BMJ Open Psychological well-being of women at high risk of spontaneous preterm birth cared for in a specialised preterm birth clinic: a prospective longitudinal cohort study

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ABSTRACT

Objectives To assess the psychological well-being of pregnant women at increased risk of spontaneous preterm birth, and the impact of care from a preterm birth clinic. Design Single-centre longitudinal cohort study over 1 vear. 2018-2019.

Setting Tertiary maternity hospital in Auckland, New Zealand.

Participants Pregnant women at increased risk of spontaneous preterm birth receiving care in a preterm birth clinic.

Intervention Participants completed three sets of questionnaires (State-Trait Anxiety Inventory, Edinburgh Postnatal Depression Scale, and 36-Item Short Form Survey)-prior to their first, after their second, and after their last clinic appointments. Study-specific questionnaires explored pregnancy-related anxiety and perceptions of care.

Primary and secondary outcome measures The primary outcome was the mean State-Anxiety score. Secondary outcomes included depression and quality of life measures.

Results 73/97 (75.3%) eligible women participated; 41.1% had a previous preterm birth, 31.5% a second trimester loss and 28.8% cervical surgery; 20.6% had a prior mental health condition. 63/73 (86.3%) women completed all guestionnaires. The adjusted mean stateanxiety score was 39.0 at baseline, which decreased to 36.5 after the second visit (difference -2.5, 95% CI -5.5 to 0.5, p=0.1) and to 32.6 after the last visit (difference -3.9 from second visit, 95% CI -6.4 to -1.5, p=0.002). Rates of anxiety (state-anxiety score >40) and depression (Edinburgh Postnatal Depression Scale score >12) were 38.4%, 34.8%, 19.0% and 13.7%, 8.7%, 9.5% respectively, at the same time periods. Perceptions of care were favourable: 88.9% stated the preterm birth clinic made them significantly or somewhat less anxious and 87.3% wanted to be seen again in a future pregnancy. Conclusions Women at increased risk of spontaneous preterm birth have high levels of anxiety. Psychological well-being improved during the second trimester: women perceived that preterm birth clinic care reduced pregnancy-related anxiety. These findings support the ongoing use and development of preterm birth clinics.

Strengths and limitations of this study

- This is the first study to assess the psychological well-being of women at high risk of spontaneous preterm birth who are cared for in a specialised preterm birth clinic.
- Strengths of the study include the prospective study design, and high rates of recruitment and participant retention in an ethnically diverse group of women.
- Limitations of the study are the modest sample size, lack of a comparison group and the use of screening tools rather than diagnostic criteria for anxiety and depression.
- Although this study demonstrates improved psycho-logical well-being of women at high risk of spontaneous preterm birth, further research is required to more directly quantify the impact of a preterm birth clinic on this.

INTRODUCTION

I train Psychological disorders are common in pregnancy.¹² Women with high-risk pregnancies ing, are more likely to suffer psychological distress with higher rates of anxiety and depression than the general pregnant population.^{3–5} Few studies have assessed the psychological well-being of women who are at high risk of spontaneous preterm birth, and in particular, the potential impact of care from a specialised preterm birth clinic. Preterm birth o clinics provide a package of care to asymptomatic women identified to be at increased risk based on their obstetric and gynaecological history. This care includes regular visits through the second trimester for ultrasound surveillance of cervical length and provision of treatments to prevent preterm birth such as cervical cerclage and vaginal progesterone therapy when indicated.⁶⁻⁸ Close monitoring and reassurance provided through a preterm birth clinic may reduce pregnancy-related

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anxiety, however, it is also possible that being labelled 'high risk' may increase psychological distress and anxiety. Further research in this area has been recommended.¹²

There is increasing recognition of the importance of psychological well-being in pregnancy. Meta-analyses show that antenatal depression is associated with a modestly increased risk of preterm birth and fetal growth restriction, and decreased rates of breastfeeding initiation.^{13 14} The effect of anxiety is less well evaluated, but is associated with increased pregnancy-related hypertension, increased rates of caesarean section, decreased rates of exclusive breastfeeding and increased anxiety in the offspring.¹⁵ Antenatal anxiety and depression are also strong predictors of postnatal depression.¹⁶ Strategies for prevention, along with improvements in the recognition and treatment of psychological disorders in pregnancy, are likely to improve outcomes for women and children.

This study aims to assess rates of anxiety, depression and health-related quality of life in pregnant women at high risk of spontaneous preterm birth who are cared for in a preterm birth clinic. The primary hypothesis is that women will have less anxiety after their second consultation in a preterm birth clinic compared with before their first (baseline), and this improvement will be sustained at the end of the second trimester. Secondary hypotheses are that women will have fewer symptoms of depression, improved quality of life, and less pregnancy-related anxiety over the same period.

