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Cohort profile: The Migrant Perinatal Depression Study: a prospective cohort study of perinatal depression on the Thai-Myanmar border

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Title: Cohort profile: The Migrant Perinatal Depression Study: a prospective cohort study of perinatal depression on the Thai-Myanmar border

Short title: Cohort profile: perinatal depression on the Thai-Myanmar border

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Cohort profile: The Migrant Perinatal Depression Study: a prospective cohort study of perinatal depression on the Thai-Myanmar border

ABSTRACT

Purpose: Perinatal depression is a significant contributor to maternal morbidity. Migrant women in resource-poor settings may be at increased risk, yet little research has been conducted in low- and middle-income settings. This prospective cohort study of migrant women on the Thai-Myanmar border aims to establish prevalence of perinatal depression, identify risk factors for perinatal depression and examine associations with infant outcomes.

Participants: Participating women are labour migrants and refugees living on the Thai-Myanmar border. A total of 568 women were recruited in their first trimester of pregnancy and are being followed up to one year post-partum.

Findings to date: At baseline, women in our study had a mean age of 26.7 years, the predominant ethnicity was Sgaw Karen (48.9%), agriculture was the main employment sector (39.2%) and educational attainment was low with a mean of 4.7 years of education. In the first trimester of pregnancy, a quarter (25.8%; 95% CI 22.3-29.5) of all women were depressed as diagnosed by the Structured Clinical Interview for the Diagnosis of DSM-IV Disorders.

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Future plans: Follow-up is on-going and expected to continue until January 2018. The prevalence of depression at later stages of pregnancy and during the first post-partum year will be identified and associations between depression status and demographic, social, medical, obstetric and infant factors will be quantified.

Registration: This study is registered on <u>ClinicalTrials.gov</u> with identifier number NCT02790905 (https://clinicaltrials.gov/show/NCT02790905).

STRENGTHS AND LIMITATIONS OF THIS STUDY

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- To our knowledge this is the first prospective study of perinatal depression among migrant women in a low-income setting, and our study contributes significantly to the underresearched field of migrant mental health.
- This study will provide the first quantification of disease burden of perinatal depression and identification of associated factors on the Thai-Myanmar border.
- Findings will enable improved detection of perinatal depression as well as earlier and better management of affected women.
- Interviews were carried out by general clinicians rather than psychiatrists. This short-coming
 was the result of an absence of psychiatric expertise in this setting. However, the use of
 generalists including local healthcare workers is a strength for the long-term sustainability of
 identifying and managing mental disorders in this population.
- There was a 20% loss to follow-up at the third trimester in this highly-mobile population.
 Statistical analyses will be conducted to explore differences between those lost and those who completed the study.

INTRODUCTION

Perinatal depression – a depressive episode occurring during pregnancy or up to twelve months post-partum – is a significant contributor to maternal morbidity (1, 2). Globally, the burden falls disproportionately upon those living in poverty. In low- and middle-income countries (LMIC), the prevalence of perinatal depression has been estimated at 25% in pregnancy and 19% postnatally (2). In high-income countries, prevalence estimates range between 18% and 19% (3).

The consequences of perinatal depression are significant. Affected women are at risk of chronic and recurrent depression, and the ability to work and provide care may be impaired. Depression in pregnancy has been linked to negative health behaviours such as substance misuse and poor uptake of antenatal care (3). Infants of depressed mothers are at increased risk of preterm birth, low birthweight, stunting in later childhood and poor neurodevelopmental and behavioural outcomes which may persist into adolescence and affect functional outcomes (4-6).

Migrant women, whom we define as those who have left their place of origin regardless of circumstances, are at particular risk of perinatal depression (7, 8). Stressors within their family, occupational and social circumstances – many of which may have contributed to their decision to migrate – continue to impact upon migrant populations in their place of settlement (7, 8). Women

who resettle within LMIC are at especially high risk (9). However, despite the bulk of global migration flows occurring in low- and middle-income regions, the evidence on migrant mental health remains heavily skewed towards high-income destinations (9). There is an urgent need for an improved understanding and detection of perinatal depression in LMIC to enable quantification of the disease burden and effective management of the condition (2).

The Thai-Myanmar border area is home to an estimated 200,000 labour migrants and 145,000 refugees from Myanmar (10, 11). The prevalence of perinatal depression within this setting has not previously been examined. A prospective cohort study of pregnant migrant women in this low-income setting was set up with the following objectives: 1) to determine the prevalence of perinatal depression; 2) to identify differences in prevalence at various stages of pregnancy and the post-partum period; 3) to identify demographic, social, medical and obstetric factors associated with perinatal depression; and 4) to examine associations between maternal depression and neurodevelopmental outcomes of infants. In this paper, we describe the design, recruitment and characteristics of the cohort.

