6.1)	20.5 (6.76)	30			

PP – Post-partum; M – month: W – Week; AN – antenatal; PI – Post Intervention; N/A – Not available; BAI – Beck Anxiety Inventory; PSS – Perceived Stress Scale; STAI – State and Trait Anxiety Inventory; DASS; Depression and Anxiety Stress Scale; PES – Pregnancy Experience Scale: PDQ- Pregnancy Distress Questionnaire; GAS – Fear of Childbirth Scale; ASI – Anxiety Sensitivity Index; PRA – Pregnancy related anxiety; PSA – Pregnancy Specific Anxiety.

1.5 Results

1.5.1 Methodological quality of included studies

Methodological quality of each study has been summarised in Table 2.

1.5.2 Population

Socioeconomic status, age and education level have been linked to anxiety during pregnancy (Biaggi 2016). Women ranged from 19-45 years old and 4-36 weeks pregnant. Generally, there was good reporting of this, although there was significant variation in gestational age in several studies (Vieten and Astin 2008; Guardino et al. 2014; Woolhouse et al. 2014; Yazdanimehr et al. 2016). Most of the reviewed studies reported a slightly skewed sample with participants of high education level and SES which is often the case when using volunteer sampling methods. All studies examined and reported group differences at baseline except for one (Zhang and Emory 2015). Other studies mentioned differences but did not complete significance tests (Vieten and Astin 2008; Milgrom et al. 2015). One study reported differences at baseline but did not control for these (Woolhouse et al. 2014). Both nationality and ethnicity were less well reported across the studies. Extensive demographics such as relationship status, pregnancy planning and lifestyle factors including alcohol use which may be pertinent to anxiety levels and treatment benefit were collected for a small number of studies (Guardino et al. 2014; Matvienko-Sikar and Dockray 2016). Overall, studies with methodological rigour were well addressed on representativeness although this was the minority (Austin et al. 2008; Guardino et al. 2014; Milgrom et al. 2015).

Utilising strict inclusion/exclusion criteria may limit generalisability and representativeness. Studies shared exclusion criteria including severe mental disorder, substance misuse, suicidal ideation and medically high risk pregnancies. Richter et al (2012) and Bittner et al. (2014) recruited participants from private healthcare facilities only and other studies included specific populations including low income ethnic minority participants (Zhang and Emory 2015; Muthukrishnan et al. 2016). Two studies with lower methodological strength excluded participants with chronic medical conditions such as hypertension, diabetes and obesity (Muthukrishnan et al. 2016; Yazdanimehr et al. 2016). A strong study excluded participants with a history of childhood trauma (Austin et al. 2008). One methodologically strong study assessed potential participants specifically for CBT suitability (Austin et al. 2008). Studies identified participants with or at risk of elevated anxiety or stress levels (Bittner et al. 2014; Guardino et al. 2014). Woolhouse et al. (2014) included a sample which did not reach clinical significant levels. On the other hand, one study excluded participants with a diagnosis of anxiety disorder though included participants experiencing stress (Matvienko-Sikar et al. 2016).

Table 2: Risk of Bias

	1. Representative sample	2. Baseline Assessed	3. Attrition	4. Randomisation	5. Sample Size	6. Follow-Up	7. Outcome measures	8. Intervention defined	9. Fidelity	10. Therapist Training	11. Statistical analyses	12. Control Group
Austin et al. 2008	Low	Low	Low	Low	Low	Low	Low	Low	Unclear	Low	Low	High
Bittner et al. 2014 Richter et al. 2012	Low	Low	High	Low	Low	Low	Low	High	Low	Low	Low	Low
Guardino et al. 2014	Low	Low	High	Low	Low	Low	Low	Low	Low	Low	Low	High
Milgrom et al. 2015	Low	Unclear	Low	Low	Low	Low	Low	Low	Low	Low	Low	Low
Muthukrishnan et al. 2016	High	Low	Unclear	Low	High	Low	Low	Low	Unclear	Unclear	Low	Low
Matvienko- Sikar & Dockray, 2016	Low	High	Low	Low	High	High	Low	High	unclear	N/A	Low	Low
Veiten & Austin, 2008	Low	Low	Low	Low	High	Low	Low	Low	Unclear	Low	Low	Low
Woolhouse et al. 2015	Low	Low	Low	Low	High	High	Low	Low	Unclear	Low	Low	Low
Yazdanimehr et al. 2016	Low	Low	Low	Low	High	Low	Low	Low	Unclear	Low	Low	Low

Zhang & Emory 2015	High	Low	High	Low	High	Low	Low	High	Low	High	Low	Low

1. Sample selected was representative of wider clinical population
2. Participants in each condition are similar at baseline in terms of stress/anxiety levels or differences were controlled for in analyses
3. Levels of attrition were reported and equivalent for each condition
4. Randomized assignment to treatment groups
5. Sample size was sufficient for analyses relating to anxiety outcomes
6. Follow-up assessment was for a suitable time-period after intervention
7. A suitably robust and validated outcome measure
8. Intervention sufficiently defined
9. Intervention delivered as planned/compliance checked
10. The therapist delivering the intervention had adequate training/competence
11. A control group was used
12. The analysis method used was appropriate to the design used and anxiety/stress outcome measure

1.5.3 Study Design

All the studies utilised RCT methodology. Seven studies included follow-ups ranging between one month and nine months. One study included post intervention measure at different times for the control and intervention group (Woolhouse et al. 2014). Overall, studies were well addressed for their main statistical analysis. Good reporting of loss to follow-up was reported and drop-out analysis was common. Only three studies reported using statistical methods to appropriately manage missing data (Austin et al. 2008; Guardino et al. 2014; Milgrom et al. 2015) and two of the studies with high ratings completed intention to treat analysis (ITT) (Austin et al. 2008; Milgrom et al 2015). Analysis of differences between participants, who declined to participate and those who participated was available for few of the studies (Austin et al. 2008; Woolhouse et al. 2014). Guardino et al. (2014) and Woolhouse et al. (2014) reported medium attrition. Several studies, both strong and weak, noted high attrition rates (Austin et al. 2008; Richter et al. 2012 Bittner et al. 2014; Zhang and Emory 2015; Muthukrishnan et al. 2016). Stronger studies noted low attrition (Vieten and Astin 2008; Milgrom et al. 2015; Matvienko-Sikar 2016).

The majority of studies utilised treatment as usual which included obstetric support. However, two studies which were otherwise methodologically strong, used a reading control group which may have contributed to the difficulties in finding an intervention effect. (Austin et al. 2008; Guardino et al. 2014)

1.5.4 Outcome measures, randomisation and concealment

Overall, the outcome measures used had good validity and reliability in the general population with some noting validity within perinatal populations (Meades and Ayers 2011). All studies used self-report measures of anxiety and stress which reduces the need for those administering the measures to be blind to the treatment condition. Several studies made the distinction between general anxiety and PRA (Table 1).

All reports stated that the studies were randomised, but how this was achieved was not always described. Randomisation methods included use of sealed sequential envelopes, cluster random sampling method, restricted blocks randomisation, computerised programme though concealment was unclear for most of the studies. Four studies mentioned successful blinding (Austin et al. 2008; Richter et al. 2012; Milgrom et al. 2015, Muthukrishnan et al. 2016). Two studies made allowances for attrition during recruitment (Austin et al. 2008; Yazdanimehr et al. 2016). A few studies simply reported participants were ‘randomly assigned’ with no further information (Zhang and Emory 2015; Muthukrishnan et al. 2016).

1.5.5 Interventions

Although several studies included similar psychosocial components in their interventions, only four studies evaluated similar interventions (Vieten and Astin 2008; Richter et al. 2012; Bittner et al; 2014; Zhang and Emory 2016). Interventions were of varying formats though predominantly group based.

Duration of interventions varied between four and eight weeks. Interventions included weekly sessions lasting between 30 minutes and 120 minutes; one study included two sessions weekly (Zhang and Emory 2015). Timing of interventions also varied between first and third trimester. Studies varied in terms of participants being classed as completers, for one study it was as low as attending 50% of sessions (Richter et al. 2012). Stronger studies had higher treatment completion rates (Milgrom et al. 2015) than those with less rigour (Zhang and Emory 2015).

Whilst all studies provided an intervention outline to varying degrees, it is unlikely that the studies could be replicated in all important aspects with this information alone. One study provided a reference to a manual for facilitators (Woolhouse et al. 2014) whilst others made comment to a manual although this was not available for the reviewer (Austin et al. 2008; Vieten and Astin 2008; Guardino et al. 2014; Milgrom et al. 2015; Matvienko-Sikar and Dockray 2016). One intervention was delivered online and stated that audio tracks were available upon request (Matvienko-Sikar and Dockray 2016). Two studies referred to fidelity checks including supervision, observations and session checklists (Bittner et al. 2014; Milgrom et al. 2015). All studies reported therapist training in relation to the intervention except for one (Muthukrishnan et al. 2016).

1.5.6 Effectiveness of interventions

Effect sizes at pre-and post-intervention between groups were calculated to allow comparison across studies (Table 1). Effect sizes could not be calculated for Austin et al. (2008) due to insufficient details despite efforts to contact the authors.

Despite many studies calculating priori power calculations, it is likely that many sample sizes were too small to find a significant difference between the conditions (Table 2). Studies with lower ratings only had 56% (Muthukrishnan et al. 2016) and 50% chance (Zhang and Emory 2016) of detecting a moderate effect size. A stronger study, Yazdanimehr et al. (2016) had similarly a 49% chance to detect an effect size (0.5).

Considering heterogeneity already mentioned, we must consider our findings with caution. When considering group interventions, overall, they appear to be methodologically more robust than other delivery methods. Online interventions appear to be methodology weaker; however, interestingly a

between-groups difference and large effect size was found. It is important to note that methodologically weak studies tend to overstate findings which may be the case.

Seven studies, including both methodologically strong and poor studies, found a statistically significant time effect whilst five studies observed a statistically significant intervention effect in terms of reduction in scores over time compared to control studies (Table 1). Stronger studies found intervention and time effects in PRA (Guardino et al. 2014; Milgrom et al. 2015) compared to less rigorous studies who did not find significant difference in PRA (Richter et al. 2012; Woolhouse et al. 2014). Two studies using bibliotherapy did not find statistically significant differences between groups (Austin et al. 2008; Guardino et al. 2014).

1.5.7 Critical appraisal of the evidence that cognitive behavioural based interventions are effective in reducing stress and anxiety in pregnant women.

Overall, seven studies found statistical improvements in anxiety or stress scores in the intervention group compared to controls at post-intervention (Table 1), of these three were maintained at follow-up in the stronger studies (Guardino et al. 2014; Milgrom et al. 2015; Yazdanimehr et al. 2016). The sample sizes for several of these studies were relatively small suggesting the significant differences found were not due to large samples being used. All studies but four reported that intervention reduced anxiety and stress levels within groups (Table 1). Despite this, one study with low methodological rigour found a between groups time effect for stress (Muthukrishnan et al. 2016).

Studies with high methodological rating (Austin et al. 2008; Guardino et al. 2014) did not find improvements in general anxiety compared to control. Reasons for this may be due to use of control acting as bibliotherapy intervention. Studies which measured PRA found intervention and time effect for well-designed study by Guardino et al. (2014). Studies with lower rigour did not find significant differences on PRA between groups.

Several studies, despite using outcome measures rated by an observer and high methodological ratings, did not make any reference to concealment to allocation (Austin et al. 2008; Woolhouse et al. 2014) It may therefore be possible that the results of these studies were biased by observers. Some studies included post-intervention and follow-up though it was difficult to ascertain whether this follow-up was within the antenatal period or post-partum (Table 1). Some studies included ITT analysis although it was unclear how missing data was managed. Some studies addressed clinical representativeness of the sample well and of these, only one demonstrated a significant impact of the intervention over the control (Table 2).

Most studies used appropriate statistical analysis though improvements could be made in the reporting of randomization, blinding and controlling for drop-out and baseline differences. Methodologically

weak studies included participants in statistical analysis that attended only a low number of sessions 50% of sessions (Richter et al. 2012). It may be that this may effect finding differences as participants did not receive the full treatment 'dose'.

1.6 Discussion

The current systematic review examined the clinical effectiveness of randomised controlled antenatal CBT based interventions in reducing anxiety/stress compared to control.

Seven of the included studies, both methodologically weak and strong, found a significant time effect improvement in anxiety/stress levels whereas only five studies found an intervention effect. Four studies did not find any statistically significant difference for either time or intervention. Surprisingly, two studies with methodology strength did not find an intervention effect whilst one of the weakest studies noted between groups effect. Methodological limitations such as small sample size, lack of follow-up, high attrition and lack of representative sample reduce the generalisability of study findings. These findings are similar to previous reviews in perinatal population (Lavender et al. 2016; Marchesi et al. 2016). Indeed, many of the difficulties with drop out, lack of generalisability and poor reference to concealment are common across health care interventions.

1.6.1 Implications for practice and research

Despite emerging studies exploring effective interventions in reducing psychological distress, the evidence base should be interpreted with caution due to methodological weaknesses and equivocal results; therefore, future research will benefit from adequately powered RCT studies where representative samples receive full treatment and include follow-up.

Considering group interventions in our review were methodologically more robust that other methods of service delivery, we therefore recommend that interventions for pregnant women, where possible, should be delivered in person in group or individual formats rather than using modern technology. Further research must be done to further explore key aspects of care for women during this period.

Drop-out levels are high in this population with popular reasons including premature delivery, time constraints and lack of transport (Austin et al. 2008). As such, brief interventions are required to maximise treatment effects at a time of high commitment and pressures. Considering current societal and economic pressures, it is important to provide cost effective, accessible and brief interventions for pregnant women.

Across studies, we found key themes and components of interventions in studies with greater methodological rigor. Consequently, we would recommend that any future interventions include

cognitive strategies such as restructuring where thought processes are challenged or Mindfulness strategies where though processes are encouraged to be accepted as they are; the latter was more commonly used within our studies. In addition, traditional behavioural strategies including relaxation exercises were common across studies and would be recommended in future interventions. An important goal of future research will be to further explore the mediators and active ingredients of effective brief interventions.

Our studies often lacked representativeness. Little research explores nationality and ethnicity differences, despite literature suggesting poor perinatal outcomes and barriers to treatment including stigma and issues related to cultural understanding (Leis et al. 2011; Zhang and Emory 2015). It would be helpful to further explore specific risk factors in pregnancy including age, previous delivery, education level and ethnicity which all may play an important role in the rate of treatment gains and increasing representative samples. Our findings confirm that general anxiety and pregnancy specific anxiety is common during pregnancy, therefore clinical screening should be widely utilised in services to detect and treat women experiencing anxiety. Women varied at baseline levels of anxiety in several studies and women with more significant anxiety may need higher intensity intervention than those with lower levels therefore further exploration of this would be useful.

