Pregnancy-Specific Anxiety Tool (PSAT):
Instrument Development and Psychometric Evaluation

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ABSTRACT

Objective: Pregnancy-specific anxiety (PSA) is a distinct construct from general anxiety and depression. The purpose of this study was to develop, evaluate, and validate the Pregnancy-Specific Anxiety Tool (PSAT), to measure PSA and its severity.

Methods: The study was carried out in 2 stages. Stage 1 involved item development and content and face validation. Stage 2 included psychometric evaluation to examine item distributions and correlational structure, dimensionality, internal consistency reliability, stability, and construct, convergent, and criterion validity, using 2 independent samples (initial sample N = 494, May–October 2018; validation sample N = 325, July 2019–May 2020).

Results: Eighty-two items were evaluated for face validity and 41 items were considered in stage 2 based on feedback from participants and experts. Model fit from exploratory factor analysis and patterns of item-factor loadings suggested a 6-factor model with 33 items. The 6 factors included items pertaining to health and well-being of the baby, labor and the pregnant person's well-being, postpartum, support, career and finance, and indicators of severity. Confirmatory factor analysis carried out using the initial sample showed good fit with the validation sample. The area under the curve (AUC) for the diagnosis of adjustment disorders (AD) was 0.73 (95% CI, 0.67–0.79), and for AD/any anxiety disorders, the AUC was 0.80 (95% CI, 0.75–0.85).

Conclusions: The PSAT can be useful for screening and monitoring of PSA, and pregnant people with scores higher than 10 should be considered for further assessment.

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Pregnancy-specific anxiety (PSA) is defined as "nervousness and fear about the baby's health, the mother's health and appearance, experience with the health care system, social and financial issues in the context of pregnancy, childbirth, and parenting that are accompanied by excessive worry and somatic symptoms."[1(p121)] Accumulating evidence indicates that PSA is a construct distinct from general anxiety and depression.[2–6] In 2004, Huizink et al[2] examined anxiety related to the baby's health and childbirth at multiple points during pregnancy and found that depression and general anxiety explained only a small portion of the variance related to such anxiety during early and midpregnancy, with no associations in late pregnancy. PSA has stronger associations with biological markers (eg, shorter telomere length,[7] higher rates of DNA methylation)[8] and clinical outcomes (eg, postnatal mood disturbance, birth and early developmental outcomes).[6,9–11] Despite its significance, measurement and diagnosis of PSA have been hindered by a paucity of valid assessment tools and clear diagnostic criteria. Based on the *Diagnostic and Statistical Manual of Mental Disorders,* Fifth Edition (*DSM-5*), anxiety disorders share excessive worry/fear but vary in the type of cognition.[12] The lack of specific items about cognition related to pregnancy in general or diagnostic measures of anxiety results in a significant proportion of pregnant people with elevated anxiety not meeting the required criteria.[5] Furthermore, some measures rely heavily on somatic signs that overlap with physiological adjustments of normal pregnancy, leading to inappropriately inflated scores.[9,13] A 2015 systematic review concluded that extant PSA measures[2,4,14–17] lacked "sufficient scope and depth."[18(p31)] For example, Levin's Pregnancy Anxiety Scale (PAS)[15] recognizes the multidimensional nature of the PSA and measures 3 domains including those related to anxiety about being pregnant, childbirth, and hospitalization. However, as Levin acknowledges, there are "missing dimensions"[15] in this scale, as it does not include several known domains of PSA. Furthermore, this tool was designed to measure PSA retrospectively and not during pregnancy. Other scales designed to measure PSA, such as the Pregnancy-Related Anxiety Scale (P-RAS),[17] the Pregnancy Outcome Questionnaire (POQ),[4] the Pregnancy-Related Anxiety Questionnaire-Short,[2] and the Pregnancy Anxiety Scale,[16] each cover a variable number of PSA domains. Although the P-RAS[17] covers a broader range of domains, it too misses several important domains. Furthermore, most items included in this scale pertain to anxiety about the fetus, and only 1 indicator addresses each of the other 4 domains, leading to concerns about the psychometric properties of the

Clinical Points

- Clinically valid tools are needed to measure pregnancy-specific anxiety and its severity.
- The Pregnancy-Specific Anxiety Tool can be useful for screening pregnancy-specific anxiety throughout pregnancy.
- People with a score > 10 may need further assessments.

scale.[17] A newly developed measure, the Pregnancy-related Anxiety Scale (PrAS),[19] includes several domains of PSA, but does not assess partner support and financial concerns. The lack of indicators for assessing the severity of PSA is another limitation common to all the available scales.[1] Severity classification is important, as mild anxiety is often transient and may represent a healthy response to ensure the safety of mother and child through pregnancy and childbirth. On the other hand, the severe anxiety is enduring and persistent and can impact a person's ability to focus, relax, or function in daily responsibilities.[20–22] The purpose of this study was to develop, evaluate, and validate a measurement tool to assess PSA and its severity.

METHODS

Study Design

This study was designed based on the principles required for developing Patient Reported Outcomes (PROs)[23,24] and Patient Reported Outcome Measures (PROMs).[25–28] The key steps in PROM development include identification of the conceptual framework, generation of items, content refinement, item reduction, scaling, and psychometric evaluation.[25] This study involved 2 main stages: stage 1—item development (ie, item generation and content and face validation) and stage 2—scale development and evaluation (ie, examining the underlying dimensionality of the item set; identifying and eliminating redundant items or those not congruent with the construct being measured; and psychometric testing to establish test-retest and internal consistency reliability and construct, convergent, and criterion validity).