MATERIAL AND METHODS

This longitudinal cohort study was carried out in a large tertiary maternity hospital in Auckland, New Zealand. All eligible women attending the preterm birth clinic over a 12-month period from August 2018 to August 2019 were invited to participate prior to their first appointment. This preterm birth clinic provides care to pregnant women perceived to be at high risk of spontaneous preterm birth and accepts local and regional referrals. Eligibility criteria for the preterm birth clinic include women with a previous spontaneous preterm birth, previous second trimester loss, history of extensive cervical surgery, or congenital uterine anomaly. Care through the preterm birth clinic includes initial assessment, risk factor modification, serial surveillance of cervical length until 24 weeks, and interventions such as vaginal progesterone and cervical cerclage when indicated (online supplemental table 1). Care in the preterm birth clinic is provided by a specialist obstetric and midwifery team on a weekly basis, and is in addition to routine antenatal care.

Inclusion criteria for the study were gestational age <24⁺⁰ weeks at first visit; live fetus; eligible for preterm birth clinic review due to ≥ 1 risk factor for spontaneous preterm birth (online supplemental table 1); written consent obtained; and sufficient English to independently complete questionnaires. Participants completed three sets of questionnaires: prior to their first clinic appointment (baseline, set 1), after their second appointment

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from electronic medical records. These data, along with questionnaire responses were entered into a passwordprotected Excel spreadsheet by a single investigator.

The primary outcome was the STAI state-anxiety score. Secondary outcomes were the EPDS score, SF-36 summary quality of life scores, and pregnancy-related anxiety (as continuous measures).

Statistical analyses

A pragmatic sample size was used. We aimed to invite all eligible women over a 1-year period to participate. Using data from medically high-risk women,²³ we estimated a sample size of 60 would provide 80% power, with alpha of 0.05, two-sided test and an estimated within subject correlation of 0.75 to detect a decrease in the mean state-anxiety score from 40.0 (SD 12.0) to 36.9.

Descriptive statistics were calculated using SPSS (V.25.0) and R software (V.3.5.3).^{24 25} Thematic analvsis was carried out on free-text responses using Braun and Clarke methodology by a single investigator.²⁶ The mixed model for repeated measures analyses (MMRM) was used to analyse repeatedly measured continuous outcomes and conducted using SAS software (V.9.4).²⁷ These analyses were used to test for time effect adjusting for prior diagnosis of a mental health condition, gestational age at first visit and obstetric history (categorised by no previous pregnancy beyond 12 weeks; loss/preterm birth at 12–28 weeks; loss/preterm birth at 28–37 weeks or term birth only), and subject was included as a random effect. Kenward-Roger method was used to estimate the denominator degrees of freedom for fixed effects. Twosided p<0.05 determined statistical significance. All CI are given at a two-sided 95% level.

Patient and public involvement

The study-specific questionnaire was piloted among the first five participants, who were asked for feedback on the clarity and importance of the questions. There was no other patient involvement in the study development.

RESULTS

The recruitment rate was 75.3% (73/97), participation is described in figure 1. Demographics, obstetric characteristics and risk factors for preterm birth are detailed in table 1. Some women had been seen in the clinic in a previous pregnancy (17/73, 23.3%) and/or for prepregnancy review (12/73, 16.4%).

The mean gestational ages at questionnaire completion were 13^{+4} weeks (SD 3^{+3}), 16^{+2} weeks (SD 3^{+2}) and 23^{+6} weeks (SD 1^{+2}). Anxiety, depression and quality of life scores and proportion of screen positive results (defined as >40 on the STAI state-anxiety scale and >12 on the EPDS) are shown in table 2. MMRM analyses, adjusting for gestation at first visit, prior mental health condition and obstetric history (fixed effects), are described in table 3. The primary outcome of the adjusted mean stateanxiety score was 39.0 at baseline and decreased to 36.5

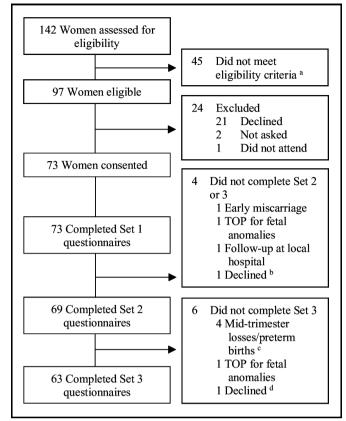


Figure 1 Participant recruitment and study flow diagram TOP, termination of pregnancy. ^aReasons not eligible: 19 were prepregnancy consultations, 2 had previously participated in study (both with pregnancy losses), 9 had insufficient English (including one who provided consent but was then identified to have insufficient written English when attempted first set of questionnaires and was withdrawn from the study), 3 were >24 weeks at first visit and 12 had a single visit planned only. ^bDistressed with new diagnosis of severe hypertension and fetal growth restriction, subsequently had fetal demise before last visit. ^cGestational ages at delivery 16⁺¹, 22⁺³, 23⁺⁴ and 24⁺⁴ weeks. ^dRecent diagnosis of severe depression with acute distress.

after the second visit (least square means difference -2.5, 95% CI -5.5 to 0.5, p=0.1), with a further reduction to 32.6 after the last visit (least squares means difference -3.9 from the second visit, 95% CI -6.4 to -1.5, p=0.002). Adjusted secondary outcomes are reported in table 3.