Improving the reporting of methodology in studies will allow reviewers to come to more accurate and useful conclusions. Furthermore, it is important to have sufficient detail of the intervention for replication within the intervention and to ensure fidelity which the majority of studies did not report.

1.6.2 Strengths and limitations of this review

This review has several limitations: the reviewed studies may lack generalisability due to interventions being delivered at varying stages during pregnancy as well as employing different intervention characteristics. There was a mix of individual and group intervention formats with varying intervention lengths studies with some offering follow-up sessions. Group interventions may increase risk of confounding variables but may also provide added value of peer support. Furthermore, all studies relied on self-report measures which could lead to response bias.

In most studies, women had elevated levels of anxiety which was specified by cut-offs in some studies. However, anxiety is known to fluctuate during pregnancy anyway resulting in greater importance of control group. Some studies targeted at risk participants and some who included a mix of participants reached clinical significance whilst others did not. It is well established lower levels of difficulties are harder to detect.

Our studies included a wide range of nationalities including American, European, Australian and Asian participants with specified inclusion criteria stated in some studies (e.g. Indian women and African-

American women). Consequently, it is important to note possible cultural factors that may influence treatment outcomes and adherence. It has been proposed that specific cultures and ethnic minority groups face further challenges in terms of treatment gains and potential barriers related to cultural understandings and stigma (Leis et al. 2011). Therefore, it is not surprising that we found studies including ethnic minorities to have higher drop-out and attrition rates and further research must explore this. This heterogeneity between studies in terms of nationalities and cultures as well as lack of representativeness is a further limitation.

This review restricted its search to solely English language papers and while this has been justified due to resource limitations, it may mean some research has been neglected.

A strength of this review is the specificity with which it has been conducted. Research focussed on psychological interventions delivered in the antenatal period has become more abundant in recent years therefore it is useful to have a narrow scope such as focussing on CBT interventions and RCTs. Another strength of this review is a proportion of the included studies were also analysed and reviewed by an independent reviewer.

Perhaps unsurprisingly, studies exploring psychological distress during pregnancy predominantly focus on women. However, emerging research suggests that partners too experience prenatal psychological distress during pregnancy with rates estimated at 10% (Singley and Edwards 2015). One of the studies in this review included partners and perhaps further research on this area would be helpful.

Clinical screening for anxiety and depression during pregnancy is widely recommended; however, opportunities to identify women experiencing psychological distress and offer treatment are often missed (NICE 2014; WHO 2016). Existing systems within pregnancy care have been called into question over their ability to effectively identify mental health need (Vesga-Lopez et al. 2008; Goodman and Tyer-Viola 2010).

1.7 Conclusions

This review used systematic review methodology to provide an evidence-based evaluation of the effectiveness of antenatal CBT interventions aimed at reducing anxiety and stress. While this review demonstrates preliminary evidence in support of the use of antenatal CBT based therapies against controls, there must be consideration of how to conduct more methodologically robust studies with larger sample size, lower attrition rates, greater representative samples with follow-up.

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2. Evaluating the effectiveness of a one-off brief CBT intervention for pregnant women delivered in the antenatal period in reducing anxiety.

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2.1 Abstract

Purpose: Pregnancy is a time of significant change and adjustment for women and families. Research to date has focussed on perinatal depression despite recent findings indicating anxiety is more common during pregnancy. Cognitive behavioural therapy is commonly used in the treatment of anxiety in the general population. Little is known about the effects of a brief approach for anxious women during pregnancy. The present study therefore aimed to evaluate the effectiveness of a single three-hour session introducing cognitive behavioural techniques to reduce anxiety, other pregnancy related distress and improve general well-being and birth outcomes.

Methods: Participants completed outcome measures at baseline, two weeks' post-intervention and follow up at 2 months' post-partum. In total, 29 participants with clinically significant levels of anxiety completed the study. A matched control group was derived from historical dataset collected locally, a total number of 37 datasets were matched for baseline levels of anxiety.

Results: The results were analysed using mixed ANCOVA, one-way repeated measures ANOVA, chi square analysis and Kruskal Wallis. Complete case analysis showed clinically significant improvements (p<0.05) in anxiety over time with a large effect size (d=0.7); however, these differences were also found in the control group (p=<0.05). There was no between-group interaction when controlling for baseline differences in age (p>0.05). Intention to Treat analysis found more modest within group changes and similar non-significant between-groups differences with small effect size. Significant improvements over time were also noted in pregnancy-related anxiety compared to baseline (p<0.05). Furthermore, women rated their birth experience of childbirth similarly regardless of delivery mode (p>0.05).

Conclusions: This study provides proof of recruitment methodology and further research with methodological robustness is warranted.

Keywords: anxiety; distress; pregnancy; antenatal; cognitive-behavioural therapy

2.2 Introduction

Anxiety is common during pregnancy, with prevalence rates varying between 10-41% (Goodman and Chenausky 2014; Fairbrother et al. 2016; Marchesi et al. 2016) with the highest levels of anxiety generally being in the first and third trimesters (Ross and McLean 2006; Goodman and Chenausky 2014; Rubertsson et al. 2014). It is reported that only 1 in 12 cases have no previous history of anxiety (Marchesi et al. 2016). Considering the overwhelming majority of women have experienced significant historical anxiety, it is unsurprising that there are ongoing disagreements about whether pregnancy-related anxiety (PRA) is a distinct disorder or closely related to generalised anxiety disorder (GAD) (Huizink et al. 2004; Goodman et al. 2014; Brunton et al. 2015).

Maternal anxiety is associated with poor quality of life for women, partners and children (Dunkel-Schetter and Tanner 2012; Guardino et al. 2014; Rouhe et al. 2015). Anxiety is strongly associated with poorer pregnancy outcomes, development of insecure attachment, slower emotional, cognitive, social and neuro development and increased risk of impulsivity and behavioural problems in childhood (Van den Burgh et al. 2004; Alder et al. 2007; Dunkel-Schetter and Tanner 2012; Goodman et al. 2014; Rubertsson et al. 2014; Marchesi et al. 2016). Despite this, mental health difficulties often go undetected and untreated in the antenatal period (Alder et al. 2007; NICE 2014). Around 50% of women who are anxious during pregnancy remain so post-partum (Heron et al. 2004; Wenzel et al. 2005; Austin et al. 2008; Grant et al. 2008; Goodman et al. 2014).

Age, lower socioeconomic status, lack of social support, being a member of an ethnic minority, lower educational attainment and history of anxiety are all associated with a greater probability of anxiety during pregnancy (Biaggi et al. 2016). Furthermore, severe anxiety including tokophobia (fear of childbirth) is more common among women with anxious temperaments and history of trauma (Bhatia 2012).

Recent systematic reviews identified the most effective treatments for generalized anxiety disorder (GAD) to be cognitive behavioral based therapies and acceptance based treatments (Tyrer and Baldwin 2006; Hunot et al. 2007; NICE 2016; Kazcurkin and Foa 2016). In recent years, systematic reviews have identified emerging research within the perinatal population which has been characterized by design limitations including lack of control groups, lack of follow-up, non-randomised designs, small sample sizes and concerns have been raised about publication bias (Ross and McLean 2008; Alderice et al. 2013; Goodman et al. 2014; Lavender et al. 2016; Matvienko-Sikar and Dockray 2016; Marchesi et al. 2016; Taylor et al. 2016; Wadephul et al. 2016).

A study exploring the effectiveness of group CBT for antenatal anxiety by Green (2015) found a significant reduction in anxiety over time. Austin et al. (2008) developed a brief CBT approach and noted reductions in anxiety though similar reductions were observed in the control group. Further recent studies have found significant treatment time effects; however, findings were limited due to small sample size, high attrition and lack of follow-up and when control was used no group effect was found (Richter et al. 2012; Bittner et al. 2014; Hall et al. 2016; Taylor et al. 2016; Matvienko-Sikar and Dockray 2016). Studies focused on mind body techniques such as deep relaxation have found preliminary evidence of effectiveness though often lack robust psychological foundations (Urech et al. 2010; Marc et al. 2011; Tragea et al. 2014).

Whilst standard CBT, typically delivered over four to eight sessions, is successful in treating anxiety in the general population, recent evidence has suggested that single session CBT may also be effective (Hoyt et al. 2014; Dryden 2016). Single session CBT challenges the traditional view of therapy and relies on a principle based definition of CBT rather than a protocol time specified approach (Fenn, 2013). However, several meta-analyses suggest that treatment effect increases with session number (Hoffmann, 2012). Studies using one session CBT for specific phobias as well as trauma, older adults and clinical health populations found some positive findings (Ost, 1987; Kunik et al. 2001; Martin et al. 2007; Zlomke & Davis 2008; Gherman, Alionescu & Sucala 2017); however, methodological flaws including lack of control group, small sample sizes and lack of follow-up cast doubt on results. In addition, it has been argued that low intensity approaches fail to find significant intervention effects (Hoffmann et al. 2006). Conversely, a recent meta-analysis (Hazel et al. 2016) highlights methodologically robust studies finding promising results from low intensity CBT based approaches.

Traditional interventions aimed at pregnant women are especially challenged by the burdens of time, travel, and cost associated with multiple visits to various medical appointments which may stand as barriers to care, thus leaving anxiety untreated and risking harm to the mother and fetus. Furthermore, medical complications and early deliveries may further prevent women attending more traditional formats of CBT. Perhaps unsurprisingly, previous studies including pregnant women have been limited by high attrition rates creating a bias due to participants not receiving the full 'treatment dose'. While observing the need to improve treatment efficiency as outlined by NICE (2015) and considering the pragmatic needs of this population, we found no reports of a single-session treatment that solely targets anxiety during pregnancy. It was hypothesised that a one session CBT approach would be highly accessible intervention format for this population.

In summary, anxiety is common during pregnancy and the impact can be profound. There is a lack of evidence to guide treatments during this time and yet pregnancy provides a unique "window of opportunity" where women are particularly motivated to engage in health improving interventions (Austin et al. 2008). In the current economic climate, it is especially important to identify brief, cost effective, accessible and early interventions (NICE, 2016).

2.2.1 The current study

This study sought to address some of the limitations of previous research including intervention drop-out and lack of follow-up by adapting and evaluating a brief single-session CBT intervention delivered fully in the antenatal period with the aim of reducing general anxiety in pregnant women. It was hypothesised that the brief CBT intervention would reduce general anxiety both post-intervention and postnatally. Furthermore, it was hypothesised that a brief CBT intervention would reduce pregnancy related anxiety and improve general well-being and pregnancy outcomes.

2.3 Methodology

Ethical approval for this trial was given by Leicester South Research Ethics Service Committee, East Midlands (Project ID 1911319) and the NHS Grampian Research and Development Department.

2.3.1 Participants

Participants were a volunteer sample of pregnant women recruited at Aberdeen Maternity Hospital between July 2016 and February 2017. Eligible participants were pregnant women over the age of 18 years of age, sufficiently literate in English, and who were experiencing elevated levels of anxiety (HADS-A ≥8); this cut-off reflects mean scores on this measure for the clinical population. Women were excluded if they had severe and enduring mental health difficulties and were unable to provide informed consent.

2.3.2 Recruitment

As part of a routine care pathway, community midwives offer pregnant women in Grampian a stress reduction session based on cognitive behavioural techniques. Those who registered for this during the study period received an invitation to participate and those interested were screened for eligibility.

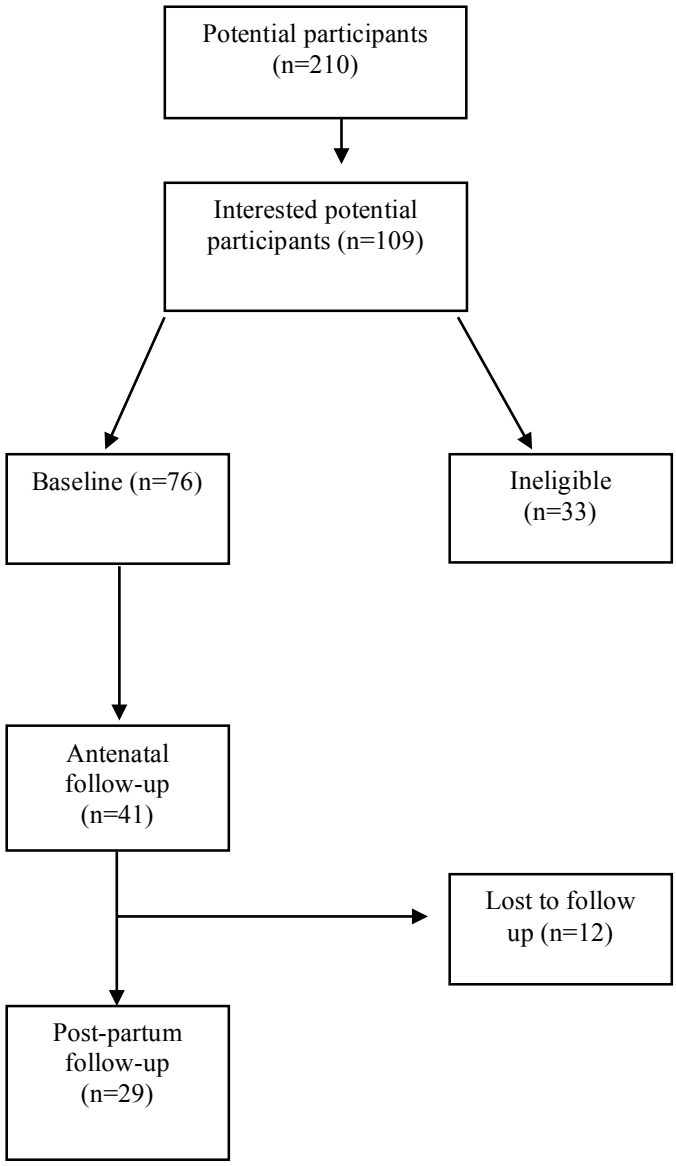

Fig. 1 Diagram showing flow of participants

2.3.3 Procedure

After determination of eligibility, participants were asked to complete baseline questionnaires before the session (Time 1). Antenatal follow-up questionnaires were completed at 2-weeks post-intervention (Time 2) and 2-months post-partum (Time 3).

2.3.4 Intervention

This study was registered with clinical trials (NCT03103217). The intervention was a 3-hour stress reduction session introducing cognitive behavioural techniques and led by senior midwife, and co-facilitated by a trainee clinical psychologist with a MSc in CBT approaches. The intervention was reviewed in collaboration with a senior midwife, trainee clinical psychologist, an NHS consultant health psychologist and a lecturer in health psychology. The intervention was delivered at the local maternity hospital. Fig. 2 details the contents of the session; further details are available on request. The intervention was delivered in a discursive way.