Stage 1: Item Development

The study was based on a conceptual framework developed through a comprehensive literature review that showed PSA to be a multidimensional construct with 9 domains (ie, anxiety about fetal health, fetal loss, childbirth, parenting and newborn care, mother's well-being, body image, health care-related issues, financial issues, and family and social support); 2 attributes (ie, affective responses and cognitions); and 3 categories of consequences (ie, excessive reassurance-seeking, avoiding behaviors, and impact on daily function).[1] This conceptual framework was shared at a multidisciplinary meeting, and feedback was elicited on the definition and domains of PSA, indicators of severity, timing of the assessment, appropriateness of inclusion of items related to sleep problems, and corresponding clinical diagnosis.

Item generation. Candidate items were generated based on an extensive literature review and items of previous scales deemed relevant in concept analysis[1] as well as from the findings of a qualitative study.[29] The qualitative study included 27 interviews with 15 pregnant persons and provided a person-identified base for item generation, particularly for severity and impact of anxiety on the pregnant person's daily life (as such evidence is sparse in the literature).[1] Using these approaches, 143 items were developed and grouped into 3 categories: severity of anxiety (40 items); confidence in managing the unknown/uncertainty related to pregnancy (10 items); and specific domains/cognition (93 items), including 11 subgroups: fetal health, loss of fetus, childbirth, pregnant person's well-being, body image, parenting and care for the child, maternity care-related, financial, family and social support, general indicators, and impacts of person's anxiety on the baby.

Content validation. Generated items were presented to a panel of 6 experts (per recommendation)[30] to evaluate individual items for clarity and readability and rate each item for both clinical relevance and importance on a 4-point ordinal scale and to provide suggestions for new items.[31] We computed a content validity index (CVI) to determine agreement among experts.[32,33] Items were retained if the CVI on both relevance and importance exceeded 0.78.[33] If an item met only 1 of the CVI requirements, the comments provided by the experts informed the deliberation on whether or not to retain the item. Based on CVI, a total of 75 items were retained. Although not meeting the CVI recommendation, 7 additional items were also retained based on further discussions with the experts. A total of 82 items were included for face validity evaluation: 30 items for severity of anxiety, 7 items for confidence in managing uncertainty related to pregnancy, and 45 items for specific domains and cognition. The expert panel recommended a Likert scale with 4 options for item presentation.

Pilot testing. We conducted a pilot test of the item pool to assess face validity and examine whether items were clearly expressed and were being interpreted correctly.[34] Cognitive interviews were undertaken with 10 pregnant persons to determine respondent comprehension and identify potential problems in responding to items.[25,35] Interviews were recorded and notes were taken on participants' feedback on each item.

Stage 2: Instrument Development and Evaluation

For this stage, 2 samples were recruited: the first sample (development sample) was used to examine the initial structure of the Pregnancy-Specific Anxiety Tool (PSAT), and the second sample (validation sample) was used for psychometric testing and for conducting clinical diagnostic interviews.

Participants. As the PSAT is intended for use in the general population of pregnant people, we recruited nulliparous and multiparous pregnant people (age ≥ 19 years; able to read/write/speak English) at any gestational

age. We chose a broad gestational range for two reasons: first, findings from a previous trajectory analysis suggest that despite slight fluctuations, symptoms of anxiety are consistent over the course of pregnancy[36]; second, research on time-specific effects of PSA shows that high levels of PSA at any time point in gestation can contribute to adverse pregnancy and child outcomes.[37]

Study procedures.

Sample 1. Participants for sample 1 were recruited from May 2, 2018, to October 11, 2018 (N = 494). Participants were recruited during pregnancy through study posters distributed in prenatal care clinics and classes, blood and other specimen collection laboratories across the province, and social media platforms. After signing an online informed consent form, participants completed the PSAT and a demographic and obstetrics characteristics questionnaire.

Sample 2. Participants were recruited from July 3, 2019, to May 18, 2020 (N = 325) using similar recruitment approaches. After signing an informed consent form, participants completed an online survey that included the Edinburgh Postnatal Depression Scale (EPDS),[38] Generalized Anxiety Disorder Scale (GAD-7),[39] State-Trait Anxiety Inventory (STAI-State),[40] Perception of Pregnancy Risk Questionnaire (PPRQ),[41] Perceived Stress Scale (PSS),[42] Pregnancy-Related Anxiety Scale (P-RAS),[17] PrAS,[19] PSAT, and a demographic and obstetric characteristics questionnaire. To determine test-retest reliability, the participants completed the PSAT again 1 week later.[34] PSS and PPRQ were used for hypothesis testing and further assessment of construct validity. We hypothesized that people who had higher PSAT scores would also have a higher perception of pregnancy risk (antecedent of PSA)[1] and higher perceived stress. To examine convergent validity, we assessed associations of the PSAT with different measures of the PSA (ie, P-RAS, PrAS), which were expected to correlate highly with PSAT scores.[43] Additionally, we measured relevant constructs of general anxiety and depression using the STAI-S, GAD-7, and EPDS.