One woman was referred to maternal mental health **o** services following review of the EPDS self-harm question. **G** Preterm birth clinic clinicians referred six women to the **g** women's health social work for psychological support and two to maternal mental health services as part of routine practice. None of the women who completed the set 3 questionnaires reported having a new diagnosis of a mental health condition made by a health practitioner during the study period. One woman declined to complete the last set of questionnaires after a diagnosis of severe depression.

Women had mixed feelings about referral to the clinic prior to review, but following their last visit 56/63 (88.9%)

Table 1 Demographic details, obstetric characteristics and risk factors for preterm birth			
Characteristic	No (%) or mean (SD), n=73		
Ethnicity			
European	36 (49.3)		
Māori	7 (9.6)		
Pacific	5 (6.8)		
Asian	11 (15.1)		
Indian	9 (12.3)		
Other	5 (6.8)		
Age (years)			
Mean	34.0 (5.1)		
Range	22–45		
Body mass index (kg/m ²)*			
Mean	26.3 (6.4)		
Range	19–57		
Current smoker	5 (6.8)		
Has a current partner	72 (98.6)		
Previous diagnosis of a mental health condition (non-exclusive)†			
Depression	10 (13.7)		
Postnatal depression	4 (5.5)		
Generalised anxiety disorder	2 (2.7)		
Panic disorder	1 (1.4)		
Social anxiety disorder	1 (1.4)		
Post-traumatic spectrum disorder	3 (4.1)		
None	58 (79.4)		
Currently taking medication for a mental health condition	4 (5.5)		
Currently under the care of a psychiatrist/ psychologist	1 (1.4)		
Nulliparous	16 (21.9)		
Previous stillbirth or neonatal death $\ge 20^{+0}$ weeks	22 (30.1)		
Current twin pregnancy	1 (1.4)		
Reasons for preterm birth clinic referral (non-exclusive)			
Previous spontaneous preterm birth/ PPROM (24 ⁺⁰ to 36 ⁺⁰ weeks)‡	30 (41.1)		
Previous second trimester loss (16^{+0} to 23^{+6} weeks)	23 (31.5)		
Previous extensive cervical surgery§	21 (28.8)		
Congenital uterine anomaly	1 (1.4)		
Short cervix in current pregnancy <25 mm	5 (6.8)		
≥2 surgical terminations and/or other uterine instrumentations	14 (19.2)		

Continued

Table 1 Continued	
Characteristic	No (%) or mean (SD), n=73
Other risk factors for spontaneous preterm birth	4 (5.5)
Multiple reasons for referral to the preterm birth clinic	23 (31.5)
*Missing data n=2. †Self-reported. ‡Includes survivors born at 23 weeks of gestation §LLETZ with depth of excision ≥10mm or >1 proc cone biopsy. LLETZ, large loop excision of the transformation z	edure, or knife

prelabour premature rupture of membranes.

Protected by copyright, incl reported care in the preterm birth clinic made them significantly or somewhat less anxious. The majority (55/63, 87.3%)would want to be cared for in a preterm birth clinic again in another pregnancy. The seven women who did not, had already had a term birth since their prior early birth, or were referred for cervical surgery or multiple uterine instrumenuses rei tations only (and only one required an intervention greater than surveillance in their current pregnancy) (online supplemental table 5).

The predominant themes causing pregnancy-related anxiety at baseline were preterm birth, pregnancy loss, and concern for the baby's health. Many women were anxious about extremely early birth-'being born too early to do anything about it,' and were worried about reaching milestones-'getting to 24 weeks to be deemed to have a 'viable' pregnancy.' Women were worried about 5 history repeating itself—'I am scared that it might happen again,' and how they would cope if it did -- 'my ability to manage emotions associated with neonatal intensive care unit if this baby is early.' Fewer women were anxious about the risks of chromosomal or fetal anomalies.

When asked at clinic discharge what they found most helpful to relieve pregnancy-related anxiety, the main theme was medical support, including close monitoring, the preterm birth clinic, regular ultrasound scans and nightly visits have really helped me! Lots of reassurance,' 'follow-up from the preterm birth clinic,' 'the weekly check-ups and reassurance from the doctors and how quickly they acted when there was an issue,' and 'the ĝ support of specialists who are willing to listen.' Other themes included support from family and friends, distraction, relaxation techniques and prayer.

The mean number of clinic visits was 5.4 (SD 2.1), range 1-11. Clinic interventions and pregnancy outcomes are reported in table 4. Elective cervical cerclage is reserved for the highest risk women, and was performed in 17/72 cases (23.6%, excludes one women with local follow-up after the first visit as no further data collected), usually at 12-14 weeks gestation. The remaining women had ultrasound surveillance of cervical length as their primary management. The