Session Outline
- Introductions/Hopes & expectations
- Introducing the CBT model
- Biological foundations
- Stress: the CBT perspective
- Stress & giving birth: biopsychological considerations
- Using CBT approaches to manange stress
- Practising the skills: four CBT approaches
- Revisiting learning points
- Planning for the future: developing the skills for a positive experience during pregnancy, birth and into early years.

Fig. 2 Outline of intervention

2.3.5 Control

The matched control group was derived from a historical dataset collected 24 years ago at the same maternity hospital in Aberdeen as part of a PhD research project on maternity care systems (Glazener et al. 1993). This cohort consisted of 125 pregnant women, who completed a range of questionnaires including the HADS during and following pregnancy. Birth outcome data was also collected. A total number of 37 datasets were matched for baseline levels of anxiety.

2.3.6 Data collection and outcome measures

Measures of anxiety, depression, pregnancy-related anxiety and general well-being were measured at baseline, 2-weeks post-intervention and at 2-months post-partum.

The Hospital Anxiety and Depression Scale (HADS) is a self-report measure of anxiety and depression (Zigmond and Snaith 1983). The 7 item HADS-A subscale was used as the primary outcome measure

to measure of general anxiety, with scores ≥8 indicating clinically significant levels of anxiety. The measure takes approximately five minutes to administer, and validation studies indicate that Cronbach's alpha for HADS-A varied from 0.68 to 0.93 and for HADS-D from 0.67 to 0.90 (mean.82) in general population (mean 0.83) and between 0.62 and 0.78 across perinatal studies (Bjelland et al. 2002; Karimova and Martin 2003).

The Pregnancy Related Anxiety Questionnaire – Revised (PRAQ-R2) is a ten-item measure devised to diagnose the psychological anxiety specific to pregnancy suitable for both nulliparous and parous women (Huizink et al. 2016). This measure is a shortened version of the Pregnancy Related Anxiety Questionnaire (PRAQ) (Huizink et al. 2004). Cronbach's alpha's was reported above 0.8 for total scale in both first time and previously pregnant women (Huizink et al. 2016).

The Warwick Edinburgh Mental Well-Being Scale (WEMWBS) is a measure of well-being that includes positively worded items related to feelings and functioning (Tennant and Hiller et al. 2007). Each item has five response categories, summed to provide a single score ranging from 1. WEMWBS showed good content validity and Cronbach's alpha was measured in both student and general populations with scores of 0.89 and 0.91, respectively (Tennant and Hiller et al. 2007).

The Childbirth Experience Questionnaire (CEQ) measures four domains of childbirth experience including, perceived safety, professional support, own capacity and participation (Dencker et al. 2010). Originally designed in Scandinavia, this measure has been validated for use in the UK (Walker et al. 2015). A statistically significant higher CEQ score for subgroups of women known to report a better birth outcome demonstrated construct validity of the CEQ in two subscales. Cronbach's alpha was ≥ 0.70 for all subscales and 0.90 for full subscale in the English language version (Walker et al. 2015).

Type of delivery was recorded and whether medical intervention was required. Basic patient demographics were collected (age, gestational age, parity, socioeconomic status)

2.3.7 Statistical Analyses

Power calculations indicated a sample size of 58 was required to detect treatment effects, assuming power = 0.95, significance set to 0.05, and an effect side of $d = 0.4$ based on similar research (Kunik et al. 2001).

One way repeated measures ANOVA and post hoc tests were used to evaluate the main effect of time on depression, PRA and wellbeing in the intervention group. A mixed ANCOVA was used to evaluate

the effect of the intervention across time on general anxiety controlling for differences in age. Chi square analysis and Kruskal Wallis measured pregnancy outcomes.

We did attempt to follow-up all individuals who completed baseline measures but observed high drop-out rates. Analysis of covariance on complete cases intervention effect (Table 2) was compared with intention to treat analysis (ITT) using last observation carried forward methods (Table 3). There was no difference between missing and observed values, once adjusted for baseline variables.

2.4 Results

Analysis included 29 who completed all three time points. Characteristics of participants are shown in Table 1. The intervention group were older, more likely to be having their first baby, were further into their pregnancies at baseline, and had a higher level of education.

Table 1 Group characteristics

	Control (N=37)	Intervention (N=29)	Difference Between groups
	Mean (SD)	Mean (SD)	*P*-value
Age (years)	26.3 (4.1)	31.25 (3.1)	<0.01
Gestation (weeks)	12.2 (3.3)	32.9 (2.8)	<0.01
	Participants (%)	Participants (%)	
First pregnancy	52%	72%	0.33
Previous pregnancies	48%	28%	
Education level			
Secondary	75.7%	20.7%	
Further Education	24.3%	79.3%	<0.01

Table 2 and 3 shows changes (complete case analysis & ITT) in general anxiety, PRA, general well-being and depression from baseline to post-treatment and follow-up. Following treatment, women participating in the CBT session showed statistically significant decreases in anxiety with a large effect size observed from complete case analysis whilst a more modest medium effect was found following ITT. This finding was also observed in the control group. Post hoc tests using the Bonferroni correction revealed that brief CBT intervention elicited a reduction in anxiety from pre-intervention to 2 weeks following the intervention and from pre-intervention to 2-months post-partum. Anxiety scores reduced with a shift from the 'clinical' to 'sub-clinical range' for both groups.

Changes in the expected direction were observed in the intervention group for pregnancy related anxiety between baseline and post-intervention with a small effect size detected. However, the effect size was once again reduced following ITT. Reductions over time with small effect sizes were noted for both well-being and depression, between baseline and post-intervention and baseline and follow-up; however, these did not reach statistical significance.

Contrary to hypotheses, after adjustment for age of participants, there was no significant group across time interaction found in anxiety in either analysis (P>0.05). The control group also noted similar significant main effect of time, such that both groups experienced significant decreases in general anxiety from Time 1 to Time 2 and from Time 1 to Time 3 (Fig.3).

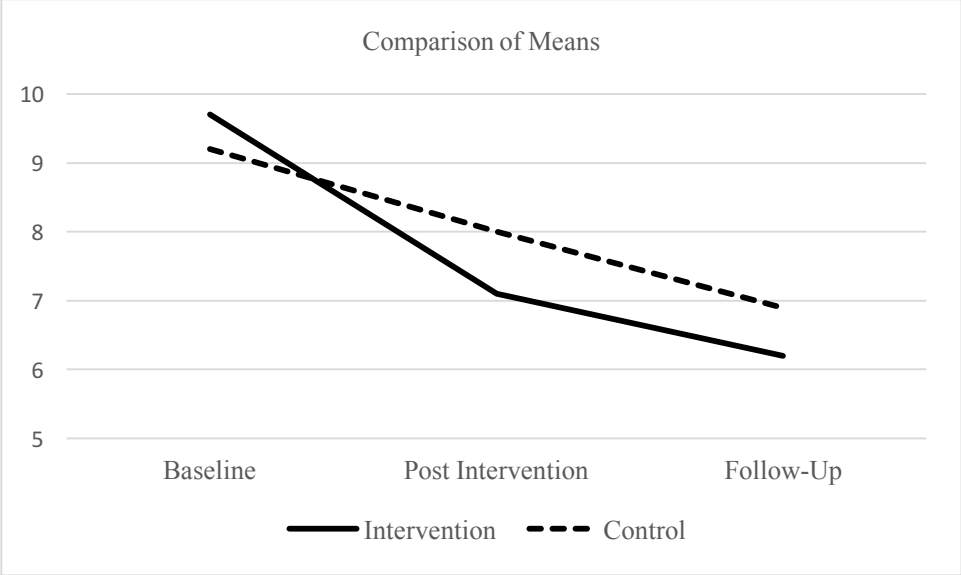

Fig.3 Comparison of mean anxiety scores

Of our sample, 52% delivered naturally and 48% required medical intervention during delivery. There was no significant difference on delivery when compared to historical data (p=0.186). Between 2015 and 2016, in Aberdeen Maternity Hospital, of the general population, 52% delivered naturally whilst 48% required medical intervention. When considering child birth experience, there was no significant differences in scores between those who required medical intervention such as CS or forceps and those who delivered naturally (p=0.48). This remained the same across different domains including capacity (p=0.172), professional support (p=0.61) and participation during labour (p=0.21).

Comparing both sets of results, it may be that complete case analysis inflated effect sizes with regards to PRAQ and anxiety.

Table 2: Treatment effects on psychological distress severity (Complete case)

	Pre-scores	**Post-scores**	**Follow-up**	**Within groups ANOVA (pre-follow-up)**			**95% *CI***	**Between-group ANCOVA**		
	Mean (SD)	*Mean (SD)*	*Mean (SD)*	*F*	***p* value**	ES (Cohen's *d*)		*F*	***p* value -**	ES (Cohen's *d*)
HADS-A										
Intervention*	9.7 (2.1)	7.1 (2.8)	6.2 (3.6)	N/A	<0.01	-0.93	(1.29 -0.55)	(1,63)	0.56	0.2
Control*	9.2 (1.5)	8.0 (3.9)	6.9 (3.4)	N/A	<0.01	0.81	(-3.2--1.5)	0.32		
HADS- D	4.31 (2.2)	3.8 (2.4)	3.6 (2.3)	(2,56) 1.3	0.29	-0.18	(0.46-0.10)	N/A	N/A	N/A
PRAQ-R2	31.3 (8.7)	28.5 (8.9)	N/A	(1,28) 14.4	0.01	-0.32	(0.50-0.13)	N/A	N/A	N/A
WEMBS	51.9 (8.4)	50.5 (6.1)	51.4 (8.9)	(1.3, 37) 0.3	0.64	-0.07	(0.36-0.23)	N/A	N/A	N/A

*Adjusted values from general linear models using observed data are tabled. Models controlled for baseline age of participants.

Table 3: Treatment effects on psychological distress severity (Intention to Treat)

	Pre-scores	**Post-scores**	**Follow-up**	**Within groups ANOVA (pre-post)**			**95% *CI***	**Between-group ANCOVA**		
	Mean (SD)	*Mean (SD)*	*Mean (SD)*	*F*	***p* value**	ES (Cohen's *d*)		*F*	***p* value -**	ES (Cohen's *d*)
HADS-A										
Intervention (N=76)*	9.3 (2.0)	7.4 (2.8)	7.1 (3.2)	N/A	<0.01	-0.74	(0.97--0.50)	0.86	0.43	0.2
Control (N=37)*	9.2 (1.5)	8.0 (3.9)	6.9 (3.4)	N/A	<0.01	-0.63				
HADS- D (N=76)	4.4(2.2)	4.0 (2.3)	3.9 (2.3)	(1.7,131.2) 4.069	0.02	-0.04	(0.16 – 0.09)	N/A	N/A	N/A
PRAQ-R2 (N=76)	30.09 (9.04)	29.42 (8.62)	N/A	(1,75) 1.65	0.20	0.08	(0.19 – 0.04)	N/A	N/A	N/A
WEMBS (N=76)	50.83 (5.75)	51.5 (7.35)	51.84 (7.43)	(1.5, 115) 1.43	0.24	0.11	(0.04 -0.26)	N/A	N/A	N/A

*Adjusted values from general linear models using observed data are tabled. Models controlled for baseline age of participants.

2.5 Discussion

From our complete case analysis and ITT, significant drops in anxiety were found pre and post intervention which was maintained at follow up in both groups. Our analysis revealed no statistically significant interaction between group and time on anxiety scores whilst controlling for age. A large effect size was observed in the intervention group in our complete case analysis but this may have been inflated as reduced to a medium effect following ITT. Studies suggest that anxiety will commonly increase during third trimester towards delivery date or at least remain stable (Heron et al. 2004; Lee et al. 2007; Teixeira et al. 2009). Our findings are contrary to the 'U-pattern' of anxiety during pregnancy (De Costa et al. 1999; Teixeira et al. 2009; Lee et al. 2007). Despite high rates of continuing anxiety into post-partum (Heron et al. 2004), it is interesting that findings were maintained at follow-up for both groups. The intervention was found not to be effective when compared against the control. Anxiety levels significantly reduced in both groups therefore we accept the null hypothesis.

Whilst well-being scores increased over time these did not reach clinical significance in either analysis. Similarly, depression reduced significantly over time although scores remained within 'normal range'; this may be due to low baseline scores. Which leads us to suspect that our complete case analysis resulted in inflated effect sizes"

Changes in the expected direction were observed for both PRA and general well-being with small effect sizes observed. Despite this, PRA reached statistical significance only in complete case analysis. This is an important finding as increasing evidence suggests anxiety related to pregnancy is a particular risk to mothers and child (Orr et al. 2007). Depression scores (HADS-D) improved over time though did not reach statistical significance. HADS-D scores may be inflated due to the somatic orientated questions which may be a consequence of pregnancy/motherhood rather than truly reflective of depression. There was no significant difference on pregnancy outcomes between the control and intervention group though research indicates that caesarean rate has tripled between 1975 and 2016 (ISD, 2016). Possible explanations for this rise include demographic changes, differences in clinical practice and women's choices. Furthermore, anxious women will have 20% higher risk of requiring medical intervention during labour (ISD, 2016). Increasing importance is being placed on experience during childbirth regardless of delivery mode (Duncan and Bardacke 2013). Interestingly, women in the intervention group rated similarly on childbirth experience regardless of delivery type which is contrary to previous literature indicating that higher rating is associated with natural delivery (Walker et al. 2015). Previous research indicates that women who require medical intervention during delivery score lower on childbirth experience (CEQ) than those who deliver naturally (Walker et al. 2015). Our study found no significant differences in scores, perhaps indicating that women rated child birth experience similarly regardless of delivery mode.

Our results are similar to other studies using a CBT approach during pregnancy; however, these include longer treatment duration and included participants with higher baseline anxiety levels (Austin et al. 2008; Bittner et al. 2014; Richter et al. 2012; Green et al. 2015). Our study attempted to address these issues in the context of cost and time pressures in health services and the need to meet clinical need in a timely manner within the antenatal period. This kind of brief intervention approach may lend itself well to a stepped care model of service delivery (Williams and Martinez 2008). Although we noted some large effect sizes and significant results within-groups for both control and intervention, our non-significant between-group findings may align with existing research where low intensity CBT approaches find lower effect sizes and fail to find a difference between groups. However, due to the clear need for this service, further research should be done on brief and single session CBT interventions for pregnant women.