After completion of the online survey, clinical diagnostic interviews were scheduled and occurred within 7 days of completing the PSAT self-report. A trained PhD-level psychologist (S.T.) conducted interviews in-person or through a phone/video call using the Structured Clinical Interview for *DSM-5* (SCID-5),[44] a validated semistructured diagnostic interview designed for assessment of a wide range of psychiatric problems, including all mood and anxiety disorders. According to *DSM-5*, for symptoms to meet the diagnostic criteria for a certain mental disorder, the disturbance must cause "clinically significant distress or impairment in social, occupational, or other important areas of functioning."[12(p21)] Although the cognitive attributes of PSA are similar to those described in the *DSM-5* for anxiety disorders, PSA may or may not be associated with behavioral responses or impaired functioning.[1] Additionally, the criterion of a 6-month duration for generalized anxiety might not be practical for pregnancy. These considerations, and consultations with experts, led us to the understanding that the diagnostic category that corresponds most closely to PSA is adjustment disorder (AD). A current diagnosis of AD was made only if symptoms were present at the time of the interview. AD was also diagnosed as a comorbidity with another mental health disorder, as long as both criteria were met. Interrater agreement for AD diagnosis was assessed by randomly selecting a subset of the SCID-5 interviews (3 interviews) and having these reviewed by an experienced clinical psychologist blind to the assessment. Interviews were recorded to allow for a review in cases of diagnostic uncertainty. Participants who met diagnostic criteria for any mental health condition were offered appropriate referrals.

Data analysis. The primary focus of psychometric evaluations involved examining (*a*) the PSAT item distributions and correlational structure; (*b*) the implied dimensionality of the PSAT; (*c*) the internal consistency and stability (ie, test-retest reliability); and (*d*) the relationships between the PSAT and criterion validation measures.

Sample 1. To examine item distributions, we determined the relative frequencies of the response options for each item. Given the ordinal nature of the data, we observed the interitem relationships based on polychoric correlations. First, a scree plot was generated using the adjusted eigenvalues obtained from a parallel analysis (PA) using a common factor approach.[45] Second, a series of 10 exploratory factor analyses (EFAs) was conducted that extracted 1 to 10 correlated factors, respectively. For each EFA, we observed the overall model fit to the data, the pattern of Geomin-rotated item-factor loadings and the presence of cross-loading items, as well as the correlations among factors. Third, confirmatory factor analysis (CFA) was fit to the data with model specification generated from both the EFA results and conceptual considerations. For all factor analyses, weighted least squares estimation with mean- and variance-adjustment (WLSMV) was used to accommodate the ordinal and non-normal characteristics of the items. Model fit was evaluated using comparative and Tucker Lewis fit indices (CFI and TLI, respectively), standardized root mean square residuals (SRMR), and the root mean square error of approximation (RMSEA). We were guided by conventional criteria for model fit assessment,[46] although such criteria served only as rough guides given the ordinal nature of the data and use of WLSMV estimation.

Sample 2. An identical CFA was conducted to replicate the findings from the initial sample. Internal consistency was evaluated using ordinal coefficient α,[47] based on the polychoric correlation matrix of the items, rather than from the scores directly. Test-retest reliability was evaluated at both the test and item levels by calculating the correlations between the PSAT scores across time points (> 0.70 considered acceptable).[32] At the item level, weighted κ estimates were computed. Evidence of convergent validity was obtained by calculating the correlations between the PSAT scores and scores from the GAD-7, STAI-S, EPDS,

Table 1. Characteristics of the Participants Recruited for Pilot Testing (June–November 2017), Sample 1 (May–October 2018) Participants, and Sample 2 (July 2019–May 2020) Participants, British Columbia, Canada

Characteristic	Pilot testing (N = 10) Mean (SD)	Sample 1 (N = 494) Mean (SD)	Sample 2 (N = 325) Mean (SD)
Age, y	32.4 (4.93)	31.7 (4.2)	31.9 (4.1)
Gravidity	…	2.0 (1.3)	2.08 (1.4)
	n (%)	n (%)	n (%)
Ethnicity			
Indigenous	0 (0.0)	14 (2.8)	6 (1.9)
White	8 (80.0)	299 (60.8)	234 (72.4)
Asian	1 (10.0)	145 (29.5)	60 (18.6)
Other	1 (10.0)	34 (6.9)[a]	23 (7.1)[b]
Annual household income			
≥ $40,000	7 (70.0)	430 (89.4)	301 (93.8)
< $40,000	3 (30.0)	51 (10.6)[c]	20 (6.2)[d]
Education			
Certificate or university degree	9 (90.0)	426 (86.2)	295 (90.8)
No schooling, elementary school/high school, non-university, or incomplete university	1 (10.0)	68 (13.8)	30 (9.2)
Relationship status			
Married or common law	9 (90.0)	482 (97.6)	319 (98.2)
Single	1 (10.0)	12 (2.4)	6 (1.8)
Unplanned pregnancy	2 (20.0)	120 (24.3)	60 (18.5)
Problems/complications during pregnancy	4 (40.0)	121 (24.5)	106 (32.6)
Self-reported history of any mental health disorder	5 (50.0)	222 (44.9)	165 (50.8)

[a]Missing data for 0.4% of the sample.
[b]Missing data for 0.6% of the sample.
[c]Missing data for 2.6% of the sample.
[d]Missing data for 1.2% of the sample.

PSS, PrAS, PPRQ, and P-RAS. To assess the criterion-related validity (diagnostic accuracy) of the PSAT, we plotted ROC curves and calculated indices for predictive performance (sensitivity, sensitivity, positive predictive value [PPV], negative predictive value [NPV], positive likelihood ratio [LR+], negative likelihood ratio [LR–] and the corresponding area under the curve [AUC], and 95% confidence intervals [CIs]). We determined a cutoff score that optimally detected the presence/absence of a current AD diagnosis based on the Youden index. In addition, we calculated values for the diagnostic performance of the PSAT for AD/any current anxiety disorders (ie, panic disorder, agoraphobia, social anxiety disorder, specific phobia, generalized anxiety disorder, separation anxiety disorder, other specified anxiety disorder, anxiety disorder due to another medical condition, and substance/medication induced anxiety disorder).

