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Validation of the post-traumatic stress disorder checklist for DSM-V (PCL-5) in the Maltese perinatal population

Rachel Buhagiar, Catherine Dimech, Ethel Felice

BACKGROUND

Perinatal post-traumatic stress disorder (PPTSD) is a stress-induced mental health condition, occurring in pregnancy and/or following childbirth. Left untreated, PPTSD can result in negative consequences for the entire family unit. This paper reports the validation of the self-report Post-Traumatic Checklist for DSM-V (PCL-5) questionnaire against the gold standard Clinician-Administered PTSD Scale for DSM-V (CAPS-5) diagnostic interview in the Maltese perinatal population.

METHODS

The original English version of the PCL-5 was translated into Maltese and culturally adapted for use in this population. A total of 175 pregnant and/or post-partum mothers were recruited and self-completed the PCL-5 questionnaire. 28 mothers met criteria for CAPS-5 assessment which was performed by one of two trained professionals, following inter-rater reliability assessment.

RESULTS

A strong, positive correlation between the Maltese and English-version of the PCL-5 was obtained (Kendall's tau-b 0.812; p-value <0.001). The internal consistency of the PCL-5 was high (Cronbach alpha=0.935) and the instrument showed a good validity (Pearson Correlation=0.710; p-value 0.004). The suggested PCL-5 cut off point for a provisional PPTSD diagnosis is 36. The prevalence of PPTSD for Malta ranges between 0% and 3.63%. This figure needs to be interpreted with caution given the relatively small sample size.

CONCLUSION

The Maltese-language version of PCL-5 has good reliability and validity, confirming its diagnostic utility as a screening instrument in the early and timely detection of PPTSD sufferers.

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Recent developments in the field of perinatal mental health have given rise to a renewed interest in perinatal posttraumatic stress disorder (PPTSD). This common and debilitating stress-induced mental disorder[1] can occur in pregnancy or in the first twelve months after delivery, as a result of an "exposure to actual or threatened death, serious injury or sexual violation".[2] Whilst pregnancy and transition to parenthood are often portrayed to be positive maternal experiences, some women perceive these events as negative and traumatic. Difficult childbirth processes, pregnancy-related complications and adverse post-partum events can lead to the development of partial or full symptoms of PTSD.[3-7] Additionally, other lifetime non-perinatal stressors can also contribute to the development of this disorder.[8-9] Indeed, a lifetime trauma history can increase the individual's risk of experiencing further traumas substantially. Similarly, routine obstetric care and/or other invasive interventions can trigger PTSD in women with a history of sexual abuse. Therefore, screening measures for PPTSD need to include any life-time traumatic experience/s. In addition to the presence of a "stressor", other diagnostic criteria for PPTSD include symptoms of 'intrusion', 'avoidance', 'negative alterations in mood and cognitions', and 'alterations in arousal and reactivity' which cause significant distress and/or impair the individual's functionality.[2]

In a descriptive phenomenological study by Beck (2004), mothers with a personal lived experience of PPTSD related to traumatic birth events described intense negative emotional feelings, infant estrangement and even suicidal thoughts. Indeed, people with unresolved trauma often find it difficult to feel secure.[10-11] PPTSD has also been linked to lower birth weights and breastfeeding[12] and possibly negative parent-infant interactions and developmental outcomes, resulting in increased morbidity, mortality and healthcare costs.[13] According to Yildiz, Ayers and Phillips (2017), PPTSD is common enough to be a public health concern and is known affect 3.3% and 4% of pregnant and post-partum mothers, respectively.[12] Over recent years, the perinatal period has been associated with higher rates of PTSD, possibly indicating increased vulnerability of women in this period.[14] However, to-date, the prevalence of PPTSD on the Maltese Islands, an archipelago at the center of the Mediterranean with an estimate total population of 460,000 occupants[15] remains unknown.

Furthermore, research evidence indicates that PPTSD remains largely undetected.[16] However, the need to introduce PTSD screening as part of routine assessments is being increasingly recognized, especially in the presence of a previous traumatic history and/or co-existing mood or anxiety disorder.[7] The lack of readily available validated measures for the assessment of trauma symptoms and PTSD may be one contributing factor to this gap in service provision.[6] These instruments would be valuable in the early and timely detection of these mothers[12, 17] helping them re-build a meaningful life and embrace again the possibility of recovery and well-being.[11]