An important strength of this study is the use of a 2-month follow up within the post-partum period demonstrating participants had maintained treatment gains. Furthermore, 50% of approached participants declined to participate though this is a common finding in perinatal settings (Carter et al. 2005). However, our response rates from women following birth are higher than previous research (Austin et al. 2008). A longer follow-up would have been more informative but unfortunately not possible due to pragmatic constraints. Use of control group in intervention studies is important and therefore a strength of the study. Despite ongoing debate around PRA (Huizinck 2004), a further strength of this study is the inclusion of measurement of both general anxiety and PRA.

The study has some important limitations. Firstly, there are significant differences at baseline between groups which may have increased risk of bias and increased type I error which may have contributed to treatment outcomes. In an attempt to address this, baseline anxiety was used to better match the control and intervention groups. However, groups remained significantly different on gestation age and age, probably reflecting changing trends pregnancies across the intervening 25 years (ISD, 2015). Therefore, a covariate for age was employed to further control for confounding variables. No further covariates were used due to the possible dilution of power. Differences at baseline in gestational age were not of serious concern due to the similar levels of anxiety expected at both first and third trimester. Similarly, historically, education level was not necessarily indicative of intelligence due to inaccessibility of higher education for many, therefore there were low concern over baseline difference.

Use of control is advocated in clinical trials in order to differentiate outcomes by the intervention or outcomes caused by other factors such as natural recovery or participation effects. However, lack of parallel treatment for both groups raises the possibility of additional historical confounding variables. Furthermore, lack of randomisation leading to increased risk of bias in our study. Employing historical controls increases the risk of finding superior intervention effects when using this type of comparator than those using more robust study design (Viele et al. 2014). This was mainly due to differences in

outcomes for the control groups, with historical controls generally doing worse than randomized controls. It is also important to keep in mind the considerable changes over the past two decades including health care systems, society, support and demographics of pregnant women with a shift towards older women. Further historical differences including increased financial pressures, single parenting and the advertisement of pregnancy ideals leads to a unique set of challenges for pregnant women. Furthermore, research participation, measurement effects and natural recovery may have contributed to anxiety reductions within the control group leading them to become more aware of their own thoughts. While the researcher made every effort to ensure independent and robust evaluation of participants' self scores, possible biases like simulation may have influenced the data. Similarly, the lead researcher co-facilitated the research trial which may have attributed to a further response bias. Our study has limited generalisability as it took place in one centre in the North of Scotland and the sample size was relatively small. Furthermore, our sample incorporated a relatively homogenous group where participants tended to be from areas of low deprivation.

Unfortunately, relatively large attrition rates were noted at both antenatal and post-partum follow-up; this perhaps reflects a time in women's lives of high commitments and would need to be factored in to the design of a definitive trial.

Interventions which are started earlier in pregnancy are likely to have greater benefit due to risk of early delivery and complications as pregnancy progresses (Guardino et al. 2014). In our intervention group, most women were in their third trimester. Considering early pregnancy is also a high-risk period for anxiety (Lee et al. 2007) perhaps research focusing on skills based early intervention may add to healthcare benefits.

Several avenues for future research exist. Firstly, further studies utilising brief intervention, large sample size, randomisation and a robust control group are required. High risk populations have been identified within perinatal populations both with physical complications and enduring mental health difficulties; future research should explore the needs of these populations. Similarly, hard to reach populations such as those with social complexities and high deprivation are important to target and provide accessible services in an attempt to meet clinical need and reduce long term costs across sectors. Developing screening for anxiety and depression during pregnancy is widely recommended, however, this poses challenges within pressurised services and many women with difficulties go undetected (NICE 2014; WHO 2016). Further work must be done to allow a system of care which lends itself to detection and treatment of anxious women using simple, effective and brief treatments approaches at this important time where possible.

2.6 Conclusions

Despite the above methodological issues mentioned, to the best of our knowledge, this study is the first empirical investigation examining a brief one off CBT stress reduction intervention to anxious pregnant women. Preliminary findings indicate that this recruitment design may be feasible and so larger more sophisticated studies are warranted.

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Appendix A: Journal author guidelines

Archives of Women's Mental Health
Editor-in-Chief: Anita **Riecher-Rössler**
ISSN: 1434-1816 (print version)
ISSN: 1435-1102 (electronic version)
Journal no. 737

Instructions for Authors

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Original Contributions / Research Articles should be arranged into sections conforming to standard scientific reporting style, i.e. under the following headings: Abstract: Should not exceed 150–250 words and be structured as follows: Purpose, Methods, Results, Conclusions Keywords: Not more than five, separated by semicolons - Introduction: A brief outline of the background literature leading to the objective(s) of the study - Materials and Methods: Describe the basic study design. State the setting (e.g., primary care, referral center). Explain selection of study subjects and state the system of diagnostic criteria used. Describe any interventions and include their duration and method of administration. Indicate the main outcome measure(s). Specify the dates in which data were collected (month/year to month/year). - Results: Include the key findings. Give specific data and their statistical significance, if possible. Subset Ns should accompany percentages if the total N is ‹100. - Discussion and Conclusions: Discuss your findings critically in comparison to existing literature and considering your methodological and other limitations. Conclusions should highlight the potential meaning for the field given the limitations. The main text (i.e. without abstract, references, figures, tables, or supplementary material) should not exceed 3000 words.

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The corresponding author collects the conflict of interest disclosure forms from all authors. (**Please note that each author should complete a disclosure form.**) Examples of forms can be found
here:

The corresponding author will include a summary statement **on the title page that is separate from their manuscript,** that reflects what is recorded in the potential conflict of interest disclosure form(s).

See below examples of disclosures:

Funding: This study was funded by X (grant number X).

Conflict of Interest: Author A has received research grants from Company A. Author B has received a speaker honorarium from Company X and owns stock in Company Y. Author C is a member of committee Z.

If no conflict exists, the authors should state:

Conflict of Interest: Author A, Author B, and Author C declare that they have no conflict of interest.

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1) Statement of human rights

When reporting studies that involve human participants, authors should include a statement that the studies have been approved by the appropriate institutional and/or national research ethics committee and have been performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

If doubt exists whether the research was conducted in accordance with the 1964 Helsinki Declaration or comparable standards, the authors must explain the reasons for their approach, and demonstrate that the independent ethics committee or institutional review board explicitly approved the doubtful aspects of the study.

The following statements should be included in the text before the References section:

Ethical approval: "All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards."

For retrospective studies, please add the following sentence:

"For this type of study formal consent is not required."

2) Statement on the welfare of animals

The welfare of animals used for research must be respected. When reporting experiments on animals, authors should indicate whether the international, national, and/or institutional guidelines for the care and use of animals have been followed, and that the studies have been approved by a research ethics committee at the institution or practice at which the studies were conducted (where such a committee exists).

For studies with animals, the following statement should be included in the text before the References section:

Ethical approval: "All applicable international, national, and/or institutional guidelines for the care and use of animals were followed."

If applicable (where such a committee exists): "All procedures performed in studies involving animals were in accordance with the ethical standards of the institution or practice at which the studies were conducted."

If articles do not contain studies with human participants or animals by any of the authors,

please select one of the following statements:

“This article does not contain any studies with human participants performed by any of the authors.”

“This article does not contain any studies with animals performed by any of the authors.”

“This article does not contain any studies with human participants or animals performed by any of the authors.”

INFORMED CONSENT
All individuals have individual rights that are not to be infringed. Individual participants in studies have, for example, the right to decide what happens to the (identifiable) personal data gathered, to what they have said during a study or an interview, as well as to any photograph that was taken. Hence it is important that all participants gave their informed consent in writing prior to inclusion in the study. Identifying details (names, dates of birth, identity numbers and other information) of the participants that were studied should not be published in written descriptions, photographs, and genetic profiles unless the information is essential for scientific purposes and the participant (or parent or guardian if the participant is incapable) gave written informed consent for publication. Complete anonymity is difficult to achieve in some cases, and informed consent should be obtained if there is any doubt. For example, masking the eye region in photographs of participants is inadequate protection of anonymity. If identifying characteristics are altered to protect anonymity, such as in genetic profiles, authors should provide assurance that alterations do not distort scientific meaning.

The following statement should be included:

Informed consent: “Informed consent was obtained from all individual participants included in the study.”

If identifying information about participants is available in the article, the following statement should be included:

“Additional informed consent was obtained from all individual participants for whom identifying information is included in this article.”

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For editors and reviewers to accurately assess the work presented in your manuscript you need to ensure the English language is of sufficient quality to be understood. If you need help with writing in English you should consider:

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Appendix B: IRAS approval letter

NHS
Health Research Authority

East Midlands - Leicester South Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Dear Miss Ross

Study title:	**Evaluation of a relaxation session introducing cognitive behavioural techniques in reducing general anxiety during pregnancy as well as pregnancy specific anxiety and labour related anxiety.**
REC reference:	**16/EM/0196**
Amendment number:	**1**
Amendment date:	**07 July 2016**
IRAS project ID:	**191319**

The above amendment was reviewed at the meeting of the Sub-Committee held in correspondence on 01 August 2016.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Letters of invitation to participant [Invite version 2]	2	18 July 2016
Notice of Substantial Amendment (non-CTIMP) [AmendmentForm_ReadyForSubmission]	1	07 July 2016
Participant consent form [Consent Form Version 3 July]	3	17 July 2016
Participant information sheet (PIS) [PIS REVISED VERSION 3]	3	18 July 2016
Research protocol or project proposal [Protocol version 2 JULY]	2	18 July 2016

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

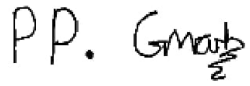
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

16/EM/0196:	**Please quote this number on all correspondence**

Yours sincerely



Mr John Aldridge
Chair

E-mail: NRESCommittee.EastMidlands-LeicesterSouth@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *R&D - Dr Susan Ridge, NHS Grampian*
Sponsor Contact - Mrs Jo-Anne Robertson

East Midlands - Leicester South Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 01 August 2016

Committee Members:

Name	*Profession*	*Present*
Mr John Aldridge	Retired Senior Lecturer in Nursing	Yes
Ms Elizabeth Gibbons	Senior Research Scientist	Yes

Also in attendance:

Name	*Position (or reason for attending)*
Mr George R. Martin	REC Assistant (Minutes)

NHS
Health Research Authority
East Midlands - Leicester South Research Ethics Committee
Royal Standard Place
Nottingham
NG1 6FS

21 May 2016

Miss Victoria Ross
35 Merkland Lane

	ation of a relaxation session introducing cognitive behavioural techniques in reducing general anxiety during pregnancy as well as pregnancy specific anxiety and labour related anxiety.
REC reference:	**16/EM/0196**
IRAS project ID:	**191319**

Thank you for your letter of 20 May 2016, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Rebecca Morledge, NRESCommittee.EastMidlands-LeicesterSouth@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" above).

Approved documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Covering letter on headed paper	01/02/2016	02 March 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		
GP/consultant information sheets or letters		01 February 2016
GP/consultant information sheets or letters		01 February 2016
IRAS Checklist XML [Checklist_20052016]		20 May 2016
Letter from sponsor		02 March 2016
Letters of invitation to participant		01 February 2016
Letters of invitation to participant		01 February 2016
Other [Research Collaborator]		02 March 2016
Other [PL Confirmation]		02 March 2016
Other [UofE PI]		
Other [COVER LETTER FOR REC]		20 April 2016
Other [RESPONSE LETTER]	1	20 May 2016
Participant consent form	2	20 May 2016
Participant information sheet (PIS)	2	20 May 2016
REC Application Form [REC_Form_25042016]		25 April 2016
Research protocol or project proposal [Protocol]	01/02/2016	02 March 2016
Summary CV for Chief Investigator (CI)	01/02/2016	02 March 2016
Summary CV for student [Clinical Supervisor CV]		02 March 2016
Summary CV for supervisor (student research)		01 February 2016
Validated questionnaire [Childbirth_Experience_Questionnaire_CEQ]		
Validated questionnaire [Hospital_Anxiety_and_Depression_Scale 2]		
Validated questionnaire [PRAQ 2]		
Validated questionnaire [wemwbs_14_item]		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

16/EM/0196	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely,

pp

Mr John Aldridge
Chair

Email: NRESCommittee.EastMidlands-LeicesterSouth@nhs.net

Enclosures: *"After ethical review – guidance for researchers"*

Copy to: *Mrs Jo-Anne Robertson*

Dr Susan Ridge, NHS Grampian

Research and Development
Foresterhill House Annexe
Foresterhill
ABERDEEN
AB25 2ZB

Miss Victoria Ross
Royal Cornhill Hospital
Cornhill Road
Aberdeen

Date 30/05/2016
Project No 2016PC006

Enquiries to Lynn Massie
Extension 53846
Direct Line 01224 553846
Email grampian.randdpermissions@nhs.net

Dear Miss Ross

Management Permission for Non-Commercial Research

STUDY TITLE: Evaluation of a relaxation session introducing cognitive behavioural techniques in reducing general anxiety during pregnancy as well as pregnancy specific anxiety and labour related anxiety.
PROTOCOL NO: V1; 1.2.14
REC REF: 16/EM/0196

Thank you very much for sending all relevant documentation. I am pleased to confirm that the project is now registered with the NHS Grampian Research & Development Office. The project now has R & D Management Permission to proceed locally. This is based on the documents received from yourself and the relevant Approvals being in place.

All research with an NHS element is subject to the Research Governance Framework for Health and Community Care (2006, 2nd edition), and as Chief or Principal Investigator you should be fully committed to your responsibilities associated with this.

R&D Permission is granted on condition that:

1) **The R&D Office will be notified and any relevant documents forwarded to us if any of the following occur:**

- **Any Serious Breaches in Grampian (Please forward to pharmaco@abdn.ac.uk).**
- **A change of Principal Investigator in Grampian or Chief Investigator.**
- **Any change to funding or any additional funding**

2) **The R&D Office will be notified when the study ends.**

3) **The Sponsor will notify all amendments to the relevant National Co-ordinating centre. For single centre studies, amendments should be notified to the R&D office directly.**We hope the project goes well, and if you need any help or advice relating to your R&D Management Permission, please do not hesitate to contact the office.