Pairwise deletion was employed for all analyses as missing data was very low. Sample characteristics were described using IBM SPSS. Other analyses were primarily conducted using version 4.1 of the R statistical programming language.[48] The lavaan package[49] was used to conduct the PAs and CFAs. The EFAs and polychoric correlations were obtained using Mplus version 8.4.[50] This study was reviewed and approved by the University of British Columbia Conjoint Health Research Ethics Board (H16-02471).

RESULTS

Item Development

In stage 1, 10 pregnant persons were recruited for pilot testing and face validity assessment (Table 1). Participants' feedback was reviewed by the research team and items were retained, revised, or removed. A total of 44 items were retained and were administered in stage 2, which included the recruitment of 2 independent samples. In this item pool, the specific cognitions category included 3 general anxiety items. These items were reviewed by the research team and were removed as these items did not capture cognition specific to pregnancy.[1] Forty-one items were considered in stage 2 for the scale development and evaluation analyses (Supplementary Table 1). The majority of these items emerged from qualitative interviews and the literature review. Five items from 2 previous scales[16,17] were retained and included with permission. A modified version of the postpartum preparation concerns item (in the avoidance domain, originated from a previous scale[4] and revised in the process) was also retained in the final item pool.

Table 3. Correlation Between the Pregnancy-Specific Anxiety Tool Scores and Validation Measures

Measure	*r*	*t*	*df*	*P*	95% CI
GAD-7	0.578	12.7	323	< .001	0.501–0.646
STAI	0.637	14.9	323	< .001	0.568–0.697
EPDS	0.591	13.2	323	< .001	0.516–0.658
PSS	0.578	12.7	323	< .001	0.501–0.646
PrAS	0.827	26.4	323	< .001	0.789–0.859
PPRQ	0.397	7.8	323	< .001	0.302–0.485
P-RAS	0.702	17.7	322	< .001	0.642–0.753

Abbreviations: EPDS = Edinburgh Postnatal Depression Scale, GAD-7 = General Anxiety Disorder-7, PPRQ = Perception of Pregnancy Risk Questionnaire, P-RAS = Pregnancy-Related Anxiety Scale, PrAS = Pregnancy-related Anxiety Scale, PSS = Perceived Stress Scale, STAI = State-Trait Anxiety Inventory.

Scale Development and Validation

Sample 1. Participants' characteristics are presented in Table 1. To determine the initial structure of the PSAT, we conducted a series of psychometric evaluations, including a PA, 10 EFAs, and a CFA, using the initial 41 retained items. To reduce the number of items, we eliminated conceptually repetitive or overlapping items (8 items) and replicated all analyses using 33 items. These items included 3 items in the fetal health domain and 1 item in each of the sleep interruption, constant worries, avoidance, pregnant person's well-being, and harm to the baby domains. The PA for the 33-item scale suggested the extraction of 8 factors. The examination of the model fit indices of the EFAs and their patterns of item-factor loadings showed that a 6-factor model ($\chi^2_{345} = 562.8$, $P < .001$, CFI = 0.979, TLI = 0.968, SRMR = 0.038, RMSEA = 0.037) best represented the PSA domains. Moreover, the 6-factor model did not represent a severe degradation of model fit compared to the 8-factor model ($\chi^2_{292} = 404.089$, $P < .001$,

Figure 1. Confirmatory Model for the Six-Factor Structure of the Final Pregnancy-Specific Anxiety Tool