Whilst clinical interviews are the gold standard in the diagnosis of PTSD, self-report measures may be the first step to assessment given the reported similar prevalence rates to the former.[18] Additionally, self-report questionnaires are more economical and do not require training.[17] Another advantage is the added privacy for respondents which decreases the likelihood of information and interviewer biases.[19] At the same time, whilst self-report measures can assist clinicians in their everyday assessments,[20] they cannot be used as

stand-alone tools or replace more comprehensive assessments.[21] Such questionnaires can also be a source of anxiety for service users,[22] therefore their proper administration needs to be ensured, as well as ascertaining that adequate referral pathways and protocols are in place prior to their implementation.[12]

Developed at the National Centre for PTSD, the Posttraumatic Stress Disorders Checklist for DSM-V (PCL-5) *(Appendix I)* is one of the most commonly used self-report tools for detection of PTSD.[23] This instrument is readily available and accessible online. Whilst it is widely used in the general adult population, to-date only few studies have attempted to validate this questionnaire within the perinatal setting,[18, 24] but many lack methodological rigour. In the context of these limitations, as well as the lack of a PSTD self-report tool in the Maltese language, this new and novel project was conducted. The primary objective was to translate the PCL-5 into Maltese and to culturally adapted the tool to reflect the nation's values, beliefs and customs,[25] whilst ensuring the "equivalence between the original source and the target language".[26] Another objective was to validate it for use within Maltese pregnant and post-partum mothers. As a secondary objective, the best PCL-5 cut off point for a provisional PPTSD diagnosis was determined. Whilst authors recommend a cut-off value of 33,[21] a range of other values between 28 to 60 have been identified in different PCL-5 validation studies.[24] Besides, authors state that the "goals of the assessment and the population being assessed" should be considered when determining the cut-off value.[23] Finally, this project will allow for an estimate prevalence of PPTSD in Malta to ascertain whether further healthcare investments need to be targeted to this field.[27]

METHODS

This study was approved by the Health Ethics Committee as part of the Directorate for Health Information and Research in Malta (Reference HEC02/18). The original English-version of the PCL-5 was translated into Maltese by two independent qualified translators and any discrepancies were discussed and resolved. The Maltese version of the PCL-5 was then back-translated into English by a team of ten independent bilingual individuals which included mental health service providers, service users and back-translators with no awareness of the intended concepts measured in the PCL-5 to avoid bias.[28] Each statement and word (content and semantic equivalence) were studied to ensure that the meaning remained unchanged in the Maltese language and idiom as the English version. Modifications for any identified discrepancies ensued until the back-translated scale was equivalent to the original English version.

This translated scale was subsequently piloted tested in a sample representative of the main study group to assess its comprehensibility, clarity and legibility, and ensure its wording, length and sequencing[29] reflected participants' educational level and culture. In this way, interpretation bias was minimized.[19] The lack of a readily available reading ease test in Maltese was one limitation here. Following this process, as part of the reliability assessment,[17] a group of twelve bilingual individuals completed both language versions of the questionnaire at two different time points.

In the next stage, a random sample of 175 pregnant and/or mothers who had delivered in the previous 6 months were recruited from the Obstetrics Department, Antenatal Classes and Breast-Feeding Clinic at Mater Dei Hospital in Malta on two designated days per week between August 2018 and February 2019 *(Figure 1).* There were no specific

exclusion criteria, except for participants needing to have a good command and understanding of both the English and Maltese language and being able to give informed consent. Recruited mothers self-completed the PCL-5 questionnaire and the Life Events Checklist for DSM-5 (LEC-5). The latter identified the index traumatic event which was subsequently used as the basis for symptom inquiry in the diagnostic interview. Basic demographics details were recorded. Those 28 participants who scored 20 or above in the PCL-5 questionnaire were invited for the CAPS-5 diagnostic interview. The

CAPS-5 is the gold standard tool in the diagnosis of PTSD.[23] This assessment was carried out in-person or over the telephone by one of two trained interviewers, both holding a medical degree and significant post-graduate experience in mental health. The inter-rater reliability for both interviewers was measured. Given that the PCL-5 questionnaire focuses on symptomatology over the previous month, the CAPS-5 interview was performed within one month of completion of the PCL-5.