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	Set 1 (baseline),	n=73*	Set 2, n=69*		Set 3, n=63*	
	Mean (SD) or proportion (%)	95% CI	Mean (SD) or proportion (%)	95% CI	Mean (SD) or proportion (%)	95% CI
STAI state-anxiety score	38.6 (11.9)	36.8 to 41.3	36.2 (11.6)	33.5 to 38.9	32.0 (9.8)	29.6 to 34.4
STAI state-anxiety positive screen†	28/73 (38.4)	27.2 to 49.5	24/69 (34.8)	23.5 to 46.0	12/63 (19.0)	9.4 to 28.7
STAI trait-anxiety score	37.3 (10.1)	35.0 to 39.6	36.5 (9.6)‡	34.2 to 38.8	34.9 (10.8)	32.2 to 37.6
STAI trait-anxiety positive screen†	28/73 (38.4)	27.2 to 49.5	23/68 (33.8)‡	22.6 to 45.1	15/63 (23.8)	13.3 to 34.3
EPDS score	7.3 (4.6)	6.2 to 8.4	6.0 (4.5)	4.9 to 7.1	5.4 (5.1)	4.1 to 6.6
EPDS positive screen§	10/73 (13.7)	5.8 to 21.6	6/69 (8.7)	2.0 to 15.3	6/63 (9.5)	2.3 to 16.8
Summary mental health score¶	63.8 (15.9), ††	60.0 to 67.8	65.7 (17.0)**	61.5 to 69.9	72.4 (17.9), ¶¶	67.8 to 77.0
Summary physical health score¶	69.3 (21.5)‡	64.3 to 74.3	66.0 (24.1)‡‡	60.2 to 71.8	71.3 (22.7)‡	65.6 to 77.0
Pregnancy-related anxiety§§	4.9 (2.5) ‡	4.3 to 5.5	-	-	2.7 (2.5)	2.1 to 3.3

*Set 1 questionnaires were completed prior to the women's first clinic appointment (baseline); set 2 after their second appointment (usually 2–3 weeks later); set 3 after their last appointment (usually at 23–24 weeks of gestation).

†Positive screen defined as STAI score >40.

‡Missing score for one woman as one incomplete question.

§Positive screen defined as EPDS >12.

¶Using the RAND 36-Item Short Form Survey. Higher scores associated with better quality of life.

**Missing scores for five women as one or more incomplete questions.

††Missing scores for nine women as one or more incomplete questions.

‡‡Missing scores for three women as one or more incomplete questions.

§§Visual Analogue Scale, 0=not at all anxious, 10=extremely anxious.

¶¶Missing scores for four women as one or more incomplete questions.

EPDS, Edinburgh Postnatal Depression Scale; STAI, State Trait Anxiety Inventory.

overall rate of birth <37 weeks was 17/72 (23.6%), including two spontaneous second trimester losses. One extremely early preterm birth followed prelabour fetal demise, all other preterm births occurred following spontaneous labour or preterm prelabour rupture of membranes. Of pregnancies that reached $\geq 20^{+0}$ weeks 67/69 (97.1%) babies were alive at hospital discharge.

DISCUSSION

This is the first study to assess the psychological well-being of women receiving care in a specialised preterm birth clinic. It identifies high rates of psychological distress, with 38.4% and 13.7% of women having significant symptoms of anxiety and depression, respectively, at the beginning of the second trimester. While the change in mean state-anxiety scores after two clinic visits did not reach statistical significance, improvement may still be clinically important. Adjusted mean state-anxiety scores were significantly improved by clinic discharge, with rates of anxiety half that of baseline. Although depression was less common than anxiety, the adjusted mean EPDS score improved by the second clinic visit and this was sustained to the end of the second trimester. Quality of life improved with regard to mental health, but not physical health. Pregnancy-related anxiety scores also improved and women perceived care in the preterm birth clinic to be a significant factor in relieving anxiety.

A number of studies have reported rates of anxiety and depression in pregnancy, with a wide range of estimates.¹² In systematic review, the overall prevalence of a clinical diagnosis of an anxiety disorder in pregnancy was 15.2%, with rates of self-reported anxiety of 18.2%, 19.1% and 24.6% in the first, second and third trimesters respectively.² Women with high-risk pregnancies have higher rates of anxiety than low risk women; 45.0% vs 16.7% in one study.²³ Rates of depression were 7.4%, 12.8% and 12.0% in the general pregnant population in the first, second and third trimesters,¹ and ranged from 11% to 28% in studies on high-risk pregnancies.^{3423 28 29} The higher rates of anxiety seen in our study are consistent with published literature for high-risk pregnancies with rates of depression in the lower range of those previously reported.

Although we do not have data for the whole pregnancy, it seems that gestational changes in rates of anxiety in women at high risk of spontaneous preterm birth may not follow the same trends as in the general pregnant population in which rates rise throughout pregnancy.² In our study, anxiety was highest at the beginning of the second trimester and then decreased to levels similar to