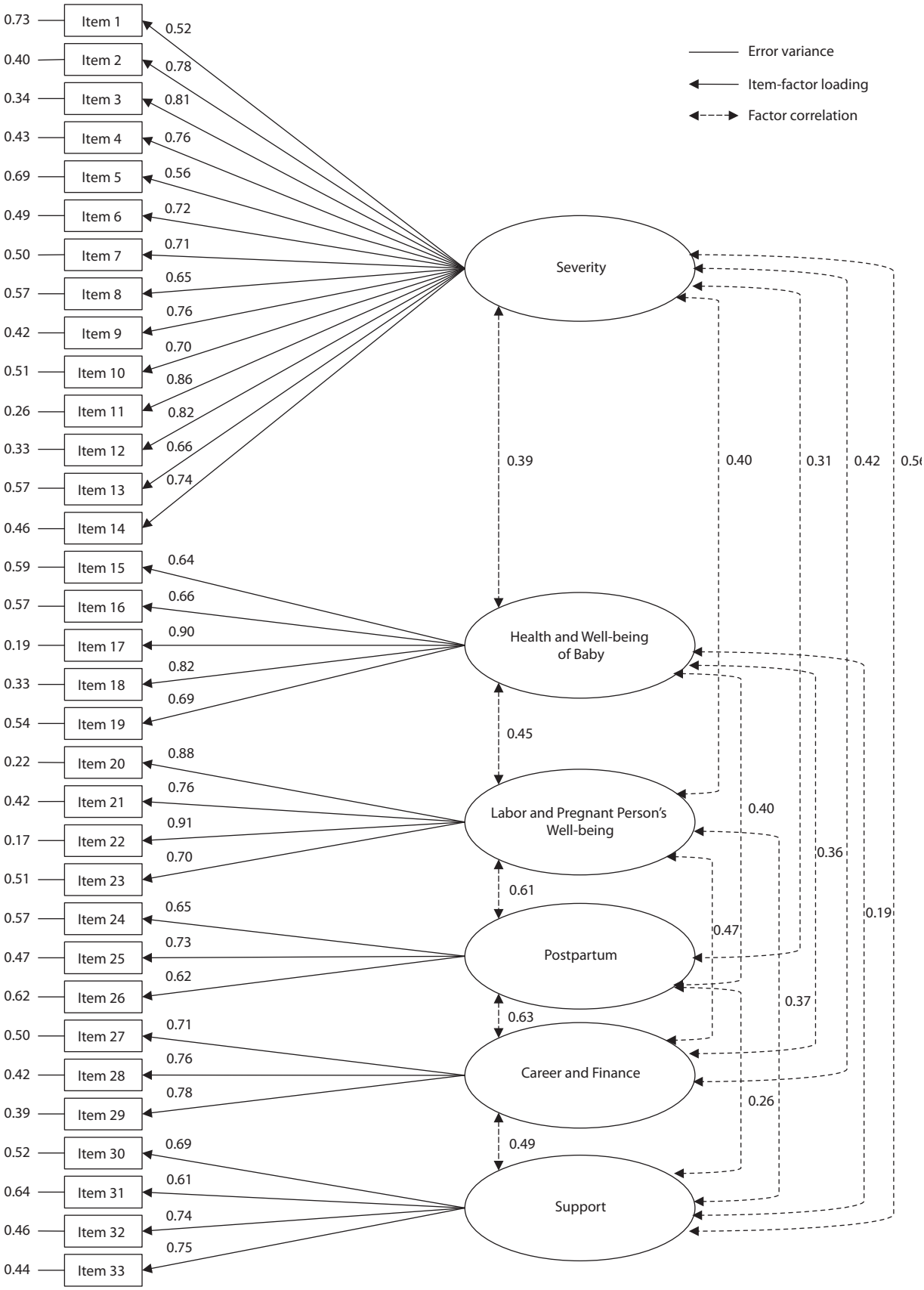


Table 2. Item Distribution, Standardized Item-Factor Loadings, and κ Estimates for the Pregnancy-Specific Anxiety Tool (Number of Items = 33)

Item	Never	Sometimes	Most times	Always	Standardized loading	κ
Factor 1: Severity						
1. I have been able to concentrate on tasks/things that I was doing	17.2	59.4	22.5	0.9	0.520	0.424
2. My worries have been constantly on my mind	20.0	0.0	17.8	2.2	0.775	0.447
3. I have worried about a lot of things	15.4	62.2	19.1	3.4	0.811	0.483
4. There has been so much on my mind that I could not take care of myself properly	64.9	31.4	3.4	0.3	0.757	0.448
5. My worries have interfered with my sleep	30.2	55.7	12.0	2.2	0.556	0.545
6. When I worried about something, I could not stop thinking about it	26.8	56.6	14.5	2.2	0.715	0.500
7. I could not make decisions because I have been worried to think about them	62.2	34.5	3.4	0.0	0.708	0.463
8. I have worried so much that it made me cry	48.6	46.8	4.3	0.3	0.653	0.436
9. My relationships have been affected negatively because of my worry	64.0	32.3	3.4	0.3	0.760	0.638
10. My mind has gone blank because of my worry	76.3	22.5	1.2	0.0	0.700	0.470
11. My anxiety has interfered with my daily life	52.6	41.2	5.5	0.6	0.861	0.615
12. I have been so worried that I couldn't think about anything else	66.5	31.4	2.2	0.0	0.820	0.536
13. I have experienced panic attacks	80.0	18.2	1.5	0.3	0.658	0.473
14. I am worried that my baby is being affected by my worry	44.3	38.2	10.2	7.4	0.735	0.674
Factor 2: Health and Well-being of the Baby						
15. I did not want to think about my pregnancy because I might lose the baby	62.5	32.3	4.9	0.3	0.637	0.467
16. I have been very afraid of doing something that could harm the baby	39.7	45.5	10.8	4.0	0.659	0.511
17. I am concerned (worried) about the health and well-being of my baby	10.8	48.0	21.2	20.0	0.899	0.564
18. I am concerned (worried) that my baby could have problems with development	20.6	51.7	17.2	10.5	0.817	0.646
19. I am confident that my baby will be healthy	25.2	40.0	31.7	3.1	0.678	0.604
Factor 3: Labor and Pregnant Person's Well-being						
20. I am scared about labor	22.2	43.1	20.9	13.8	0.881	0.712
21. I am concerned (worried) that the baby could be injured during labor	41.8	42.5	8.9	6.8	0.764	0.696
22. I am concerned (worried) that I might have a difficult delivery/labor	17.8	44.3	23.7	14.2	0.914	0.674
23. I am afraid that I could die during the pregnancy or labor	69.8	23.4	4.6	2.2	0.703	0.783
Factor 4: Postpartum						
24. I am worried about getting back into shape after the birth	26.5	37.2	20.0	16.3	0.653	0.733
25. I am worried whether I am going to be a good parent	33.5	39.7	18.2	8.6	0.730	0.707
26. I am worried that I won't be able to bond with this baby	63.4	26.8	6.8	3.1	0.620	0.656
Factor 5: Career and Finance						
27.* I am worried that my partner has to make up for the income I lose during maternity/parental leave	35.5	27.0	17.9	19.5	0.707	0.730
28. I am worried if I can afford the baby's expenses	44.9	36.0	12.0	7.1	0.759	0.693
29. I am worried how my pregnancy and raising the baby will impact my career/study	36.0	32.9	16.6	14.5	0.778	0.696
Factor 6: Support						
30. I am worried that my health care provider won't support my decisions about my pregnancy	75.1	18.8	4.0	2.2	0.691	0.674
31.* I feel my partner is available when I need him/her	65.4	19.6	12.5	2.5	0.605	0.571
32. I am worried that I don't have enough support	52.9	31.1	10.8	5.2	0.735	0.725
33.* I am worried because my relationship with my partner is not going well	81.1	14.2	2.5	2.2	0.752	0.720