Yours sincerely

Susan Ridge
Non-Commercial Manager

cc: Dr Andrew Keen
Research Monitor

Sponsor: University of Edinburgh

Research and Development

Foresterhill House Annexe
Foresterhill
ABERDEEN
AB25 2ZB

Miss Victoria Ross
Royal Cornhill Hospital
Cornhill Road
Aberdeen

Date 03/08/2016
Our Ref 2016PC006

Enquiries to Lynn Massie
Extension 53846
Direct Line 01224 553846
Email grampian.randdpermissions@nhs.net

Dear Miss Ross

STUDY TITLE: Evaluation of a relaxation session introducing cognitive behavioural techniques in reducing general anxiety during pregnancy as well as pregnancy specific anxiety and labour related anxiety.
PROTOCOL NO: V2; 18.2.16
REC REF: 16/EM/0196
R&D REF: 2016PC006
AMENDMENT NO: AM01 dated 7.7.16

We are in receipt of a copy of the amendment to the above project relating to changes to the following documents:

• Letter of Invitation to participant (invite version 2)	V2	18.7.16	
• Participant Consent Form	V3	17.7.16	
• Participant Information Sheet (PIS REVISED)		V3	18.7.16
• Protocol	V2	18.7.16	

This letter is confirmation that this amendment does not alter local NHS Grampian R&D management permission of the

Yours sincerely

Susan Ridge
Non Commercial Manager
projec

Appendix D: Research Protocol

NHS Grampian

Exploring the effectiveness of a brief CBT treatment for anxious pregnant women

Victoria Ross

Trainee Clinical Psychologist

STUDY PROTOCOL

Full Title:	Exploring the effectiveness of a brief CBT intervention for anxious pregnant women.
Sponsor:	University of Edinburgh
Sponsor Reference Number:	AC 16012
Funder:	University of Edinburgh
Chief Investigator:	Victoria Ross (Trainee Clinical Psychologist)
REC Reference Number:	16/EM/0196
R&D Reference Number:	2016PC006
ISRCTN / Clinicaltrialsgov No:	NCT03103217
Version Number and Date:	2 18/07/2016

TABLE OF CONTENTS

PROTOCOL APPROVAL
Signatures
By signing this document, I am confirming that I have read, understood and approve the protocol for the above study.

Victoria Ross Chief Investigator	Signature	Date
Andy Keen Clinical Supervisor	Signature	Date
Mo Tabib Research Collaborator	Signature	
Date		

LIST OF ABBREVIATIONS

GCP	Good Clinical Practice
ISF	Investigator Site File
CBT	Cognitive Behavioral Therapy
SOP	Standard Operating Procedure
CRF	Case Report Form
CNORIS	Clinical Negligence and Other Risks Scheme
CS	Caesarean

SUMMARY

Pregnancy is a time of significant adjustment and uncertainty. Anxiety is common among this group and is associated with emotional difficulties and poor pregnancy outcomes for both the mother and child. Few trials have been conducted to ascertain the effectiveness of brief psychological interventions designed to alleviate general anxiety, pregnancy specific anxiety and promote well-being.
The aim of this project is to establish if an introduction to Cognitive Behavioural techniques (CBT) is effective in reducing general anxiety during pregnancy. The study will also explore whether the treatment has an impact on reducing pregnancy specific anxiety and reducing medical intervention.

INTRODUCTION

Background

Anxiety is common during pregnancy. It has been suggested that anxiety will complicate approximately every fifth pregnancy in Western Countries.

Anxiety is associated with substantial suffering and significant impact on daily living for mother, child and family. People with anxiety exhibit poorer quality of life and substantial disease burden.

Phenomenology of anxiety during pregnancy is largely similar to that of adults experiencing anxiety at other times in their lives. Disadvantaged groups are especially vulnerable to anxiety generally and also during pregnancy. Risk factors associated with anxiety during pregnancy include: younger women, unemployment, smoking, lower socioeconomic status, previous negative experience of pregnancy/labour, lower education level and poor social support. Severe anxiety during this period is known to relate to people with anxious temperaments, low self-esteem and history of trauma.

Anxiety is associated with poorer pregnancy outcomes and increased chance of medical intervention during labour. This includes low birth weight, prolonged labour, use of instruments, increased use of pain relief and increased requests for caesareans (CS).

As far as we are aware, there have been no RCTs designed to specifically alleviate anxiety among pregnant women using a brief one off CBT approach.

Most studies including randomised controlled trials have focused on psychological interventions for the postnatal period or have utilised several sessions over a course of time. Few studies have focused on the perinatal period.

Rationale for Study

Despite guidance indicating psychological intervention during pregnancy, there are relatively few studies have focused on the perinatal period which are cost effective and accessible.

Austin et al. (2008) developed a brief CBT intervention aimed at an 'at risk' population of pregnant woman and found no difference between those who received the intervention and those in the control group, although both groups reported significantly lower depression during the early postnatal period. Overall, depression scores were significantly reduced from pre-intervention to post-intervention and through the early post-natal period regardless of group allocation. Interestingly, the CBT intervention itself was not found to be better than the control group. Methodological flaws of these studies have been highlighted which has casted doubt over the results. Austen (2008) highlights a need for one session tailored CBT antenatal interventions which provide psychoeducation and educational material.

Saisto et al. (2006) found that women with labour specific anxiety attending a group psychoeducation group were significantly more likely to have a natural delivery compared to control women receiving conventional care. These studies and their results have been criticized for their focus on short term results, lack of follow-up, selection bias and lack of randomization (Khianman et al. 2012).

A recent RCT exploring the effects of a 6-week stress management programme found significant effects of techniques including relaxation on perceived stress and increased sense of control. Moreover, a non-randomized study, psychoeducation combined with relaxation have shown positive results on CS rates on maternal request in woman with anxiety (Kianhman et al., 2012).

Furthermore, a recent systematic review and meta analyses exploring interventions to reduce maternal distress found that providing interventions to those who are more vulnerable or already suffering from anxiety is most useful (Kuipers *et al.,* 2014). Furthermore, they highlight a need for further research to address the major gap in literature.

Therefore, the aim of this study is to explore the effectiveness of a one off brief CBT treatment for anxious pregnant women.

STUDY OBJECTIVES

Primary Objective

The aim of this study is to investigate whether a relaxation session introducing cognitive behavioural techniques is effective in reducing general anxiety during pregnancy.

Secondary Objectives

There are a number of key questions which we hope to explore to
Will a relaxation session introducing cognitive behavioural techniques reduce pregnancy specific anxiety?
Will a relaxation session introducing cognitive behavioural techniques lead to reduced medical intervention during labour?
Will a relaxation session introducing cognitive behavioural techniques increase general wellbeing?

OUTCOMES

Primary Outcome

General anxiety levels at 2 weeks post-intervention and post-partum.

Secondary Outcome

Pregnancy-related anxiety at pre-intervention 2 weeks' post-intervention. Depression and general well-being measured at pre-intervention, 2 weeks post-intervention and 2 months' post-partum. Pregnancy outcomes collected post-delivery.

Procedure

As part of a preexisting maternity care system, women are routinely offered a relaxation session introducing Cognitive Behavioural techniques by their community midwives. Those who wish to attend are routinely allocated a date and time for the 3-hour session. This is recorded by community midwives on a database held by midwifery Lecturer and midwife (Ms. Mo Tabib) who organizes and runs the sessions. Everyone who has been put forward for the group will be sent a covering letter (signed by lead clinician, Mo Tabib) and PIS. It will be made clear to all those who have registered for the relaxation course, that they can attend the course without participating in the research project. Interested potential participants make telephone contact or meet with researcher for further information prior to the session. Following this, a screening measure, baseline measures and consent forms will be completed either before the session (returning in pre-paid envelopes) or on the day of the group (drop in confidential box at session or given to researcher). Participants will then attend routine relaxation session at Aberdeen Maternity Hospital. Following session, participants will be sent questionnaires at 2-weeks post group and a reminder email will be sent at this point. The final set of questionnaires will be sent at 2-months post- partum where another email reminder will also be sent. It will also be made clear that the research is entirely voluntary and participants can withdraw without giving a reason whilst the data is identifiable. When data becomes anonymized it will be not be possible for participants to withdraw. An online record of interested potential participants will be kept.

Consent will also be sought for access to medical records and consent to contact participants following the group by phone/ email where one or two reminders are required to collect as fully as possible follow-up data.

We collect questionnaire data at two weeks' post-intervention and then again 2 months post-delivery. Moreover, we will collect a small amount of information about the nature of the delivery, for example, the pregnancy duration, birth weight, and any complications etc.

Intervention

The intervention is a one-off brief three-hour session introducing Cognitive Behavioural techniques and is led by midwife and lecturer, Mo Tabib and co-facilitated by Victoria Ross, trainee clinical psychologist with a MSc in CBT approaches. The intervention consists of education about the nature of anxiety and stress from a CBT perspective, formal practices of anxiety management strategies, and planning of how to apply this knowledge and these skills when giving birth.

Participants will be welcomed to the session and be invited to share individual hopes and expectations of attending the session. Following this, the CBT model will be introduced. Participants will be invited to complete an exercise where they are to imagine a situation which might elicit worrying thoughts and feelings; they will be encouraged to map out these in a chart. This exercise will highlight the links between thoughts, feelings, behavior & physiological response as well as emphasizing the importance of individual appraisal and interpretation of situations. General biases will also be discussed.

Psychoeducation around the biological foundations and the fight and flight response will be presented. A further exercise will generate ideas from participants of what may happen when this system is activated using a CBT model. The biological basis of the threat system will be discussed in further

detail outlining the evolutionary adaptive function and potential benefits as well as costs.

We will then apply this knowledge of the threat system to general situations, pregnancy specific situations and labour. We will continue to link back to the 5 areas model where the importance of interpretation, behavior and physiology is highlighted with regards to the progression of pregnancy and labour. We will then move on to using cognitive behavioral techniques to activate the parasympathetic nervous system and break the vicious cycle of stress in pregnancy/labour and general situations. The biological basis of the activation of this system will be explored in relation to pregnancy and labour highlighting a desired state for labour.

There will be experiential practice of four cognitive behavioural approaches. These exercises include traditional behavioural relaxation, body scan, breathing, visualization and imagery. Participants will be given an opportunity to reflect on their experience and practice using the 5 areas model following each exercise. Repeated practice of these exercises will be encouraged as a means to dampen overall threat system.

Finally, we will spend some time reviewing the learning points and participants will construct an indvidualised plan for the future which will enable them to develop the skills for a positive experience during pregnancy, birth and into the early years.

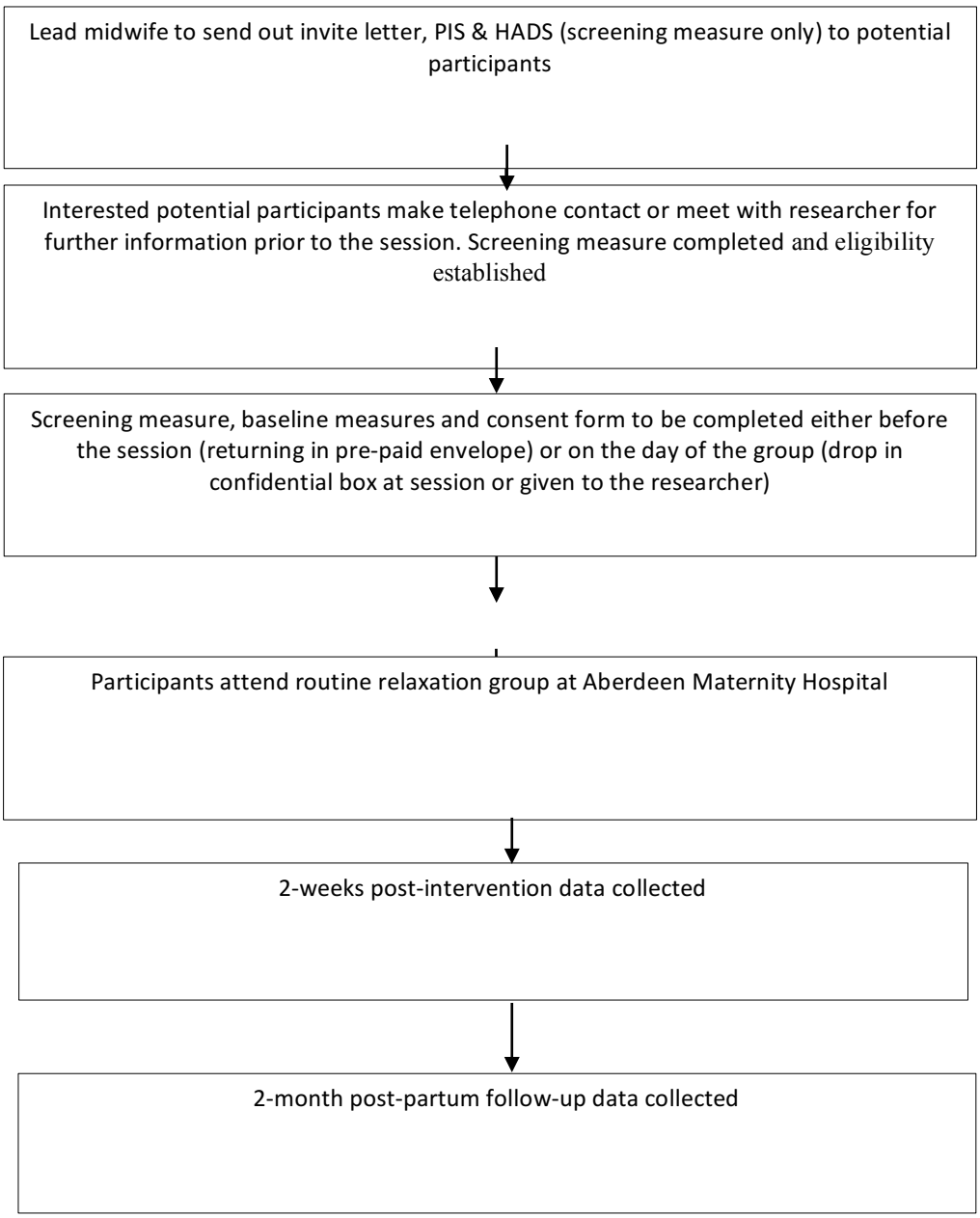


Fig a. Flow of participants through the study.

Relaxation Session Outline

- Introductions
- Hopes/Expectations
- Introducing the CBT model
- Biological foundations
- Stress: the CBT perspective
- Stress and giving birth: biopsychological considerations
- Using CBT approaches to manage stress
- Practising the skills: four cognitive behavioural approaches
- Revisiting our learning points
- Planning for the future: developing the skills for a positive experience during pregnancy, birth and into the early years.

Fig. b: Study outline

STUDY POPULATION

Inclusion:
Pregnant woman
Referred to group and screened for suitability
Attended brief pregnancy session
Contact with community midwife
General anxiety (Score >8 on HADS)
Able to read, write and understand English
Aged over 16
Ability to give consent

Exclusion:
Exclusion criteria will include severe mental health problems such as severe depression with suicidal ideation, psychosis, personality disorder; terminal illness; inability to give informed consent in English, and inability to understand written and spoken English as questionnaires are not standardized in other languages.