Figure 1   Traumatic events based on experience and exposure type for CAPS-5 participants
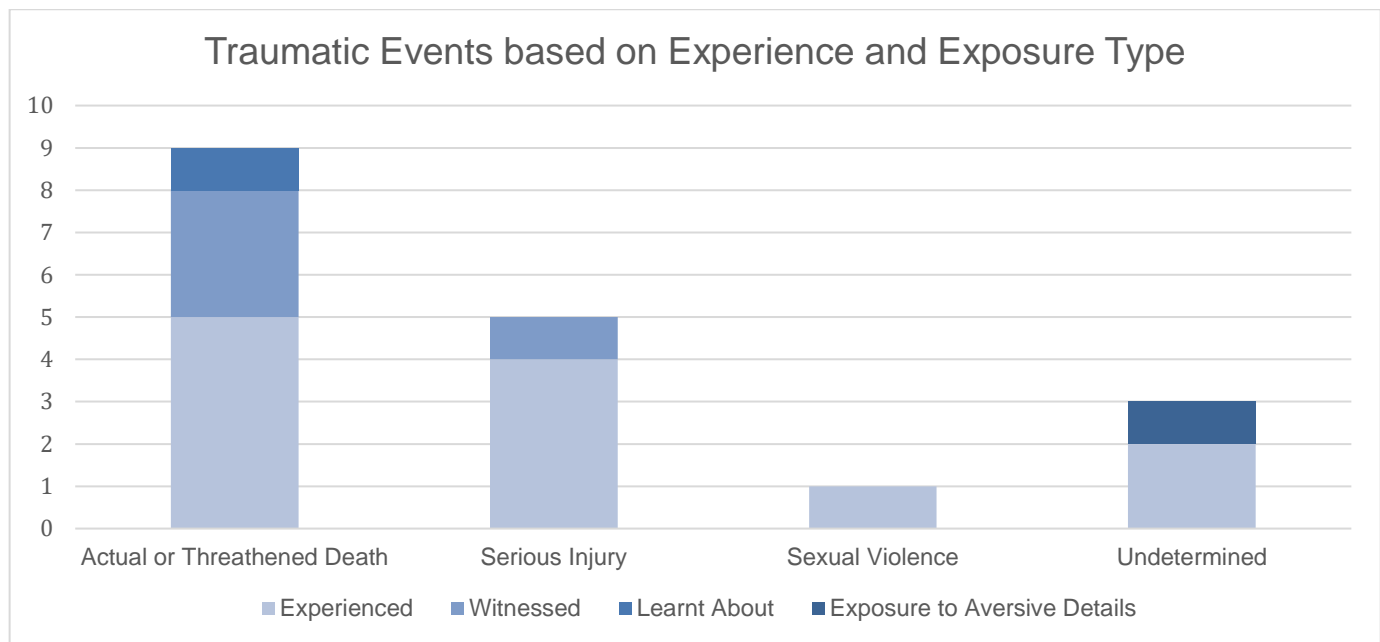
RESULTS & STATISTICAL ANALYSIS

The SPSS version 25 was used in the data analysis process.

Participant Characteristics

A total of 175 mothers between the ages of seventeen and forty-five years were recruited *(Table 1)*. At the time of participation, most of the mothers were pregnant with the majority of them being in their third trimester. Only seven out of the 175 recruited participants (4%) were new mothers who had recently given birth. The majority were married and/or living with partner, employed and with at least twelve years of education. Most of the mothers had previous pregnancy experiences. The current pregnancy was planned for nearly 75% of the participants (*n*=131). Less than 10% of subjects (15/175) had a previous history of abuse during their lifetime.

Table 1   Characteristics of the Study Population

Characteristic	All Participants (N=175)		CAPS-5 Interview (N=18)		PCL-5 Screening Only (N=157)	
	n	%	n	%	n	%
Antenatal Mothers	168	96	15	83.3	153	97.4
Gestational Age (Weeks)						
<10	2	1.1	0	0	2	1.3
10-19	34	19.4	3	16.7	31	19.7
20-29	34	19.4	5	27.8	29	18.5
30-40	83	47.4	7	38.9	82	52.2
40+	10	5.7	0	0	4	2.5
Unknown	5	2.6			5	3.2
Postpartum Mothers	7	4	3	16.7	4	2.5
Age Group (Years)						
<20	5	2.9	0	0	5	3.2
20-29	64	36.6	4	22.2	60	38.2
30-39	100	57.1	13	72.2	87	55.4
40+	6	3.4	1	5.6	5	3.2
Educational Level (Years)						
<6	2	1.1	0	0	2	1.3
6-12	14	8	0	0	14	8.9
>12	149	85.1	18	100	131	83.4
Unknown	10	5.7	0	0	10	6.4
Married/Living with Partner						
Yes	162	92.6	17	94.4	145	92.3
No	10	5.7	0	0	10	6.4
Unknown	3	1.7	1	5.6	2	1.3
Employed						
Yes	138	78.9	15	83.3	123	78.3
No	37	21.1	3	16.7	34	21.7
Any other Pregnancies						
Yes	71	40.6	11	61.1	60	38.2
No	98	56	7	38.9	91	58.0
Unknown	6	3.4	0	0	6	3.8
Planned Pregnancy						
Yes	131	74.9	12	66.7	119	75.8
No	43	24.6	6	33.3	37	23.6
Unknown	1	0.6	0	0	1	0.6
Any Past History of Abuse						
Yes	15	8.6	3	16.7	12	7.6
No	158	90.2	15	83.3	143	91.1
Unknown	2	1.1	0	0	2	1.3