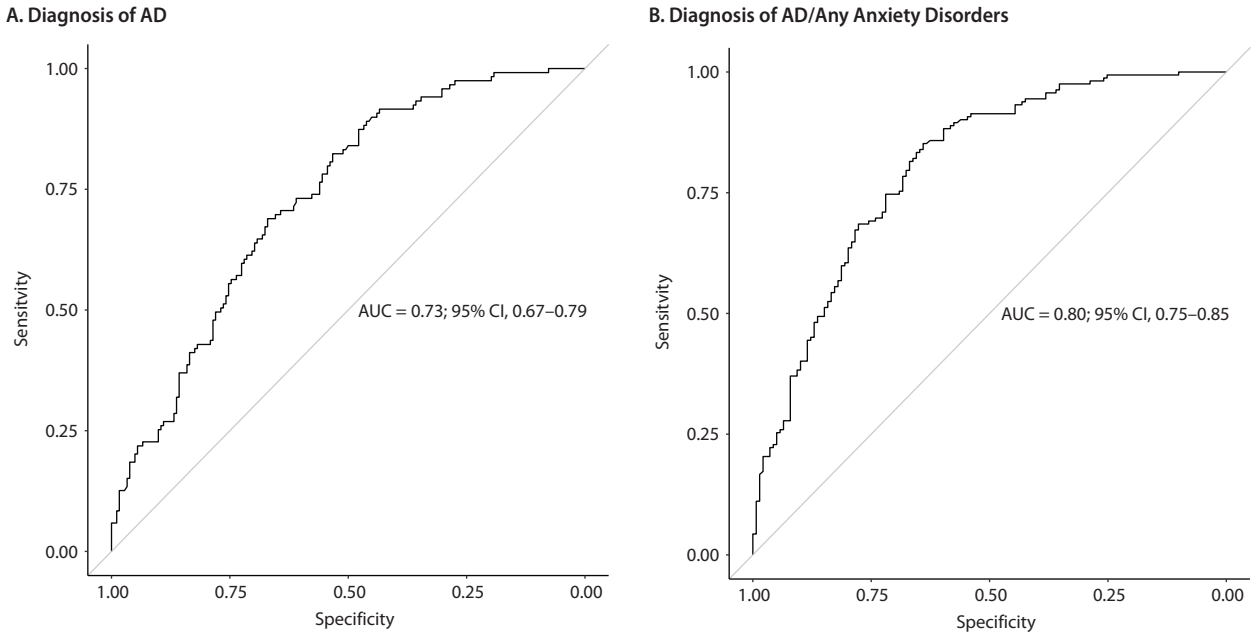
*Possible to answer "not applicable." All standardized loadings were significant at $P < .001$.

CFI = 0.989, TLI = 0.981, SRMR = 0.030, RMSEA = 0.029). The matrix of item-factor loadings for the 6-factor model also contained fewer cross-loading items (n = 4) than were observed in the 8-factor model (n = 9), where cross-loading items were defined as items that had loadings greater than or equal to 0.300 for multiple factors. The 4 cross-loading items (1 item each in childbirth, career/study, harm to the baby, and daily life/relationship interruptions subdomains; Supplementary Appendix 1) were evaluated by a PSA content expert (H.B.), who determined which factors the items should conceptually load on. For all cross-loading items, this corresponded to the items being assigned to the factors on which they loaded most strongly. The 6-factor model included the following factors: Severity, Health and Well-being of the Baby, Labor and Pregnant Person's Well-being, Postpartum, Career and Finance, and Support. A CFA was then fit that used the model specification obtained from the 6-factor EFA. The CFA model fit the data well ($\chi^2_{480} = 1{,}184.440$, $P < .001$, CFI = 0.937, TLI = 0.931, SRMR = 0.071, RMSEA = 0.055) and resulted in loadings ranging from 0.526 to 0.907 (mean = 0.739, median = 0.757, SD = 0.105).

Sample 2. The CFA model obtained from sample 1 showed good fit for sample 2 data ($\chi^2_{480} = 883.8$, $P < .001$, CFI = 0.942, TLI = 0.937, SRMR = 0.080, RMSEA = 0.051) and a pattern and distribution of item-factor loadings that was similar to the first sample (mean = 0.728, median = 0.730, SD = 0.092, minimum = 0.520, maximum = 0.914). The item-factor loadings and item distributions are summarized in Table 2, and the model is shown in Figure 1.