Control Group – Existing data from previously published study

Inclusion
Pregnant woman
Women with anxiety
Previously published data

Exclusion
Non-clinical levels of anxiety (Score<8 on HADS)

Key predictors of anxiety
- -baseline anxiety
- - age
- -pregnancy number
- -gestational age
- -income
- -support
- -education level

.

PARTICIPANT SELECTION AND ENROLMENT

Identifying Participants

NHS Grampian midwives have first contact with pregnant women. Midwives identify during their routine practice anxious woman who they feel would benefit from stress management session and discuss this option. Those who decline will continue with treatment as usual through the usual maternity pathway. Those who express an interest will be allocated a space at the next available session using a database system. This is part of a pre-existing system of care which provides referrals to a relaxation session (which has been partly redesigned for this study). Following this, the lead clinician (Mo Tabib, senior midwife) will send PIS and HADS screening tool to potential participants. It will be made clear to all those who have registered for the relaxation course, that they can attend the course without participating in the research project. Interested potential participants make telephone contact or meet with

researcher for further information prior to the session. Screening measure, baseline measures and consent form to be completed either before the session (returning in prepaid envelope) or on the day of the group (drop in confidential box at session or given to researcher). Participants will then attend routine relaxation session at Aberdeen Maternity Hospital. An online record of interested potential participants will be kept.

Consenting Participants

The chief researcher will seek informed consent which can be withdrawn at any time during ongoing involvement whilst the data is identifiable. Consent will be discussed with potential participants either during a telephone consultation or on the day of the session following being sent the invite letter and PIS. There are two options for potential participants who are interested and eligible consenting. Firstly, for those who have completed a telephone discussion, the chief researcher will send out a written consent form where participants will be offered choice of returning in post or deposit in a confidential box at the session. A second option would be for potential participants to consent immediately prior to the session. The chief researcher will explain what research entails in small groups and each person will have the opportunity to ask questions individually. Each individual will then be given a screening measure, baseline measures and consent form and asked to complete these if they wish to participate. It will be highlighted that participants can withdraw from the study at any point.

Screening for Eligibility

All participants who are interested will complete the HADS screening measure, baseline measures and a consent form. HADS will be used as screening tool where a score of >8 will be included in the study. This screening measure will not be used as study data.

Ineligible and Non-Recruited Participants

A list of patients attending the group will be routinely kept by midwives therefore basic demographic details of ineligible participants will be kept. This will not be used for the research.

Withdrawal Procedures

The only reason that we will encourage withdrawal from the study is if we feel participants' psychological wellbeing is deteriorating to the point they need other clinical services. If this situation occurs, then we will facilitate referral to appropriate care. Participants will not be replaced as a key outcome of this study is to ascertain recruitment and retention.
Give a full description of the withdrawal criteria and the process for withdrawing participants from the study. Include information on documentation to be completed, if participants will be replaced and if data will be retained (with permission).

STUDY AND SAFETY ASSESSMENTS

All participants will continue to receive their usual maternity care. Facilitators will monitor participants' emotional wellbeing at sessions. It will be made clear to all participants that they have access to the group facilitators before and after all meetings if there are issues they need to discuss.

DATA COLLECTION AND MANAGEMENT

Questionnaire data will be collected at 3 time points and be returned via pre paid envelopes or deposited in confidential box at session. Participants will be provided with a pack which will include questionnaires to be completed at two later dates following the session. The researcher will send participants a reminder text/email at 2 weeks following the session and at follow up, 2 months' post partum. We will collect all baseline medical and demographic data through demographic questionnaires and medical files. The University computers and filing systems used to collate the data will have limited access measures via user names, passwords, and keys. These measures will be in-keeping with University and NHS guidance and best practice. Published results will not contain any personal data that could allow identification of individual participants.

The Warwick-Edinburgh Metal Well-being scale was developed to enable the monitoring of mental well being in the general population and the evaluation of projects, programs and policies which aim to improve mental well being. It is a 14 item scale with 5 response categories, summed to provide a single score ranging from 14-70. The items are all worded positively and cover both feeling and functioning aspects of mental well being. A Cronbach's alpha score of 0.89 (student sample) and 0.91 (population sample) suggests some item redundancy in the scale.

Hospital Anxiety and Depression Scale-anxiety subscale (HADS-A; Zigmond and Snaith, 1983) will be used to as the primary outcome measure to measure general anxiety. This measure will identify clinically significant levels of anxiety (Score >8 identifies mild levels of anxiety). Measured using the Hospital Anxiety and Depression Scale (HADS) which is a self-report Questionnaire consisting of 14 items (Zigmond and Snaith, 1983) which provides sub-scores for anxiety and depression. It takes approximately five minutes to administer. The measure has been shown to have acceptable levels of reliability and validity in the general population (Bjelland et al., 2002). Moreover, this measure has also been validated for use in pregnancy population (Jomeen et al., 2004).

The Pregnancy Related Anxiety Questionnaire – R2 will be used (Huizink et al., 2015) is a shortened, 10 item measure devised to diagnose the psychological distress specific pregnancy. This measure is a shortened version of the The Pregnancy Related Anxiety Questionnaire (PRAQ) (Van Den Bergh 1989) which consisted of 55 items over five sub-scales, rated on a 7-point scale. Huizink et al. (2015) conducted CFA on a three factor model of the PRAQ-R: 'fear of giving birth', 'fear of bearing a handicapped child' and 'concern about one's appearance', these factors demonstrated a good fit to the data across all time points. Cronbach's alpha = 0.76-0.88 has been reported.

The Childbirth Experience Questionnaire (CEQ) was developed in Sweden in 2010 and validated in 920 primiparous women (Dencker *et al.,* 2010). It measures 4 main domains of the childbirth experience: Own capacity, Professional support, Perceived safety and Participation. Face validity of the CEQ in a UK population was demonstrated with all respondents reporting that the questionnaire was easy to understand and complete. A statistically significant higher CEQ score for subgroups of women known to report a better birth outcome (shorter labour, no oxytocin augmentation and vaginal delivery) demonstrated construct validity of the CEQ in 2 subscales. A weighted kappa of 0.68 for the full scale demonstrated test-retest reliability of the CEQ. A Pearson

correlation co-efficient of 0.73 demonstrated a strong correlation between the results of the CEQ (total score) and the results of the 'gold standard' assessment of childbirth experience in the UK.

All subscales had moderate correlations and the total scale had a strong correlation with the Maternity Survey.

This measure will be completed at one time point, follow up: 2 months' post-partum.

STATISTICS AND DATA ANALYSIS

Sample Size Calculation

A priori power analysis was carried out. All power calculations have assumed power of 0.8 and an error value of 0.05. G-power was used for calculations (Erdfelder et al., 1996).

A power calculation was carried out to estimate the required sample size to find investigate whether general anxiety is reduced. G* Power 3.1.9.2 was used to calculate a sample size for a one-way ANOVA, based on a medium effect size F=0.25 and with power at 0.8 and an alpha level of 0.05. This would require a total of 58 participants.

Aberdeen Maternity Hospital is the tertiary maternity unit for the North of Scotland NHS region, with over 5000 births per annum and it is estimated that every fifth pregnant women have difficulties with anxiety (Haines et al., 2011). Given these figures, you would expect 1000 woman to experience anxiety and fear of labour.

Around 25 people (woman mainly and some partners) currently attend per month (12 or 13 per session). They find out about the sessions through their midwife. Not all midwifes routinely let their participants know about the sessions and there is no advertisement. Clinical supervisor and midwife both confident in achieving sample size.

Austin et al. (2008) carried out a study where in total 774 women were approached, of those 38.9% (N=301) accepted and 61.1% (N=473) refused to take part. Of those accepting, 92% were eligible to take part. 191 entered a CBT group and 86 entered a control booklet group. At 'time 2- antenatal follow up' 15.2% attrition rate was found in CBT group and 17.2% attrition group; 'Time 3 – 2 months' postpartum attrition rate for CBT group was 31.9% and 26.7% for booklet group and time '4 – 4 months postpartum'. Overall, complete data sets for this study attrition rate in CBT group was 53.4% and 50% for control group. For the purposes of our study, we will be collecting data at the antenatal follow up period so we will assume attrition rate of 20% between pre (day of session) and post (2 months postpartum) and that 15% may not meet inclusion criteria.

Based on previous studies (Austin et al., 2008) who had 191 in intervention group and 86 in control group where they found a significant difference across

time was detected in the measure with F= 9.27 which converts to Cohen's d= 0.4, medium effect size.

Proposed Analysis

Primary Objective

The aim of this study is to see whether a brief CBT treatment is effective in reducing general anxiety during pregnancy.

For the primary outcome we will use ANCOVA where we will control for covariates such as age and socioeconomic status. This control data will be matched for.

Secondary Objectives
There are a number of key questions which we hope to explore to
1. Will a relaxation session introducing cognitive behavioural techniques reduce pregnancy specific anxiety?
2. Will a relaxation session introducing cognitive behavioural techniques reduce labour specific anxiety?
3. Will a relaxation session introducing cognitive behavioural techniques increase general wellbeing?

For the above secondary aims we will use a mixed design ANOVA for analyses.

Will a relaxation session introducing cognitive behavioural techniques lead to reduced medical intervention during labour?

For the above secondary aim, we will use a chi squared for the categorical data.

INSPECTION OF RECORDS

The CI and institution involved in the study will permit study related monitoring, audits, and REC review. The CI agrees to allow the Sponsor or, representatives of the Sponsor, direct access to all study records and source documentation.

GOOD CLINICAL PRACTICE

Ethical Conduct of the Study
The study will be conducted in accordance with the principles of good clinical practice (GCP) (Training completed).

In addition to Sponsorship approval, a favorable ethical opinion will be obtained from the appropriate REC and appropriate NHS R&D approval(s) will be obtained prior to commencement of the study.

Confidentiality

All evaluation forms, reports, and other records will be identified in a manner designed to maintain participant confidentiality. All records will be kept in a secure storage area with limited access to study staff only. Clinical information will not be released without the written permission of the participant, except as necessary

for monitoring and auditing by the Sponsor or its designee. The CI and study staff involved with this study will not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished, confidential information disclosed to those individuals for the purpose of the study. Prior written agreement from the Sponsor or its designee will be obtained for the disclosure of any said confidential information to other parties.

Data Protection

The CI and study staff involved with this study will comply with the requirements of the Data Protection Act 1998 with regard to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. The CI and study staff will also adhere, if appropriate, to the current version of the NHS Scotland Code of Practice on Protecting Patient Confidentiality. Access to collated participant data will be restricted to the CI and appropriate study staff.
Computers used to collate the data will have limited access measures via user names and passwords.
Published results will not contain any personal data that could allow identification of individual participants.

Insurance and Indemnity

The study will be covered under the University of Edinburgh. The university have a policy in place that provides indemnity against legal liability for non negligent harm caused to a research subject, arising from the management of the research.

The University of Edinburgh has insurance in place (which includes no fault compensation) for negligent harm caused by poor protocol design by the chief investigator and researchers employed by the university.

STUDY CONDUCT RESPONSIBILITIES

Study Record Retention

Archiving of study documents will be for at least 10 years after publication of the study data.

End of Study
The end of study is defined as day that the last follow-up data is collected. The Sponsor and CI have the right at any time to terminate the study for clinical or administrative reasons. The end of the study will be reported to the Sponsor and REC within 90 days, or 15 days if the study is terminated prematurely. The CI will ensure that any appropriate follow up is arranged for all participants. A summary report of the study will be provided to the Sponsor and REC within 1 year of the end of the study.

REPORTING, PUBLICATIONS AND NOTIFICATION OF RESULTS

Authorship Policy

Ownership of the data arising from this study resides with the study team and their respective employers. On completion of the study, the study data will be analyzed and tabulated, and a clinical study report will be prepared.

Publication

As this is a student study, this will be written up as part of a PhD thesis. The thesis will be used for publication and presentation at scientific meetings. Investigators have the right to publish orally or in writing the results of the study. Summaries of results will also be made available to participants if they wish.

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

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Huizink, A. C., Delforterie, M. J., Scheinin, N. M., Tolvanen, M., Karlsson, L., & Karlsson, H. (2015). Adaption of pregnancy anxiety questionnaire–revised for all pregnant women regardless of parity: PRAQ-R2. *Archives of women's mental health*, 1-8.
Jomeen, J., & Martin, C. R. (2004). Is the Hospital Anxiety and Depression Scale (HADS) a reliable screening tool in early pregnancy?. *Psychology & Health*, *19*(6), 787-800.

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Van den Bergh, B. R. H. (1989). De emotionele toestand van de (zwangere) vrouw, obstetrische complicaties en het gedrag en de ontwikkeling van de foetus en van het kind tot de leeftijd van zeven maanden (Deel 2).

Rouhe, H., Salmela-Aro, K., Halmesmäki, E., & Saisto, T. (2009). Fear of childbirth according to parity, gestational age, and obstetric history. *BJOG: An International Journal of Obstetrics & Gynaecology*, *116*(1), 67-73.

Rouhe, H. (2015). *Fear of Childbirth*. Unpublished manuscript. Medical Faculty of University of Helsinki.

Saisto, T., Salmela-Aro, K., Nurmi, J. E., Könönen, T., & Halmesmäki, E. (2001). A randomized controlled trial of intervention in fear of childbirth. *Obstetrics & Gynecology*, *98*(5, Part 1), 820-826.

Saisto, T., Toivanen, R., Salmela-Aro, K., & Halmesmäki, E. (2006). Therapeutic group psychoeducation and relaxation in treating fear of childbirth. *Acta obstetricia et gynecologica Scandinavica*, *85*(11), 1315-1319.

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Zigmond, A. S., & Snaith, R. P. (1983). The hospital anxiety and depression scale. *Acta psychiatrica scandinavica*, *67*(6), 361-370.

Appendix E: Participant Forms

nhsg.relaxation@nhs.net
Research contact: 01224 557297

Dear Sir/Madam
RE: Research Study – Evaluation of a relaxation session for pregnant women.

I understand that your community midwife has referred you to a one-off relaxation session. As it happens, we are conducting a research study to evaluate how effective this is in reducing stress and anxiety.
By way of this letter I would like to invite you to take part in this research. I have enclosed a Participant Information Sheet to provide you with further information about what taking part would entail. Please feel free to discuss this with your friends and families.

You can of course still come along to the relaxation session even if you don't want to take part in this research. If you do wish to attend the relaxation session and take part in the study, we will ask you to fill out some questionnaires. Taking part is entirely voluntary.

If you would like to find out more about the study or are keen to take part, then please contact me by calling or emailing using the contact details above. I will call you at a time to suit you, and do my best to answer any questions you have. Alternatively, if you would like to discuss the research on the day of the session please arrive early.