Life-Events Checklist for DSM-V (LEC-5)

Figure 1 summarizes the traumatic events according to the type of experience and form of exposure for the eighteen participants completing the CAPS-5 diagnostic interview. Criterion A, or the presence of a stressor, was met for most of the mothers (n=15/18; 83%). Actual/threatened death to self/others was the commonest form of stressor, followed by serious injury and sexual violence. Most mothers had direct exposure to the traumatic event. Four out of the eighteen participants (22%) had pregnancy-related stressor events, namely pregnancy losses and unwanted pregnancies in the context of abuse.

Reliability & Validity, Cut-Off Point & Prevalence

Reliability was assessed across three areas: over time (test-retest), across interviewers (inter-rater) and across items of the questionnaire (internal consistency). A p-value of <0.05 was taken to represent a statistically significant result.

Test-retest reliability for the Maltese and English language variants of the PCL-5 questionnaire was evaluated using Kendall's tau-b coefficient. Table 2 shows the rating responses for question 4 of the English and Maltese-versions of the PCL-5 for the 12 participants. This question was selected randomly for the purpose of this exercise. The p-value obtained (approximately 0) (Table 3) indicates consistent responses between the two language variants. A similar compliance was seen for the remaining 19 questions.

Table 2   Kendall-tau for Question 4 of Maltese and English Versions of the PCL-5

		Question 4 (English)				
		Not at all	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**
Question 4 (Maltese)	**Not at all**	4	0	0	0	0
	A little bit	0	1	0	0	0
	Moderately	1	2	2	0	0
	Quite a bit	0	0	0	0	0
	Extremely	0	0	0	0	0

Table 3   The Kendall's tau-b correlation and p-value for question 4 of the PCL-5

		Value	Standard Error	Approximate T	P-value
Ordinal by Ordinal	Kendall's tau-b	0.812	0.111	5.495	0.000
N of Valid Cases		12			

The Kendall's Tau-b Coefficient was also applied to determine the inter-rater reliability. Similarly, both interviewers gave consistent independent estimates as evidenced in the Kendall-Tau p-values which were less than the 0.05 level of significance *(Table 4 and 5)* indicating satisfactory reliability. For the internal consistency of the PCL-5, the

Cronbach's alpha (*Table 6*) was calculated for the four symptom clusters (*Table 7 and 8*), individually and combined. The values obtained ranged between 0.764 and 0.934 showing satisfactory to excellent reliability. The inter-item correlation across all 20 questions was also analyzed *(Table 8).*

Table 4 & 5   Kendall's tau-b and p-value for inter-rater reliability

		Recurrent involuntary and intrusive distressing memories of traumatic event		
		Absent	Mild	Severe
Recurrent involuntary and intrusive distressing memories of traumatic event	Absent	2	0	0
	Mild	0	1	0
	Severe	0	0	2

	Value	Standard Error	Approximate T	P-value
Ordinal by Ordinal Kendall's tau-b	1.000	0.000	8.944	0.000

Table 6   Internal Consistency for Cronbach's Alpha

Cronbach's Alpha	Internal Consistency
0.9-1.0	Excellent
0.8-0.9	Good
0.7-0.8	Acceptable
0.6-0.7	Questionable
0.5-0.6	Weak
Less than 0.5	Unacceptable

Table 7   Cronbach's Alpha for the individual and combined symptom clusters of intrusion, avoidance, cognition and mood, and arousal and reactivity

All variables combined		
Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.934	.935	20
Intrusion symptoms		
Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.873	.880	5
Avoidance symptoms		
Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.764	.766	2
Cognition and mood symptoms		
Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.846	.848	7
Arousal and reactivity symptoms		
Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.813	.823	6

Table 8   Inter-Item Correlation Matrix

	q1	q2	q3	q4	q5
q1	1.000	.683	.711	.694	.592
q2	.683	1.000	.569	.494	.535
q3	.711	.569	1.000	.601	.505
q4	.694	.494	.601	1.000	.557
q5	.592	.535	.505	.557	1.000

	q6	q7
q6	1.000	.621
q7	.621	1.000

	q8	q9	q10	q11	q12	q13	q14
q8	1.000	.481	.284	.400	.355	.378	.295
q9	.481	1.000	.656	.654	.429	.403	.440
q10	.284	.656	1.000	.595	.360	.345	.466
q11	.400	.654	.595	1.000	.455	.320	.350
q12	.355	.429	.360	.455	1.000	.553	.488
q13	.378	.403	.345	.320	.553	1.000	.610
q14	.295	.440	.466	.350	.488	.610	1.000

	q15	q16	q17	q18	q19	q20
q15	1.000	.550	.387	.371	.506	.362
q16	.550	1.000	.206	.374	.419	.363
q17	.387	.206	1.000	.559	.469	.447
q18	.371	.374	.559	1.000	.570	.411
q19	.506	.419	.469	.570	1.000	.567
q20	.362	.363	.447	.411	.567	1.000