To obtain the overall scale scores for the PSAT, we used a factor-averaged method,[51] in which items are first averaged within each latent factor for every participant. The empirical distribution of the overall PSAT scores ranged from 6.39 to 18.54, encompassing much of the scale's possible range from 6 to 24, with a mean score of 11.00 (median = 10.58, SD = 2.49). The PSAT scores were approximately normally

Figure 2. Area Under the Curve (AUC) for Pregnancy-Specific Anxiety Tool Scores for (A) Diagnosis of Adjustment Disorder (AD) and (B) Diagnosis of AD/Any Anxiety Disorders



distributed, with a slight positive skew. As a whole, the PSAT demonstrated a high degree of internal consistency (α = .93, 95% CI, 0.92–0.94)* and test-retest reliability (r_{12} = 0.83, P < .001, 95% CI, 0.80–0.86). Weighted-κ estimates obtained for each item (Table 2) ranged from 0.424 to 0.783 (mean = 0.597, median = 0.615, SD = 0.110), indicating that all individual items demonstrated "moderate" to "good" stability over time.[52] Internal consistency estimates for the PSAT domains ranged from adequate to strong for Support (α = .73), Career and Finance (α = .75), Health and Well-being of the Baby (α = .84), Labor and Pregnant Person's Well-being (α = .86), and Severity (α = .93), while the Postpartum (α = .69) domain estimate fell just short of the conventional threshold for adequate reliability. The PSAT correlations with criterion validation measures were significant and ranged from 0.397 to 0.827 (Table 3).

The AUC using PSAT for the diagnosis of AD was 0.73 (95% CI, 0.67–0.79), and for AD/any anxiety disorders the AUC was 0.80 (95% CI, 0.75–0.85; Figure 2). The optimal cutoff points calculated using the Youden index were 10.4 (sensitivity = 74%, specificity = 56%, PPV = 52.3%, NPV = 76.7%, LR+ = 1.68, LR– = 0.47) and 10.1 (sensitivity = 81%, specificity = 67%, PPV = 74.2%, NPV = 75.6%, LR+ =2.45, LR– = 0.28) for AD and AD/any anxiety disorders, respectively. Internal validation using bootstrap methods showed that the optimal cutoff points identified were reasonably consistent. Univariate odds ratios between each PSAT item and diagnoses (as an outcome) were typically quite large (eg, > 2), indicating most items were significantly associated with the diagnoses.

*The estimate of internal consistency calculated from the item scores yielded α = .895.

The finalized version of the PSAT is provided in Supplementary Appendix 1.

DISCUSSION

Anxiety is common during pregnancy, with prevalence rates of 23% and 15% for anxiety symptoms and disorders, respectively.[53] The PSAT was developed to measure PSA and its severity and consists of 6 factors:

- **Health and Well-being of the Baby** factor (5 items) measures concerns related to health, development, and potential loss of the baby. All previous PSA scales assessed this domain. The PSAT is unique insofar as it includes an item pertaining to developmental concerns.
- **Labor and Pregnant Person's Well-being** factor (4 items) assesses cognition related to labor and delivery. All previous measures except one[16] cover this factor.
- **Postpartum** factor (3 items) measures concerns related to body image, parenting, and bonding with the baby. Body image[2,19] and parenting concerns[4,17,19] were covered by previous measures. However, to our knowledge, no previous PSA scale assesses concerns related to bonding.
- **Career and Finance** factor (3 items) measures concerns related to financial challenges and impact of pregnancy and parenting on career/education trajectory, another factor unique to the PSAT. Pregnant people are more likely to experience occupational stress than non-pregnant counterparts.[54] They may experience anxieties

related to employer's/colleagues' reactions to pregnancy disclosure, impact on work contract extensions, and promotion and earning capacity,[54] as well as concerns about stigmatization and discrimination.[55] Perceived pregnancy discrimination can increase the risk of a shorter gestation, smaller baby, and postpartum depression due to increased maternal stress.[56]

- **Support** factor (4 items) measures concerns related to overall provision of social support and health care provider and partner's support. While 2 previous scales included items related to care providers' attitudes,[15,19] to our knowledge no scales have included items related to partner and overall support. As a societal matter, issues provoking anxiety during pregnancy extend beyond health concerns and may include the extent of support network and interpersonal relationships.[57]
- **Severity** factor (14 items) measures the consequences of elevated anxiety, including difficulty in concentration and making decisions, experiencing multiple and constant worries, and the extent to which anxiety interferes with the ability for self-care and daily function. The severity of PSA was an undermeasured domain in most previous scales with the exception of the POQ,[4] which included 6 items pertaining to the consequences of PSA. The recently developed scale by Brunton et al[19] also included a few items that could be considered severity indicators. However, these items are focused on preferences for and safety of cesarean birth that would depend on the health-related characteristics of pregnancy.

Psychometric testing of the PSAT showed a high degree of internal consistency, test-retest reliability, and construct, convergent, and divergent validity. The PSAT showed high correlation with PSA measures (P-RAS, PrAS, with estimates ranging from 0.70–0.83) and moderate correlation with general anxiety and depression measures (GAD-7, STAI-S, EPDS, with estimates ranging from 0.58–0.64) and theoretically related constructs (PSS, PPRQ, with estimates ranging from 0.40–0.58). To our knowledge, the PSAT is the first measure of PSA created with concurrent validation embedded in the scale development process. The PSAT showed a moderate accuracy for identifying AD and anxiety disorders.

Strengths of the PSAT include the utilization of a conceptual framework based on the literature dating back to the 1950s,[1] incorporation of input from stakeholders and pregnant people, utilization of PRO principles, development of a severity metric, inclusion of contemporary dimensions of PSA, and validation against a clinically relevant diagnosis.