Yours sincerely,

Mo Tabib
Lead Midwife

PATIENT INFORMATION SHEET GUIDE

Exploring the effectiveness of a relaxation session for pregnant women.

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others, such as your GP, your midwife and relatives, if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part. Thank you for reading this.

WHAT IS THE PURPOSE OF THE STUDY?

We know that many women who are pregnant may experience stress and anxiety.

Our study aims to find out if a brief relaxation session can reduce general anxiety, pregnancy and labour specific anxiety as well as improving well being and pregnancy outcomes.

We will be providing an introduction to Cognitive Behavioural techniques. We will be trying to help you to develop skills and strategies so that you can identify and manage stress and anxiety. The intervention will invite you to think about situations or thoughts that you sometimes worry about in order to help you develop strategies to reduce and manage those worries. Like most skills, people develop CBT skills by practicing and you will be encouraged to do this following the session.

The session is 3 hours long and will take place at Aberdeen Maternity Hospital. We will ask you to complete some questionnaires before the group, 2 weeks after you have finished the group and again 2 months after your baby is born.

WHY HAVE I BEEN CHOSEN?

We are recruiting a total of 68 participants in Aberdeen and Aberdeenshire. We are asking everybody who is keen attend the relaxation session as part of standard care if they would be interested in taking part in the research study.

DO I HAVE TO TAKE PART?

No. It is up to you to decide whether to take part. You are invited to the session whether you decide to take part in the study or not. If you do decide to take part in the study, you will be asked to sign a consent form. If you decide to take part, you are still free to withdraw without giving a reason. A decision to withdraw or a decision not to take part, will not affect the standard of care you receive.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

You will be involved in the research for no longer than 9 months. This will involve attending one relaxation session and being asked to complete questionnaires before the group and follow up questionnaires at two time points.

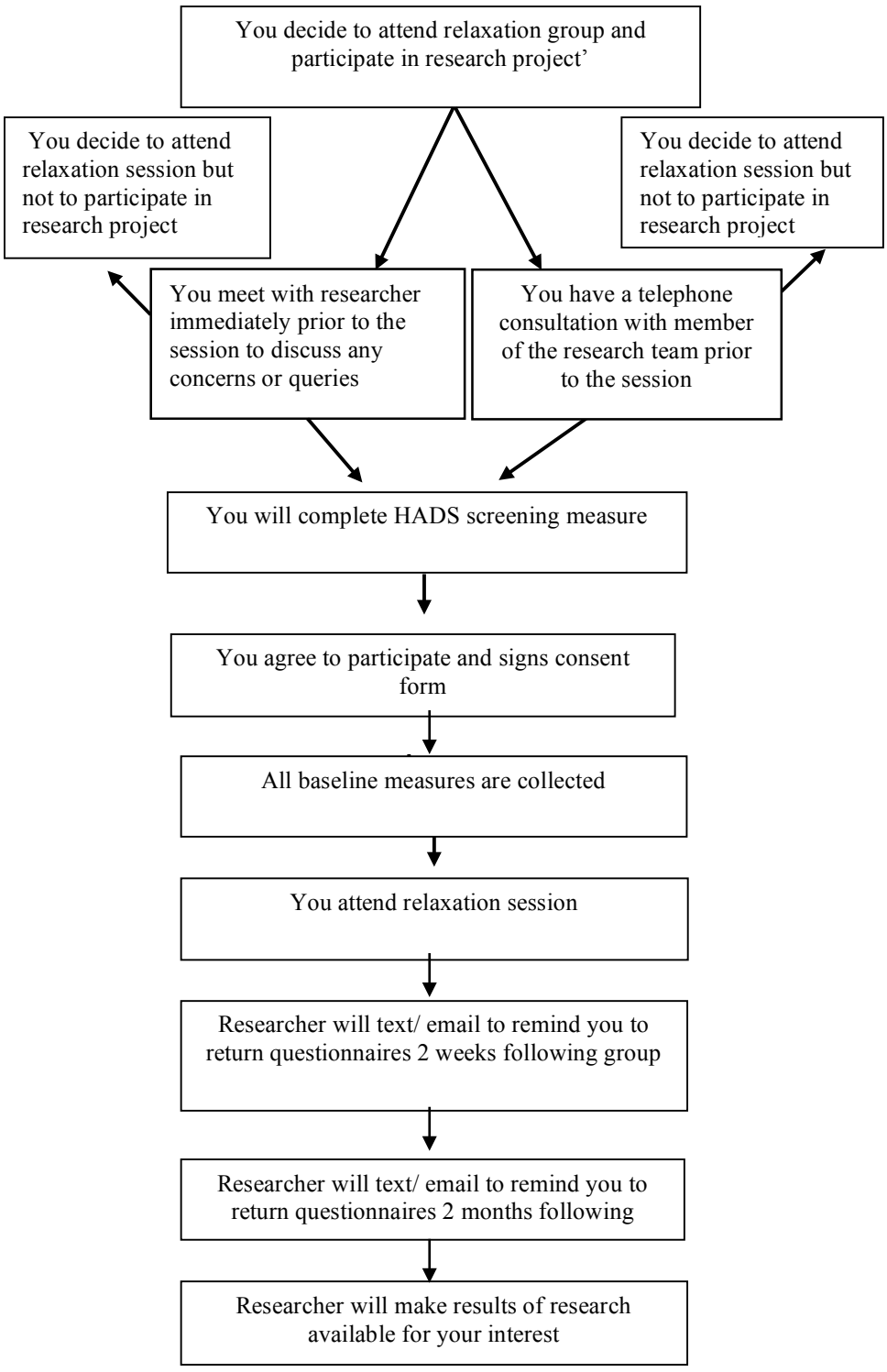
You are invited to the session whether you decide to take part in the study or not. If you choose to take part in this study, then you will attend one 3 hour session alongside other women. There will be about 12 people in your session and they will be in a similar situation to you, for example, others will be pregnant women looking for some relaxation strategies.

At the session we will spend some time discussing experiences of pregnancy as well as any worries or anxiety. We will then explore the impact of anxiety on pregnancy and the body. The second part of the session involves several relaxation exercises for you to practice. We would also ask you to practice these at home following the session on a daily basis to increase the value and benefit of attending the session.

We will ask you to complete a number of questionnaires before and after the course and then again 2 months following birth of your baby. These will include questions about your emotional wellbeing, anxiety and depression. In total, these will take about 10 minutes to complete. Please bring along your reading glasses if you use them.

There is a simple diagram on the next page of what happens next if you decide to participate in this study or if you chose not to.

Apart from attending the relaxation session and practicing, you can carry on living your life as usual.


You decide to attend relaxation group and participate in research project'
You decide to attend relaxation session but not to participate in research project
You decide to attend relaxation session but not to participate in research project
You meet with researcher immediately prior to the session to discuss any concerns or queries
You have a telephone consultation with member of the research team prior to the session
You will complete HADS screening measure
You agree to participate and signs consent form
All baseline measures are collected
You attend relaxation session
Researcher will text/ email to remind you to return questionnaires 2 weeks following group
Researcher will text/ email to remind you to return questionnaires 2 months following
Researcher will make results of research available for your interest

WHAT ARE THE ALTERNATIVES FOR DIAGNOSIS OR TREATMENT?

There may be other locally available treatments for mild-moderate anxiety, and you would be very welcome to discuss these with your GP.

It may be useful to discuss with the chief investigator if you are already receiving therapy somewhere else.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

There are no known risks associated with CBT. However, as with all psychological approaches, people can become upset during the programme, and a key aim of CBT is to help people manage more skillfully the more challenging aspects of life.

If you feel you are especially struggling at any time, then a member of the research team or one of the facilitators will arrange to meet you quickly. The facilitators will be at the venue before and after the group meetings and that may be a suitable time for you to approach us and let us know that things are tough. We will discuss with you the nature of your difficulties and what may be the best options for you.

It may be the case that at the end of the follow up period, your emotional wellbeing has not improved and in this case we will contact your GP to let them know. Furthermore, if you reveal information which is concerning or highlights risk to yourself or others, that information will have to be passed on to your GP.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

We hope that our session will improve your emotional wellbeing and your pregnancy journey. However, this cannot be guaranteed. The information we get from this study may help us to design future treatments that could help participants with mild-moderate levels of anxiety.

WHAT IF NEW INFORMATION BECOMES AVAILABLE?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the research team will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, then you will of course receive your usual NHS care. If you decide to continue in the study, you will be asked to read a new information sheet and sign an updated consent form.

In addition, on receiving new information the research team might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons for this and arrange for your care to continue.

WHAT HAPPENS WHEN THE RESEARCH STUDY ENDS?

We will not be providing any further services to help you improve your anxiety or pregnancy journey after this point.

However, if there is a clear need for further support either with emotional wellbeing (anxiety and/or depression), then the research team will facilitate further support from appropriate services, or help you identify who you need to approach to discuss your options, locally.

WHAT IF SOMETHING GOES WRONG?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting NHS Grampian Feedback Service, Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE Tel: 0845 337 6338.

If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

All information which is collected about you during the course of the research will be kept strictly confidential on either NHS or University property and systems. The data will be made unidentifiable.

To ensure that the study is being run correctly, we will ask your consent for responsible representatives from the Sponsor and NHS Institution to access your medical records and data collected during the study, where it is relevant to you taking part in this research. The university will only access unidentifiable data and no individuals will be identifiable in any reports or publications arising from the project.

Furthermore, we will be seeking permission to access online medical records to record the nature of your pregnancy and birth. The Sponsor is responsible for overall management of the study and providing insurance and indemnity.

With your permission, we will let your GP know that you are participating in this study.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

As this is a student study, at the end of this study it will be written up for a professional doctorate qualification. Furthermore, we hope to publish our results in scientific journals that and present them at local meetings and conferences. This study also has the potential of improving services for pregnant women and their families. If you let us know, then we would be very happy to provide you with a summary of the results.

We will not publish or present any information in ways that could identify you.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

The study is being sponsored by the University of Edinburgh.

WHO HAS REVIEWED THE STUDY?

The study has also been reviewed by a group of independent people called a Research Ethics Committee, to protect your interests. It was given a favourable opinion by the the NHS Research Ethics Committee. NHS management approval has been given.

CONTACT FOR FURTHER INFORMATION

Victoria Ross: Tel: 01224 557 497
Email: nhsg.relaxation@nhs.net

If you would like to discuss this study with someone independent of the study, please contact: Bruce Downey, Clinical Paediatric Neuropsychologist, 01224 550139

Thank you very much for considering to take part in our study.

PARTICIPANT CONSENT FORM

Project Title: Exploring the effectiveness of a relaxation session for pregnant women.

Name of Researcher: Victoria Ross
Trainee Clinical Psychologist
Aberdeen
Contact Number: 01224 557 497
email: nhsg.relaxation@nhs.net

Thank you for reading the information about our research project. If you would like to take part, please read and sign this form and return it to the box provided at the session.

Please insert initials in the box below

I have read and understand the information sheet (version 3) dated 18.07.16 and have had the opportunity to ask questions.	☐
I understand that participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	☐
I can ask to talk to the researcher at a later date if I would like to discuss anything I talked about during the session.	☐
All the information I provide in the study will be confidential. However, if I reveal information which is concerning or highlights risk to myself or others, that information will have to be passed on to my GP.	☐
I give permission for my GP to be informed of my participation and given any relevant information.	☐
I give permission for access to relevant section of my medical notes to record the nature of birth.	☐
I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor, from the NHS organisation or other authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	☐
I agree to take part in the above study.	☐

Name of Participant Signature
Date

Name of person taking consent Signature Date

Original (x1) to be retained in site file. Copy (x1) to be included in patient notes. Copy (x1) to be retained by the participant.

Dear GP

RE: Patient involvement in a research study – Evaluating the effectiveness of a relaxation session for pregnant women.

I am writing to inform you that X has consented to take part in the above research study. The study involves attending a one-off relaxation session where cognitive behavioural techniques will be introduced. They will also be invited to complete questionnaire sets at two time points following the session.

I do not plan to contact you again, however, if following the there are any concerns or if X scores clinically for anxiety and depression, I will contact you to make you aware of this.

Best wishes,

Victoria Ross

Trainee Clinical Psychologist/Chief investigator

Appendix F: Outcome Measures

Hospital Anxiety and Depression Scale (HADS)

I feel tense or 'wound up':	**A**
Most of the time	3
A lot of the time	2
Time to time, occasionally	1
Not at all	0

I feel as if I am slowed down:	**D**
Nearly all of the time	3
Very often	2
Sometimes	1
Not at all	0

I still enjoy the things I used to enjoy:	**D**
Definitely as much	0
Not quite so much	1
Only a little	2
Not at all	3

I get a sort of frightened feeling like 'butterflies in the stomach':	**A**
Not at all	0
Occasionally	1
Quite often	2
Very often	3

I get a sort of frightened feeling like something awful is about to happen:	**A**
Very definitely and quite badly	3
Yes, but not too badly	2
A little, but it doesn't worry me	1
Not at all	0

I have lost interest in my appearance:	**D**
Definitely	3
I don't take as much care as I should	2
I may not take quite as much care	1
I take just as much care as ever	0

I can laugh and see the funny side of things:	**D**
As much as I always could	0
Not quite so much now	1
Definitely not so much now	2
Not at all	3

I feel restless as if I have to be on the move:	**A**
Very much indeed	3
Quite a lot	2
Not very much	1
Not at all	0

Worrying thoughts go through my mind:	**A**
A great deal of the time	3
A lot of the time	2
From time to time but not too often	1
Only occasionally	0

I look forward with enjoyment to things:	**D**
A much as I ever did	0
Rather less than I used to	1
Definitely less than I used to	3
Hardly at all	2

I feel cheerful:	**D**
Not at all	3
Not often	2
Sometimes	1
Most of the time	0

I get sudden feelings of panic:	**A**
Very often indeed	3
Quite often	2
Not very often	1
Not at all	0

I can sit at ease and feel relaxed:	**A**
Definitely	0
Usually	1
Not often	2
Not at all	3

I can enjoy a good book or radio or TV programme:	**D**
Often	0
Sometimes	1
Not often	2
Very seldom	3

Pregnancy Related Anxiety Questionnaire (Revised 2)

Please circle each answer that applies most accurately to your situation.