In the validity process, Pearson's Correlation Coefficient was used to analyze the total PCL-5 and the CAPS-5 scores. The Pearson Correlation coefficient (0.710) was statistically significant (p-value 0.004) *(Table 9),* meaning that the two scales complement each other. Therefore, participants scoring high on one scale tend to score high on the other and vice versa *(Figure 2).*

The logistic regression model was then applied to determine the best PCL-5 cut-off point for a provisional diagnosis of PPTSD. This model *(Table 10)* identifies the total PCL-5 score as a significant predictor of the PTSD diagnosis (p-value <0.005). Moreover, this one predictor model explains 59.1% of the total variation in the PTSD diagnosis outcomes (Nagelkerke Pseudo-R Square Value of

0.591). Also, the odds ratio *(Table 11)* indicates that for every unit increase in the total PCL-5 score, the odds of having a PPTSD diagnosis increases by 36.8%. The scatter plot *(Figure 3)* displays two logistic curves, showing the probability of having or not having a PTSD diagnosis. The two curves meet when the PCL-5 score is 36, implying that individuals with a total PCL-5 score equal or greater than 36 are more likely to suffer from this disorder.

The prevalence of PPTSD in the Maltese population according to the CAPS-5 diagnostic interview, based on a 95% confidence limit, ranges between 0% to 3.63% (*n*=3/175). However, only 18 out of the 28 participants (64%) scoring above the PCL-5 cut-off point were assessed using the CAPS-5 *(Figure 4).*

Table 9 Pearson Correlation and the corresponding p-value for PCL-5 and CAPS-5

PCL-5	Pearson Correlation	0.710
	P-value	0.004

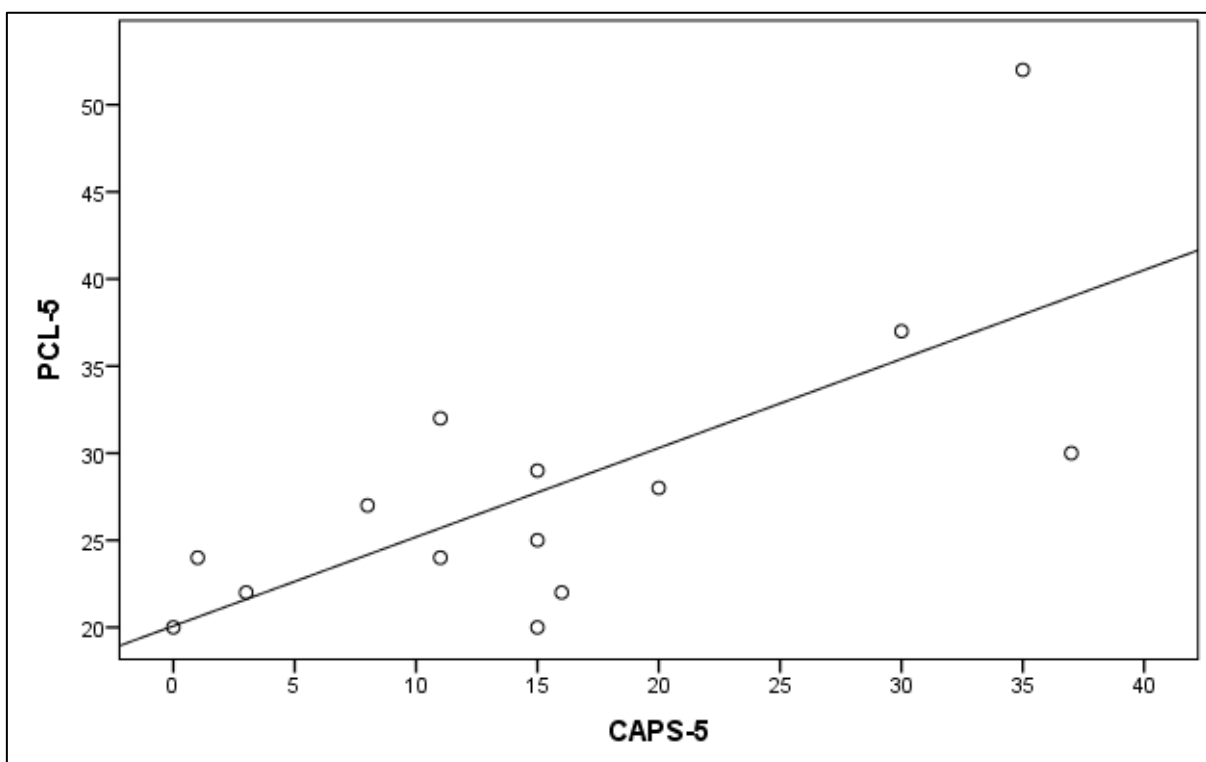**Figure 2** The relationship between total PCL-5 scores and total CAPS-5 scores