Table 3 Mixed	model for rep	Mixed model for repeated measures analyses for anxiety, depression and quality of life scores	es analyses	for anxiety, c	depression and	duality of lif	e scores				
	STAI state-a	STAI state-anxiety score		EPDS score	0		Summary ph	Summary physical health score*		Summary mental health score*	*0
Fixed effect	P value†			P value†			P value†		P value†		
Questionnaire set no	<0.0001			0.0001			0.3		<0.0001		
Gestation at first visit‡	0.7			0.4			0.2		0.2		
Prior mental health condition‡	0.7			0.09			0.6		0.006		
Obstetric history ‡¶	0.4			0.04			0.8		0.3		
Least squares means	Estimate	95 % CI		Estimate	95 % CI		Estimate	95 % CI	Estimate	95 % CI	
Set 1	39.0	35.6 to 42.4		7.5	6.1 to 8.9		70.9	63.9 to 77.8	60.7	55.8 to 65.6	
Set 2	36.5	33.0 to 40.0		6.3	4.9 to 7.7		67.2	60.1 to 74.4	62.5	57.5 to 67.4	
Set 3	32.6	29.1 to 36.1		5.7	4.3 to 7.1		71.5	64.3 to 78.6	69.5	64.6 to 74.5	
Least squares means difference	Estimate	95 % CI	P value§	Estimate	95 % CI	P value§	Estimate	95%CI P	P Estimate value §	95 % CI	P value§
Set 2-1	-2.5	-5.5 to 0.5	0.1	-1:2	–2.3 to 0.2	0.02	-3.7	-10.1 to 2.8 0.3	3 1.8	-3.1 to 6.6	0.5
Set 3-1	-6.4	-8.8 to 4.0	<0.0001	-1.8	-2.6 to 1.0	<0.0001	0.6	-4.6 to 5.8 0.8	3 8.9	4.7 to 13.0	<0.0001
Set 3–2	-3.9	-6.4 to 1.5	0.002	-0.6	-1.4 to 0.2	0.2	4.2	-1.1-9.6 0.1	1 7.1	–3.0 to –11.2	0.001
*RAND 36-Item Short Form Survey. Higher scores associated with better quality of life. †Pr >F. Type 3 tests of fixed effects. ‡Analysis adjusted for these factors. §Pr > [tl.	hort Form Surv ts of fixed effe d for these fact	/ey. Higher scor cts. tors.	es associate	ed with better c	quality of life.						
ICategorised by no previous pregnancy beyond 12 weeks; loss/preterm birth at 1 STAI, State Trait Anxiety Inventory; EPDS, Edinburgh Postnatal Depression Scale.;	no previous pre nxiety Inventor	egnancy beyon ry; EPDS, Edink	d 12 weeks; ourgh Postna	loss/preterm	iirth at 12–28 we N Scale.;	seks; loss/pre	term birth at 2	flCategorised by no previous pregnancy beyond 12 weeks; loss/preterm birth at 12–28 weeks; loss/preterm birth at 28–37 weeks; or term birth only. STAI, State Trait Anxiety Inventory; EPDS, Edinburgh Postnatal Depression Scale.;	m birth only.		

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Characteristics	Proportion (%) or mean (SD)
Shortest transvaginal cervical length measurement	
Mean (SD) (in mm)	27.0 (9.1)
Range (in mm)	0–39
No <25 mm (threshold for intervention)	21/72 (29.2)
Treatments given to reduce the risk of preterm birth	
Cervical cerclage only	16/72 (22.2)
Vaginal progesterone only	4/72 (5.6)
Both cervical cerclage and vaginal progesterone	10/72 (13.9)
No treatment	40/72 (55.6)
Antenatal hospital admission from clinic due to preterm birth risk	2/72 (2.8)
Risk of preterm birth for those who had an exit visit†	
Low	45/66 (68.2)
Intermediate	18/66 (27.3)
High	3/66 (4.5)
Pregnancy outcome	
Termination of pregnancy for fetal anomalies	2/72 (2.8)
First trimester miscarriage (<13 ⁺⁰ weeks)	1/72 (1.4)
Second trimester loss (13 ⁺¹ to 22 ⁺⁶ weeks)	2/72 (2.8)
Extremely early preterm birth (23 ⁺⁰ to 27 ⁺⁶ weeks)‡	3/72 (4.2)
Very early preterm birth (28 ⁺⁰ to 31 ⁺⁶ weeks)	1/72 (1.4)
Moderate to late preterm birth $(32^{+0} \text{ to } 36^{+6} \text{ weeks})$	11/72 (15.3)
Term birth (\geq 37 ⁺⁰ weeks)	52/72 (72.2)
Mode of birth for pregnancies that reached $\geq 20^{+0}$ weeks§	
Normal vaginal birth	44/68 (64.7)
Instrumental birth	7/68 (10.3)
Caesarean section	
Neonatal outcome for pregnancies that reached $\geq 20^{+0}$ weeks§¶	
	67/69 (97.1)
	· · ·
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Caesarean section Neonatal outcome for pregnancies that reached ≥20 ⁺⁰ weeks§¶ Alive at hospital discharge Early neonatal death Stillbirth *Excluding one with all follow-up at local hospital after first visit as not tRisk assessment defined in online supplemental table 4. Quantitative women who did not have an exit appointment. Includes three women was their second visit, both were high risk and delivered prior to plan declined. \$Includes one prelabour fetal demise.	re fetal fibronectin was included in 29/66 (44%) cases. Exclu n who did not complete Set 3 questionnaires—for two the ex
xcluding one termination of pregnancy >20 weeks. acludes one set of twins. se seen in general pregnant populations by the end of second trimester. This may be due to reduced anxiety r second trimester loss once this gestational time iod is complete (31.5% of our cohort had experienced	The provision of an overall ongoing risk assessment at the final clinic visit is likely to be beneficial; the majority o women were considered to have a relatively low ongoing risk of preterm birth and encouraged to return to a low

those seen in general pregnant populations by the end of the second trimester. This may be due to reduced anxiety over second trimester loss once this gestational time period is complete (31.5% of our cohort had experienced a second trimester loss previously). However, advancing gestation is unlikely to be the sole factor in anxiety levels returning to those of the general pregnant population, as the risk of early preterm birth was still ongoing at the time of last clinic visit. This, along with women's perception of care, suggests that preterm birth clinic care may have had a role in improving psychological well-being.