Answer categories: 1. Absolutely not relevant 2. Hardly ever relevant 3. Sometimes relevant 4. Reasonably relevant 5. Very relevant

1. I am anxious about the delivery. * 1 2 3 4 5

2. I am worried about the pain of contractions and the pain during delivery. 1 2 3 4 5

3. I am worried about the fact that I shall not regain my figure after delivery. 1 2 3 4 5

4. I sometimes think that our child will be in poor health or will be prone to illnesses.

1 2 3 4 5

5. I am concerned about my unattractive appearance.

1 2 3 4 5

6. I am worried about not being able to control myself during labour and fear that I will scream.

1 2 3 4 5

7. I am worried about my enormous weight gain.

1 2 3 4 5

8. I am anxious about the delivery because I have never experienced one before. **
1 2 3 4 5 (N/A)

9. I am afraid the baby will be mentally handicapped or will suffer from brain damage.

1 2 3 4 5

10. I am afraid our baby will be stillborn, or will die during or immediately after delivery.

1 2 3 4 5

11. I am afraid that our baby will suffer from a physical defect or worry that something will be physically wrong with the baby.

1 2 3 4 5

The Childbirth Experience Questionnaire - CEQ

Dear new mother,

One of the goals of childbirth care is to ensure a positive childbirth experience for the mother. The purpose of this questionnaire is to learn about how you experienced childbirth. Your answers, along with answers from other new mothers, will be used to evaluate childbirth care. It is important that you answer all the questions.

There are two ways to rate your experience, either by ticking a box or marking a line.

Examples:

Tick the box below the response choice that best corresponds to your opinion.

I eat fruit every day.

Totally agree	Mostly agree	Mostly disagree	Totally disagree
☐	☒	☐	☐

Indicate your opinion by marking on the line between the two end-points.

How much do you like apples?

Not at all — My favorite fruit

The questionnaire begins on the next page.
Thank you for participating and sharing your views.

1. Labour and birth went as I had expected.

Totally agree	Mostly agree	Mostly disagree	Totally disagree
☐	☐	☐	☐

2. I felt strong during labour and birth.

Totally agree	Mostly agree	Mostly disagree	Totally disagree
☐	☐	☐	☐

3. I felt scared during labour and birth.

Totally agree	Mostly agree	Mostly disagree	Totally disagree
☐	☐	☐	☐

4. I felt capable during labour and birth.

Totally agree	Mostly agree	Mostly disagree	Totally disagree
☐	☐	☐	☐

5. I was tired during labour and birth.

Totally agree	Mostly agree	Mostly disagree	Totally disagree
☐	☐	☐	☐

6. I felt happy during labour and birth.

Totally agree	Mostly agree	Mostly disagree	Totally disagree
☐	☐	☐	☐

7. I have many positive memories from childbirth.

Totally agree	Mostly agree	Mostly disagree	Totally disagree
☐	☐	☐	☐

8. I have many negative memories from childbirth.

Totally agree	Mostly agree	Mostly disagree	Totally disagree
☐	☐	☐	☐

9. Some of my memories from childbirth make me feel depressed.

Totally agree	Mostly agree	Mostly disagree	Totally disagree
☐	☐	☐	☐

10. I felt I could have a say whether I could be up and about or lie down.

Totally agree	Mostly agree	Mostly disagree	Totally disagree
☐	☐	☐	☐

11. I felt I could have a say in deciding my birthing position.

Totally agree	Mostly agree	Mostly disagree	Totally disagree
☐	☐	☐	☐

12. I felt I could have a say in the choice of pain relief.

Totally agree	Mostly agree	Mostly disagree	Totally disagree
☐	☐	☐	☐

13. My midwife devoted enough time to me.

Totally agree	Mostly agree	Mostly disagree	Totally disagree
☐	☐	☐	☐

14. My midwife devoted enough time to my partner.

Totally agree	Mostly agree	Mostly disagree	Totally disagree
☐	☐	☐	☐

15. My midwife kept me informed about what was happening during labour and birth.

Totally agree	Mostly agree	Mostly disagree	Totally disagree
☐	☐	☐	☐

16. My midwife understood my needs.

Totally agree	Mostly agree	Mostly disagree	Totally disagree
☐	☐	☐	☐

17. I felt very well cared for by my midwife.

Totally agree	Mostly agree	Mostly disagree	Totally disagree
☐	☐	☐	☐

18. My impression of the team's medical skills made me feel secure.

Totally agree	Mostly agree	Mostly disagree	Totally disagree
☐	☐	☐	☐

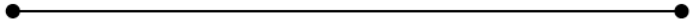
19. I felt that I handled the situation well.

Totally agree	Mostly agree	Mostly disagree	Totally disagree
☐	☐	☐	☐

20. As a whole, how painful did you feel childbirth was?

No pain — Worst imaginable pain

21. As a whole, how much control did you feel you had during childbirth?



No control — Complete control

22. As a whole, how secure did you feel during childbirth?

Not at all secure — Completely secure

Additional comments:

Thank you for your input!

Below are some statements about feelings and thoughts.

Please tick (√) the box that best describes your experience of each over the **last 2 weeks**

STATEMENTS	None of the time	Rarely	Some of the time	Often	All of the time
I've been feeling optimistic about the future	1	2	3	4	5
I've been feeling useful	1	2	3	4	5
I've been feeling relaxed	1	2	3	4	5
I've been feeling interested in other people	1	2	3	4	5
I've had energy to spare	1	2	3	4	5
I've been dealing with problems well	1	2	3	4	5
I've been thinking clearly	1	2	3	4	5
I've been feeling good about myself	1	2	3	4	5
I've been feeling close to other people	1	2	3	4	5
I've been feeling confident	1	2	3	4	5
I've been able to make up my own mind about things	1	2	3	4	5
I've been feeling loved	1	2	3	4	5
I've been interested in new things	1	2	3	4	5
I've been feeling cheerful	1	2	3	4	5

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Appendix G: Published Prospero Protocol

UNIVERSITY of York
Centre for Reviews and Dissemination

NHS
National Institute for Health Research

PROSPERO International prospective register of systematic reviews

Review title and timescale

1 Review title
Give the working title of the review. This must be in English. Ideally it should state succinctly the interventions or exposures being reviewed and the associated health or social problem being addressed in the review.

2 Original language title
For reviews in languages other than English, this field should be used to enter the title in the language of the review. This will be displayed together with the English language title.

3 Anticipated or actual start date
Give the date when the systematic review commenced, or is expected to commence.

4 Anticipated completion date
Give the date by which the review is expected to be completed.

5 Stage of review at time of this submission
Indicate the stage of progress of the review by ticking the relevant boxes. Reviews that have progressed beyond the point of completing data extraction at the time of initial registration are not eligible for inclusion in PROSPERO. This field should be updated when any amendments are made to a published record.

The review has not yet started ×

Review stage	Started	Completed
Preliminary searches	No	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Provide any other relevant information about the stage of the review here.

Review team details

6 Named contact
The named contact acts as the guarantor for the accuracy of the information presented in the register record.

7 Named contact email
Enter the electronic mail address of the named contact.

8 Named contact address
Enter the full postal address for the named contact.

9 Named contact phone number
Enter the telephone number for the named contact, including international dialing code.

10 Organisational affiliation of the review
Full title of the organisational affiliations for this review, and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.
Website address:

11 Review team members and their organisational affiliations
Give the title, first name and last name of all members of the team working directly on the review. Give the organisational affiliations of each member of the review team.

Title	First name	Last name	Affiliation

25 Secondary outcomes
List any additional outcomes that will be addressed. If there are no secondary outcomes enter None.

Give information on timing and effect measures, as appropriate.

26 Data extraction (selection and coding)
Give the procedure for selecting studies for the review and extracting data, including the number of researchers involved and how discrepancies will be resolved. List the data to be extracted.

27 Risk of bias (quality) assessment
State whether and how risk of bias will be assessed, how the quality of individual studies will be assessed, and whether and how this will influence the planned synthesis.

28 Strategy for data synthesis
Give the planned general approach to be used, for example whether the data to be used will be aggregate or at the level of individual participants, and whether a quantitative or narrative (descriptive) synthesis is planned. Where appropriate a brief outline of analytic approach should be given.

29 Analysis of subgroups or subsets
Give any planned exploration of subgroups or subsets within the review. 'None planned' is a valid response if no subgroup analyses are planned.

Review general information

30 Type and method of review
Select the type of review and the review method from the drop down list.

31 Language
Select the language(s) in which the review is being written and will be made available, from the drop down list. Use the control key to select more than one language.
Will a summary/abstract be made available in English?

32 Country
Select the country in which the review is being carried out from the drop down list. For multi-national collaborations select all the countries involved. Use the control key to select more than one country.

33 Other registration details
Give the name of any organisation where the systematic review title or protocol is registered together with any unique identification number assigned. If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here.

34 Reference and/or URL for published protocol
Give the citation for the published protocol, if there is one.
Give the link to the published protocol, if there is one. This may be to an external site or to a protocol deposited with CRD in pdf format.

I give permission for this file to be made publicly available

35 Dissemination plans
Give brief details of plans for communicating essential messages from the review to the appropriate audiences.
Do you intend to publish the review on completion?

36 Keywords
Give words or phrases that best describe the review. (One word per box, create a new box for each term)

37 Details of any existing review of the same topic by the same authors
Give details of earlier versions of the systematic review if an update of an existing review is being registered, including full bibliographic reference if possible.

12 Funding sources/sponsors
Give details of the individuals, organizations, groups or other legal entities who take responsibility for initiating, managing, sponsoring and/or financing the review. Any unique identification numbers assigned to the review by the individuals or bodies listed should be included.

13 Conflicts of interest
List any conditions that could lead to actual or perceived undue influence on judgements concerning the main topic investigated in the review.
Are there any actual or potential conflicts of interest?

14 Collaborators
Give the name, affiliation and role of any individuals or organisations who are working on the review but who are not listed as review team members.

Title	First name	Last name	Organisation details

Review methods

15 Review question(s)
State the question(s) to be addressed / review objectives. Please complete a separate box for each question.

16 Searches
Give details of the sources to be searched, and any restrictions (e.g. language or publication period). The full search strategy is not required, but may be supplied as a link or attachment.

17 URL to search strategy
If you have one, give the link to your search strategy here. Alternatively you can e-mail this to PROSPERO and we will store and link to it.

I give permission for this file to be made publicly available

18 Condition or domain being studied
Give a short description of the disease, condition or healthcare domain being studied. This could include health and wellbeing outcomes.

19 Participants/population
Give summary criteria for the participants or populations being studied by the review. The preferred format includes details of both inclusion and exclusion criteria.

20 Intervention(s), exposure(s)
Give full and clear descriptions of the nature of the interventions or the exposures to be reviewed

21 Comparator(s)/control
Where relevant, give details of the alternatives against which the main subject/topic of the review will be compared (e.g. another intervention or a non-exposed control group).

22 Types of study to be included
Give details of the study designs to be included in the review. If there are no restrictions on the types of study design eligible for inclusion, this should be stated.

23 Context
Give summary details of the setting and other relevant characteristics which help define the inclusion or exclusion criteria.

24 Primary outcome(s)
Give the most important outcomes.
Give information on timing and effect measures, as appropriate.

38 Current review status
Review status should be updated when the review is completed and when it is published.

39 Any additional information
Provide any further information the review team consider relevant to the registration of the review.

40 Details of final report/publication(s)
This field should be left empty until details of the completed review are available.
Give the full citation for the final report or publication of the systematic review.
Give the URL where available.

Appendix H: Quality Criteria

Risk of Bias Tool

Aim: The review aims to assess the methodological quality of randomised controlled trials delivering antenatal CBT based interventions to determine whether these interventions reduce stress and anxiety symptoms when compared to a control.

1. Sample selected was representative of wider clinical population	
Low risk	A representative recruitment procedure is applied to reduce selection bias and appropriate eligibility criteria are applied to address the review aims/ appropriate attempts have been made to address sample representativeness
High risk	Recruitment method inappropriate or poorly described and no attempt to apply eligibility criteria or apply stringent eligibility criteria/insufficient attempts to reduce bias in sample selection
Unclear risk	Recruitment method poorly described and little discussion around eligibility criteria
2. Participants in each condition are similar at baseline in terms of stress/anxiety levels or differences were controlled for in analysis	
Low risk	Treatment and control groups comparable at baseline or sufficient attempts are made to statistically control for the differences
High risk	The treatment & control group are not comparable at baseline or no attempts have been made to address the differences
Unclear risk	Differences at baseline have not been explored or reported.
3. Levels of attrition were reported and equivalent for each condition	
Low risk	Attrition rates are low or equivalent to control group at post-treatment and follow-up.
High risk	Attrition rates are high or differ substantially from control group at post-treatment & follow-up.
Unclear risk	Attrition rates are not reported or considered.
4. Randomized assignment to treatment groups	
Low risk	
High risk	
Unclear risk	Information not available on randomisation.
5. Sample size was sufficient for analyses relating to anxiety/stress outcomes	
Low risk	Number of participants who completed both pre & post measures in the intervention group is sufficient to achieve Power of at least 0.8, where effect size is anticipated to be medium & alpha 0.05.
High risk	Number of participants who completed both pre & post measures in the intervention group is sufficient to achieve power of less than 0.7, where effect size is anticipated to be medium & alpha is 0.05.
Unclear risk	Sample size not reported
6. Follow-up assessment was at a suitable time period after intervention	
Low risk	Follow up anxiety > 1month
High risk	Follow-up anxiety < 1month
Unclear risk	No follow-up anxiety/stress measure administered.
7. A suitably robust and validated outcome measure	
Low risk	The primary anxiety/stress measure are clearly suitably, valid, reliable, standardised and appropriately administered.
High risk	Primary anxiety/stress measures are adequately appropriate, valid & reliable or adequately administered.

Unclear risk	Not appropriate primary anxiety measures are selected or these are inappropriately administered.
8. Intervention sufficiently defined	
Low risk	Sufficient detail available about intervention allowing enough information for replication (e.g manualised intervention, protocol, checklists)
High risk	Intervention not sufficiently defined and not standardised/manualised.
Unclear risk	Not enough information available.
9. **Intervention delivered as planned/compliance checked**	
Low risk	Sufficient procedures are available to ensure treatment is applied accurately and consistently (e.g. standardised measure to assess adherence, checklists, recordings and supervision)
High risk	or no appropriate measures to ensure treatment fidelity
Unclear risk	or procedure to assess treatment fidelity.
10. The therapist delivering the intervention had adequate training/competence	
Low risk	Intervention carried out by experienced therapists in CBT/Mindfulness &
High risk	Intervention is not carried out by suitably trained therapists
Unclear risk	No information available on therapist background.
11. A control group was used	
Low risk	Passive control group
High risk	Active control group
Unclear risk	No information available.
12. The analysis method was appropriate to the design used and anxiety/stress outcome measure	
Low risk	An appropriate statistically analysis is conducted and the outcomes are appropriately reported
High risk	Inappropriate or poorly conducted statistical analysis is used and the outcomes are poorly reported.
Unclear risk	Statistical analysis not carried out or not reported