Table 10   Logistic regression model

Effect	Model Fitting Criteria	Likelihood Ratio Tests		
	-2 Log Likelihood of Reduced Model	Chi-Square	df	P-value
Intercept	17.226	11.567	1	0.001
Total PCL-5 Score	13.448	7.788	1	0.005

Table 11   Odds Ratio

		B	Std. Error	Wald	df	P-value	Odds Ratio
PTSD = Yes	Intercept	-11.290	5.930	3.624	1	.057	
	Total PCL-5 Score	.313	.183	2.943	1	.086	1.368

The reference category is: No.

Figure 3   Scatter plot showing cut-off point of 36 for provisional PPTSD diagnosis
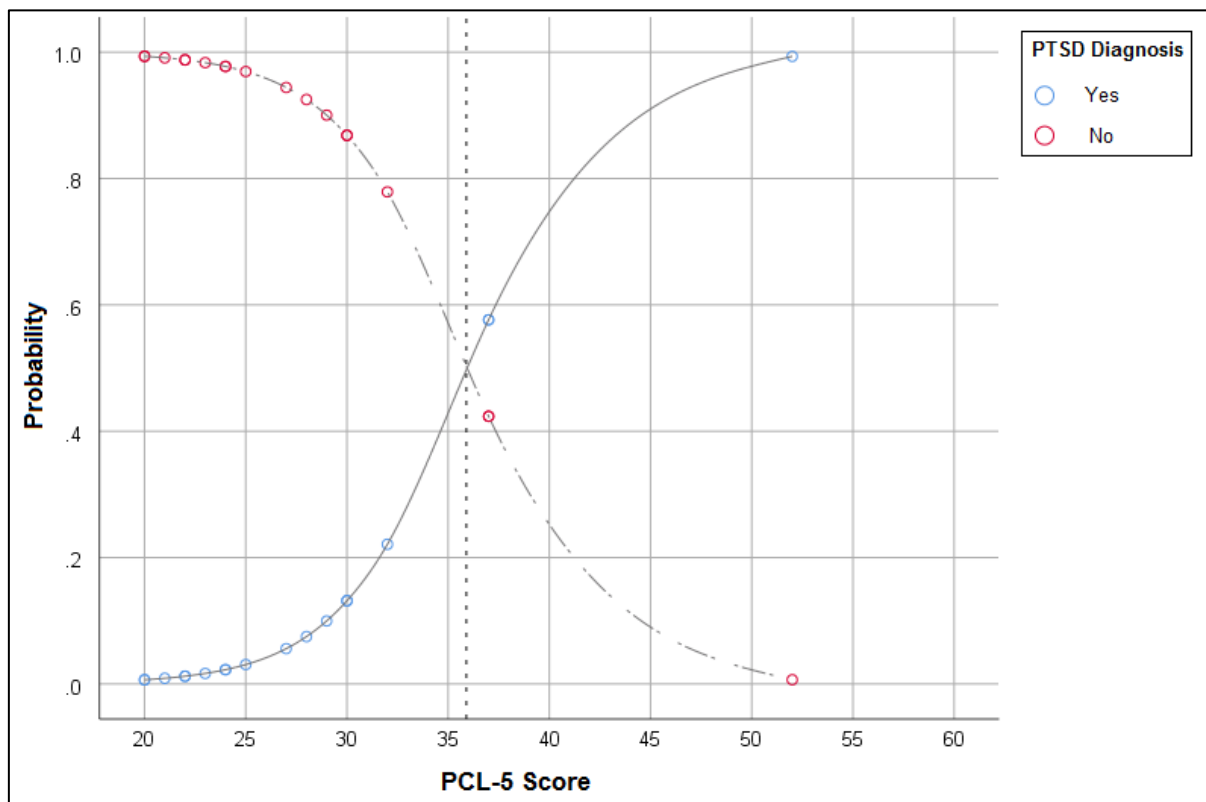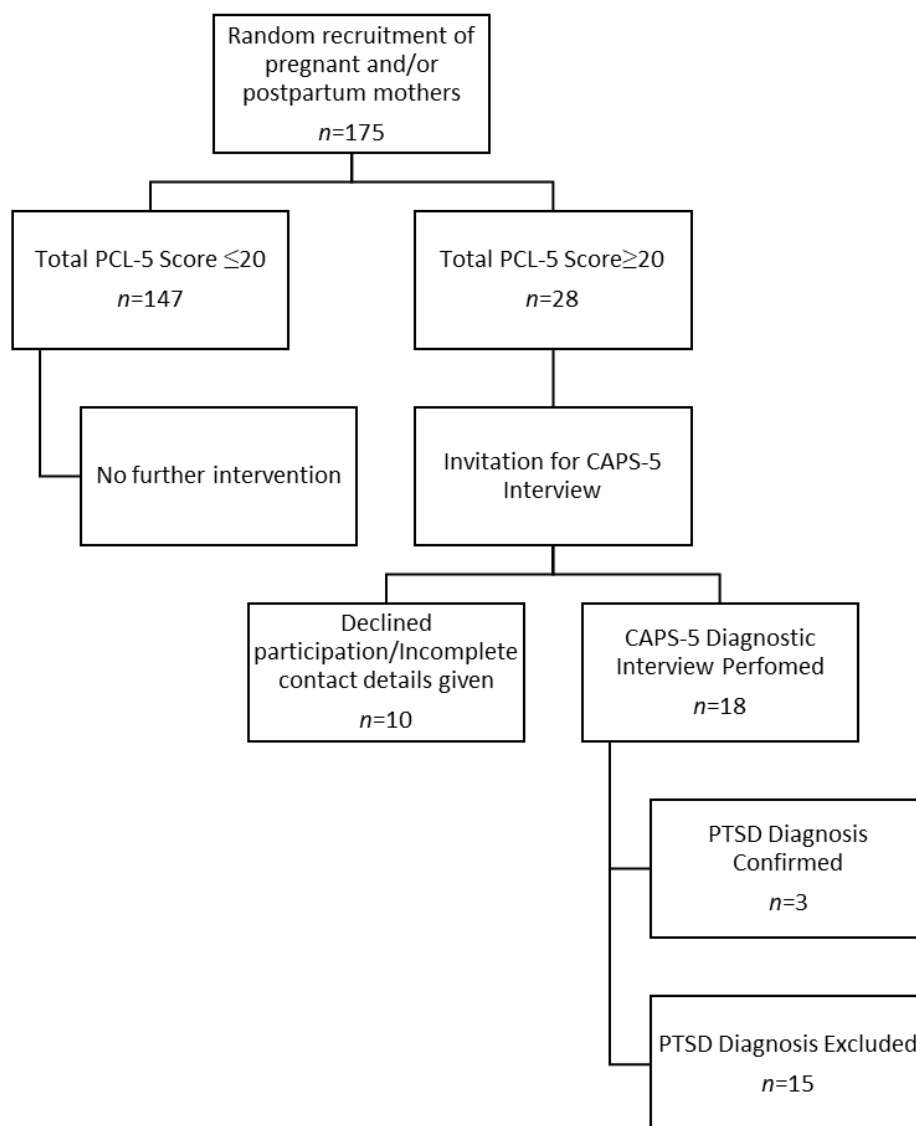
Figure 4   Flowchart of recruited participants and their outcome