While there is some evidence that simply labelling a pregnancy 'high risk' may increase anxiety and fear, other studies identified that women embrace this label in a positive way.^{10 11} A qualitative study has assessed women's perceptions of care in a preterm birth clinic in the UK, with all women viewing their high-risk status positively.¹¹

These women reported that regular reassurance from the clinic was a helpful coping strategy and that other health professionals were not always sensitive to their worries about having another preterm birth.¹¹ Our results are consistent with these findings.

Preterm birth clinics offer individualised, coordinated and evidence-based care with the aim of reducing spontaneous preterm birth and improving perinatal outcome. Any potential to reduce psychological distress is an additional benefit. Further research should aim to include a comparison group to more directly quantify the effect of preterm birth clinics in improving psychological wellbeing. A larger sample size would also be required to direct practice change if considering the psychological, as well as clinical, benefit of preterm birth clinics. However, the new knowledge from our study should reassure clinicians and policy makers that preterm birth clinics do not seem to cause psychological harm.

Symptoms of anxiety and depression were underrecognised by clinicians in this study, with low referral rates for psychological support or maternal mental health review based on usual indications. Early recognition of anxiety and depression with provision of support or referral for other interventions may reduce maternal morbidity and improve pregnancy outcomes, and is likely to reduce the risk of postnatal depression.³⁰ Our findings suggest there are currently missed opportunities for care and preterm birth clinics should ensure they have referral pathways and access to psychological assessment and support, or should incorporate this into part of standard care within the clinic.

The main limitations of our study are the lack of a comparison group and modest sample size. The most appropriate comparison is with women of similar preterm birth risk who do not receive care in a preterm birth clinic; however, withholding clinic care is not possible when a clinic is well established within an area and available to all. Use of the general population or a medically high-risk group as a comparator is not appropriate as background anxiety levels for these women may increase over gestation due to increasing risk of other pregnancy complications, whereas the risk of preterm birth decreases with advancing gestation. Sample size was directed by the duration of the study and the number of women referred to the preterm birth clinic over the 12-month period. We are aware that not all women eligible for the clinic (and therefore for the study) were referred during this time period, and the women seen may have a higher risk profile than those who were eligible but not referred.

A further limitation is the use of screening tests rather than diagnostic criteria for anxiety and depression. While diagnostic interviews are the gold standard, they are time consuming, require special training and are expensive.³¹ Screening tests are reliable and have been validated for use in pregnancy.^{28 32–38} The STAI with a cut-off >40 has a sensitivity of 81% and specificity of 80% for diagnosis of an anxiety disorder in pregnancy when compared with DSM-IV (Diagnostic and Statistical Manual of Mental

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Data availability statement No data are available. Data are available on reasonable request.

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ORCID iDs

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Supplementary Information

Supplementary Table 1. Standard practice in the preterm birth clinic

Clinic referral	At least one of the following risk factors for spontaneous preterm
criteria	birth:
ci nel la	 Previous spontaneous preterm birth or PPROM <36 weeks of gestation
	 Previous spontaneous second trimester loss at 16⁺⁰ to 24⁺⁰ weeks of gestation
	• Previous LLETZ with >10 mm depth of excision or ≥ 2 procedures of any depth
	 Previous knife cone biopsy or trachelectomy
	 Congenital uterine and/or cervical anomaly
	 Short cervix detected on transvaginal ultrasound scan in current pregnancy of <25 mm at <24⁺⁰ weeks of gestation
	 Other risk factors e.g. ≥2 surgical termination of pregnancy
	and/or evacuation of retained products of conception procedures,
	complicated caesarean section at full dilatation, history of
	diethylstilboestrol exposure (woman or her mother), known
	collagen or connective tissue disorders
Initial consultation	Obstetric and medical review is undertaken to identify risk factors
at around 12 weeks	for preterm birth, along with vaginal examination, microbiological
	swabs, midstream urine for culture and transvaginal ultrasound
	assessment of the cervix. ¹ Women are provided with information
	regarding their individualised risk for preterm birth and counselled on potential interventions including lifestyle and behaviour change
	(including support for smoking cessation), serial cervical length
	assessment, cervical cerclage and progesterone therapy, and an
	individualised plan of care is made. History-indicated (elective)
	cervical cerclage is generally reserved for women with multiple
	second trimester miscarriages or spontaneous preterm births, in line
	with current evidence. ² Progesterone is not offered as prophylactic
	treatment and use is considered only in women who develop a short
	cervix.
Psychological	Clinician assessment of psychological wellbeing was performed
support	during routine clinical assessment. Referral to women's health social
	work or maternal mental health services was offered to women
Subsequent reviews	identified as needing additional psychological support. In the majority of cases, subsequent visits are fortnightly from 14 to
Subscruciit i eviews	24 weeks and include a review of pregnancy progress and
	transvaginal ultrasound assessment of the cervix. Ultrasound-
	indicated cervical cerclage or vaginal progesterone are
	recommended if the cervix shortens to <25 mm. Decisions regarding
	these interventions are made on an individual basis including further
	review of risk factors, other signs and symptoms and cervical length.
On-going care	Women are discharged back to their lead maternity carer at 23 to 25
	weeks. An overall risk assessment for very early preterm birth is