While we enrolled participants from across a wide geographic region including remote and rural areas, our participants were mostly educated and partnered and had a relatively high household income. Studies are needed with more diverse populations to examine the contextual and cultural validity of the PSAT among different ethnic groups as well as low- and middle-income settings. Part of the data collection for sample 2 occurred during the COVID-19 pandemic. We collected qualitative data from participants recruited during the pandemic, and their overall pandemic experience has been published previously.[58] Data analyses for samples 1 and 2 were conducted after the completion of participant recruitment for these samples, and thus participants in both samples completed the initial version of the PSAT. All items were scored from 1 to 4, except partner-related items (items 27, 31, 33) that were scored from 1 to 5, with 5 being "not applicable." The number of people with no partner in our sample was relatively small (1.8%–2.4%). The implications of this scoring in samples with a larger proportion of people without a partner need to be explored. Further studies for the continued development of the PSAT are needed particularly for the Postpartum factor (due to a lower internal consistency and lack of associations between 2 of its items and the AD diagnosis; results not shown). Finally, we used AD as an equivalent clinical diagnosis for PSA. The PSA is a relatively new construct—it has been recognized as a distinct entity for less than a few decades. As such, the clinical course and diagnostic criteria for PSA require further study to facilitate improved diagnosis.

CONCLUSION

The PSAT advances the measurement of PSA by tapping additional dimensions of the concept (eg, career/finance, bonding, and developmental concerns) and through an assessment of severity. As a PROM tool, the PSAT can be useful for screening and monitoring PSA among the general population of pregnant people throughout pregnancy, with scores higher than 10 indicating a need for further assessment. Future research is needed for refining the PSAT and for developing a shorter version of the instrument.

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Supplementary Material

Article Title: Pregnancy-Specific Anxiety Tool (PSAT): Instrument Development and Psychometric Evaluation

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List of Supplementary Material for the article

1. Table 1 Domains and Sub-domains of the Initial Item Pool (number of items=41)
2. Appendix 1 Pregnancy Specific Anxiety Tool (PSAT) Scoring Guide

Disclaimer

This Supplementary Material has been provided by the author(s) as an enhancement to the published article. It has been approved by peer review; however, it has undergone neither editing nor formatting by in-house editorial staff. The material is presented in the manner supplied by the author.

Supplementary Table 1. Domains and Sub-domains of the Initial Item Pool (number of items=41)

Domain and sub-domains
Specific cognitions
- Fetus/baby's health (6 items)
- Childbirth (3 items)
- Pregnant person's wellbeing (2 items)
- Body image (1 item)
- Parenting and care for baby (2 items)
- Maternity care-related (1 item)
- Financial (2 items)
- Career/study (1 item)
- Support (3 items)
Severity
- Constant and multiple worries (8 items)
- Avoidance (3 items)
- Sleep interruption (2 items)
- Daily life and relationship interruptions (4 items)
- Harm to baby (2 items)
Confidence
- Having a healthy baby (1 item)

Supplementary Appendix 1: Pregnancy Specific Anxiety Tool (PSAT) [in public domain]

Scoring Guide

All items except partner items are scored from 1 to 4. Partner items are scored 1 to 5, with 5 being "not applicable." Items 1, 19, and 31 are reverse scored. The averages of the items within each latent factor are calculated and then summed across all factors for each participant.
Factor 1: items 1-14; Factor 2: items 15-19; Factor 3: items 20-23; Factor 4: items 24-26; Factor 5: items 27-29; Factor 6: items 30-33

PSAT score = [(person's score on factor 1)/14]+ [(person's score on factor 2)/5]+ [(person's score on factor 3)/4]+ [(person's score on factor 4)/3]+ [(person's score on factor 5)/3]+ [(person's score on factor 6)/4]

Instrument

The following questions are about how often you have experienced each statement during the past week (last 7 days). Please choose the option that most closely describes your experience for each statement. Please remember there are no right or wrong answers.
[Response Options: 1. Never; 2. Sometimes; 3. Most times; 4. Always]

1. I have been able to concentrate on tasks/things that I was doing.
2. My worries have been constantly on my mind.
3. I have worried about a lot of things.
4. There has been so much on my mind that I could not take care of myself properly.
5. My worries have interfered with my sleep.
6. When I worried about something, I could not stop thinking about it.
7. I could not make decisions because I have been worried to think about them.
8. I have worried so much that it made me cry.
9. My relationships have been affected negatively because of my worry.
10. My mind has gone blank because of my worry.
11. My anxiety has interfered with my daily life.
12. I have been so worried that I couldn't think about anything else.
13. I have experienced panic attacks.
14. I am worried that my baby is being affected by my worry.

The following questions ask about your feelings about your pregnancy and baby. For each statement, please indicate your feelings and experiences by choosing one of the response options. Please remember there are no right or wrong answers.
[Response Options:1. Not at all; 2. Somewhat; 3. Moderately; 4. Very much; *5. Not Applicable]

15. I did not want to think about my pregnancy because I might lose the baby.
16. I have been very afraid of doing something that could harm the baby.
17. I am concerned (worried) about the health and well-being of my baby.
18. I am concerned (worried) that my baby could have problems with development.
19. I am confident that my baby will be healthy.
20. I am scared about labour.
21. I am concerned (worried) that the baby could be injured during labour.
22. I am concerned (worried) that I might have a difficult delivery/labour.
23. I am afraid that I could die during the pregnancy or labour.
24. I am worried about getting back into shape after the birth.
25. I am worried whether I am going to be a good parent.
26. I am worried that I won't be able to bond with this baby.
27. * I am worried that my partner has to make up for the income I lose during maternity/parental leave.
28. I am worried if I can afford the baby's expenses.
29. I am worried how my pregnancy and raising the baby will impact my career/study.
30. I am worried that my health care provider won't support my decisions about my pregnancy.
31. * I feel my partner is available when I need him/her.
32. I am worried that I don't have enough support.
33. * I am worried because my relationship with my partner is not going well.

All items except partner items are scored from 1 to 4.
* Partner items are scored 1 to 5, with 5 being “not applicable.”