DISCUSSION & LIMITATIONS

To our knowledge, this is the first study to translate and validate the PCL-5 for use within the Maltese perinatal population. Prior to the conduction of the project, educational sessions about PPTSD and the study itself were organized for healthcare providers and service users to create an effective teamwork with a "collective identity and shared responsibility".[30] Every individual was empowered to contribute, share ideas, and raise any questions. In this way, "societal acceptance and local ownership"[31] was ensured. This collaborative approach characterized by open dialogue,[32] workforce development and planning, and partnership with communities[11] is in keeping with the recovery model. At the same time, the translation, cultural adaptation and validation of the tool was specifically targeted for use within Maltese perinatal women and failed to consider other female residents in Malta, such as those from refugee and immigrant background in Malta. The latter would have necessitated a separate ethical application, as well as the establishment of inter-professional partnership with healthcare providers serving this particular population and with service

users' representative of this sample. Furthermore, another key aspect is that given that this study did not include women residing in Gozo, the results obtained cannot be really generalized to this cohort.

Amongst the strengths of this study is the design and delivery of a multi-stage translation process based on guidelines[28] and the assessment of inter-rater reliability for research interviewers. In the test-retest reliability exercise, a two-week period was the selected time period between the administration of the two language variants of the PCL-5 to participants. There is paucity of literature data on the best timeframe for this assessment[28]; however, research evidence shows that if the duration is too short or too long, inaccurate results may be achieved. Another strength was the use of the LEC-5 trauma index tool for the identification of any lifetime traumatic events which extend beyond perinatal experiences. The use of the CAPS-5 gold standard interview in the validation process was another positive point. A total PCL-5 score of 20 or above was the determining factor for CAPS-5 evaluation, as opposed to a value of 33 which is the recommended cut-off point for a provisional diagnosis of PTSD. Nonetheless, this follows authors' recommendation of using a lower score when using the tool for research purposes.[21] Blinding of interviewers to the total PCL-5 score was also ensured throughout this stage. The CAPS-5 interview was conducted over the telephone for most participants. Apart from enhancing compliance and minimizing drop-out rates, phone interviews were found to be a more reliable method of interviewing when assessing patients for PTSD.[33] Furthermore, in the absence of face-to-face contact, participants had added privacy when answering personal questions.[24]

Failure to base sample size on a pre-study consideration of statistical power was one limitation. A sample size of 175 participants was selected because of the unexpected increased difficulty in recruitment. Whilst a larger sample size may have yielded stronger and more accurate results, "there are no absolute rules for the sample size needed for the validation of a questionnaire".[28,34] Additionally, Comrey and Lee (2013) state that a sample of 200 participants is considered "fair" for validation processes.[35] Another area for improvement is evaluation for any potential confounding factors, such as co-morbid mental health difficulties. People experiencing PTSD are commonly found to have other co-existing difficulties[5] with the vast majority meeting criteria for at least one other mental health disorder.[36] In a systematic review by Agius et al. (2016), it was found that triple co-morbidity consisting of depression, anxiety and PTSD occurs in 2 to 3% of post-partum mothers.[37] Furthermore, women from Gozo were not included in this study, and therefore, the inclusion of this cohort might have yielded different results.

Based on the study results, the suggested PCL-5 cut-off point for a provisional PPTSD diagnosis in the Maltese population is 36. This is similar to the cut-off point of 33 recommended by the authors.[21] Also, this study identifies the prevalence of PPTSD in Malta to be in the range of 0% to 3.63%, lower than international figures.[18] More supportive networks and the still prevalent religious background of our target population might be possible explanatory factors for this difference.[38-39] Despite this finding, the slowly changing demographic characteristics of our population are likely to alter this identified prevalence over time, towards an increased rate. However, this area requires further exploration before any definite conclusions can be drawn. Moreover, in this study, ten out of the twenty-eight participants (35%) who scored above the PCL-5 cut-off point for CAPS-5 diagnostic interview failed to

provide contact details and/or refused participation in this assessment. Possible reasons for this non-engagement could be fear of being stigmatised and/or judged and having limited time availability due to motherhood demands. Such barriers to care need further exploration, especially when developing screening methods and treatment pathways for this population. These non-respondents were not accounted for in the final prevalence estimate, possibly limiting the accuracy of the result obtained.

CONCLUSION

In conclusion, PCL-5 may be used as a screening tool in Maltese perinatal mothers given its good reliability and validity. A cut-off value of 36 is recommended for a provisional diagnosis of PPTSD, however further assessment is recommended before confirming or refuting a diagnosis. Furthermore, the relatively high trauma rate (10%; *n*=18/175) identified within our study sample reinforces the need to consider the possibility of unresolved trauma and/or PTSD within all healthcare settings, including perinatal services, and to ensure the provision of trauma-informed care.[11] Implementation of the PCL-5 instrument within local healthcare services can therefore ensue to allow for the early and timely detection of PPTSD sufferers and assist clinicians in their routine assessments without extra effort, training or financial costs.

SUMMARY BOX

What is already known about the subject?

- Perinatal PTSD is a significant complication of pregnancy and the post-partum period. Left untreated this condition, can have devastating implications for the entire family unit.

- This condition is not routinely screened for, mainly as a result of lack of validated measures, with the dire consequence that perinatal PTSD sufferers remain undetected and untreated.

- The Post-Traumatic Stress Disorder Checklist for DSM-V (PCL-5) is a widely used screening tool for PTSD; however little is known about its validity in the perinatal population, more especially for expectant women or new mothers of Maltese origin.

What are the new findings?

- The PCL-5 may be used as a screening tool in Maltese perinatal women given its good reliability and validity.

- The recommended cut-off point for a provisional diagnosis of perinatal PTSD is 36.

- However, following the use of this tool, clinical assessment is still recommended before confirming or refuting a diagnosis of perinatal PTSD.

- The prevalence of PPTSD in the Maltese population according to the CAPS-5 diagnostic interview, based on a 95% confidence limit, ranges between 0% to 3.63%.

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