made at the final visit and includes the selective use of quantitative fetal fibronectin and the QUiPP App for those thought at highest risk. The QUiPP App ³ combines history, cervical length and fetal fibronectin to predict spontaneous preterm birth within certain timeframes and is used to guide decisions on hospital admission and
antenatal corticosteroid use.

LLETZ, large loop excision of the transformation zone; PPROM, preterm pre-labour rupture of membranes.

Supplementary Table 2. Study specific questionnaires from Set 1

Stu	Study specific questionnaire Set 1		
1.	Which ethnic group do you belong to? Mark the space or spaces which apply to you.		
	New Zealand European		
	Māori		
	Samoan		
	Cook Island Māori		
	Tongan		
	Niuean		
	Chinese		
	Indian		
	Other such as Dutch, Japanese, Tokelauan. Please state:		
2.	Were you aware that you had an increased risk of your baby being born early in this		
	pregnancy before you got pregnant?		
	Yes If yes, please go to question 3		
	No If no, please go to question 4		
3.	Did you contemplate not getting pregnant prior to this pregnancy because you were		
	worried about your increased chance of having a baby born early?		
	Yes		
	No		
4.	Once you were pregnant, did your lead maternity carer (midwife, GP or obstetrician)		
	identify that there was an increased chance of your baby being born early in this		
	pregnancy?		
	Yes If yes, please go to question 5		
	No If no, please go to question 6		
5.	How did you feel when your lead maternity carer (midwife, GP or obstetrician)		
	identified that there was an increased chance of your baby being born early in this		
	pregnancy?		
	Very anxious		
	Somewhat anxious		
	No different / the same		
	Somewhat reassured		
	Very reassured		
6.	How did you feel after your maternity care provider (midwife, GP or obstetrician)		
	suggested you come to the Preterm Birth Clinic?		
	Significantly more anxious		
	Somewhat more anxious		
	No different / the same		
	Somewhat more reassured		
	Significantly more reassured		
7.	How did you feel after you read the pamphlet about what to expect in the Preterm		
	Birth Clinic that was included with your appointment details?		
	Significantly more anxious		
	Somewhat more anxious		
	No different / the same		
	Somewhat more reassured		

Significantly more reassured		
8. Do you have a partner?		
Yes		
No		
9. How would you describe your social support network (for example your partner,		
whānau/family, friends)?		
Very unsupportive		
Somewhat unsupportive		
Neither supportive nor unsupportive		
Somewhat supportive		
Very supportive		
Very supportive 10. Note how anxious (on average) you have felt about your pregnancy over the past 7		
days with a mark () on the line below.		
Not at all Extremely		
anxious anxious		
11. What are you most anxious about in this pregnancy? <i>(space for response)</i>		
12. What do you find most helpful to relieve any pregnancy-related anxiety? (space for		
response)		
13. Have you ever been diagnosed with any of the following mental health conditions?		
Depression		
Postnatal depression		
Generalised anxiety disorder		
Post-traumatic stress disorder		
Social anxiety disorder		
Panic disorder		
Obsessive-compulsive disorder		
Bipolar disorder		
*		
Schizophrenia		
Borderline personality disorder		
Other, please name		
None		
14. Are you currently taking any prescribed medication for a mental health condition?		
Yes. If so, what is the name of this medication?		
No		
15. Have you ever taken any prescribed medication for a mental health condition?		
Yes. If so, what is the name of this medication?		
No		
16. Are you currently under the care of a psychiatrist or psychologist?		
Yes. If so, what is this for? No		
17. Have you ever been seen by a psychiatrist?		
Yes. If so, when was this and what was it for?		
No		
18. Are you taking any pregnancy supplements or probiotics, other than folic acid, Elevit		
or iodine?		

Yes. If so, what is the name of the supplement/s	?
No	

Supplementary Table 3. Study specific questionnaires from Set 3

Stu	ıdy specific questionnaire Set 3		
1.	How have you found the quality of your general pregnancy care?		
	Very low quality		
	Low quality		
	Neither high or low quality		
	High quality		
	Very high quality		
2.	How have you found the quality of your care through the Preterm Birth Clinic?		
	Very low quality		
	Low quality		
	Neither high or low quality		
	High quality		
	Very high quality		
3.	Do you think that being seen in a preterm birth clinic made you more or less anxious		
	about your pregnancy?		
	Significantly more anxious		
	Somewhat more anxious		
	Neither more or less anxious		
	Somewhat less anxious		
	Significantly less anxious		
4.	If you have another pregnancy, would you want to be cared for through a preterm birth		
	clinic again?		
	Yes		
	No		
-	Unsure		
5.	Note how anxious (on average) you have felt about your pregnancy over the past 7		
	days with a mark () on the line below.		
	Not at all Extremely		
	Ndt at all Extremely anxious anxious		
6.	What are you most anxious about in this pregnancy? (space for response)		
7.	7. What do you find most helpful to relieve any pregnancy-related anxiety? (space for		
0	response)		
8.	J 8 J		
	the Preterm Birth Clinic this pregnancy?		
	Yes, if so please provide		
	details		
	No		

Supplementary Table 4. Criteria for risk classification for study purposes at discharge from the preterm birth clinic

Risk classification	Criteria
Low	Cervical length >25 mm, AND
	Quantitative fetal fibronectin level of <50 ng/ml if performed
	(based on usual clinical indications), AND
	No intervention (progesterone or cerclage) required during the
	current pregnancy due to cervical change
Intermediate	Shortened cervical length to 11-25 mm, AND/OR
	Quantitative fetal fibronectin level of 50-199 ng/ml if performed
	(based on usual indications), AND/OR
	Need for progesterone and/or cerclage during the current pregnancy
	due to cervical change
High	Shortened cervical length to <10 mm, AND/OR
-	Quantitative fetal fibronectin level of ≥200 ng/ml if performed
	(based on usual indications)

Supplementary Table 5. Women's knowledge of their preterm birth risk and their perceptions of preterm birth clinic care

Question and response	Number (%)
Set 1 (baseline)	
1. Were you aware that you had an increased risk of your baby being	
born early before you got pregnant?	
Yes	59/73 (80.8)
No	14/73 (19.2)
2. Did you contemplate not getting pregnant because you were worried	
about your increased chance of having a baby born early? ^a	
Yes	19/59 (32.2)
No	40/59 (67.8)
3. Once you were pregnant, did your lead maternity carer (midwife, GP	
or obstetrician) identify that there was an increased chance of your	
baby being born early?	
Yes	51/71 (71.8)
No	20/71 (28.2)
4. How did you feel when your lead maternity carer (midwife, GP or	
obstetrician) identified that there was an increased chance of your baby	
being born early? ^b	
Very anxious	11/51 (21.6)
Somewhat anxious	20/51 (39.2)
Neither anxious nor relieved	12/51 (23.5)
Somewhat relieved	5/51 (9.8)
Very relieved	3/51 (5.9)
5. How did you feel after your maternity care provider (midwife, GP or	
obstetrician) suggested you come to the Preterm Birth Clinic?	
Significantly more anxious	8/71 (11.3)
Somewhat more anxious	12/71 (16.9)
Neither more or less anxious	11/71 (15.5)
Somewhat less anxious	24/71 (33.8)
Significantly less anxious	16/71 (22.5)
6. How did you feel after you read the pamphlet about what to expect in	
the Preterm Birth Clinic that was included with your appointment	
details?	
Significantly more anxious	1/69 (1.4)
Somewhat more anxious	13/69 (18.8)
Neither more or less anxious	30/69 (43.5)
Somewhat less anxious	20/69 (29.0)
Significantly less anxious	5/69 (7.2)
8. How would you describe your social support network (for example	
your partner, whānau/family, friends)?	
Very unsupportive	7/72 (9.7)
Somewhat unsupportive	1/72 (1.4)
Neither supportive nor unsupportive	2/72 (2.8)
Somewhat supportive	6/72 (8.3)
Very supportive	56/72 (77.8)
Set 3 (after last visit)	50/12 (11.0)

1. How have you found the quality of your general pregnancy care?	
Very low quality	0/63 (0.0)
Low quality	1/63 (1.6)
Neither high or low quality	4/63 (6.3)
High quality	13/63 (20.6)
Very high quality	45/63 (71.4)
2. How have you found the quality of your care through the Preterm	
Birth Clinic?	
Very low quality	0/63 (0.0)
Low quality	1/63 (1.6)
Neither high or low quality	1/63 (1.6)
High quality	12/63 (19.0)
Very high quality	49/63 (77.8)
3. Do you think that being seen in a preterm birth clinic made you more	
or less anxious about your pregnancy?	
Significantly more anxious	2/63 (3.2)
Somewhat more anxious	2/63 (3.2)
Neither more or less anxious	3/63 (4.8)
Somewhat less anxious	14/63 (22.2)
Significantly less anxious	42/63 (66.7)
4. If you have another pregnancy, would you want to be cared for	
through a preterm birth clinic again?	
Yes	55/63 (87.3)
No	7/63 (11.1)
Unsure	1/63 (1.6)

GP, general practitioner.

Denominator reflects numbered of respondents that answered each individual question.

^a Only answered if responded 'Yes' to question 1.

^b Only answered if responded 'Yes' to question 3.

Supplemental material

References for Supplementary Material

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