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COHORT DESCRIPTION

Setting

The study was carried out at Shoklo Malaria Research Unit (SMRU) in Mae Sot, Tak Province, Thailand. SMRU is a field station of the Mahidol-Oxford Tropical Medicine Research Unit (MORU), a research collaboration between Mahidol University (Thailand) and the University of Oxford (UK). SMRU has carried out research and provided maternity services on the Thai-Myanmar border area since 1986. Its clinics are located along the Thai side of the border, 30-60 kilometres north and south of Mae Sot. Care is provided to refugee women and infants in Maela camp (MLA) and to rural labour migrants at Mawker Tai (MKT) and Wang Pha (WPA) (figure 1).

Figure 1. Map of study area showing refugee (Δ) and migrant clinics (■) (Credit: Dr Verena Carrara, SMRU)

Population

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Refugees live in camps on the Thai side of the border. MLA is the largest refugee camp with a population of 37,000 (12). Within the refugee camp, non-governmental organisations (NGO) provide health care, education, food rations and housing, and the United Nations High Commissioner for Refugees (UNHCR) manages repatriation and resettlement programmes (12). Though the refugee camps provide a degree of security, opportunities for work and freedom of movement are severely limited. By contrast, labour migrants are a highly mobile population, residing in rural villages on both sides of the border and often many making daily commutes across the border for work. Labour migrants in this setting work predominantly in the agricultural sector and are paid minimal daily wages (10, 11). Many labour migrants lack official documentation rendering them vulnerable to fines, arrest and deportation by the Thai authorities, and excluding them from accessing healthcare, social care and education (10, 11). In this paper, we use the term 'migrant' to include both refugee and labour migrant populations.

Eligibility and recruitment

This prospective cohort study includes first trimester pregnant migrant women attending SMRU antenatal clinics (ANC) at MLA, MKT and WPA. Women were eligible if they were aged 18 years or over, their estimated gestational age (EGA) as determined by ultrasound dating scan was less than 14 weeks, they had a viable pregnancy, planned to deliver at SMRU and were willing and able to participate. Eligible women were approached by a member of the study team whilst waiting to be seen at ANC. Recruitment took place between October 2015 and April 2016. Follow-up assessments will take place regularly until twelve months post-partum and will be complete in January 2018. Further follow-up is subject to funding.

Ethics and consent

At recruitment, study staff provided eligible women with verbal and written explanations of the study. It was explained that participation was voluntary, that non-participation would not affect care and that consent could be withdrawn at any time. Women who agreed to participate provided consent in the form of a signature or thumbprint for those with low literacy. Participants are offered a small gift (of approximate value £1 GBP) at each visit and any travel costs incurred are reimbursed. Ethics approval was granted by the University of Oxford Tropical Research Ethics Committee (OxTREC 28-15), Mahidol University Faculty of Tropical Medicine Ethics Committee (TMEC 15-045) and the Tak Border Community Advisory Board (T-CAB 6/2/2015) (13).

Instruments

Depression status is being ascertained using the ten depression items of the *Structured Clinical Interview for the Diagnosis of DSM-IV Disorders* (SCID), a widely used, semi-structured diagnostic tool (14). Prior to the start of the study, the SCID was translated into Burmese and Sgaw Karen by two SMRU clinicians fluent in Burmese, Karen and English. Back-translation was carried out by two further SMRU clinicians who had not seen the original English version. Original and back-translated English versions were compared to ensure semantic equivalence had been maintained. DSM-IV criteria are applied to SCID responses to establish diagnoses of Major Depressive Disorder, Minor Depressive Disorder and Depressive Disorder Not Otherwise Specified (NOS). At inclusion in trimester one (T1), the *Refugee Health Screener-15* (RHS-15) was also administered. The RHS-15 screens for psychological and somatic symptoms of depression, anxiety and post-traumatic stress disorder (15). The RHS-15 consists of fourteen Likert-type response items and a distress thermometer which asks respondents to rate their distress on a visual scale of one to ten. Burmese and Sgaw Karen versions of the RHS-15 were acquired from the RHS-15 authors (16).

Demographic and social data were collected using questionnaires. Medical and obstetric data will be obtained from participants' computerised medical records following delivery. Infant measurements including length and weight are being conducted using standardised instruments. Infant development is being assessed using the Griffiths Mental Development Scale and the Shoklo Developmental Test (17, 18). Mothers' bonding with infants is being assessed with the Mother-to-Infant Bonding Scale (19).

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Procedure

A study timeline is shown in **Table 1**. Data is being collected at eight time points: in the first (T1), second (T2) and third (T3) trimesters of pregnancy and at one (T4), three (T5), six (T6), nine (T7) and twelve (T8) months post-partum. Questionnaires and interviews are conducted by study staff in a private room in Sgaw Karen or Burmese according to women's preference. Verbal administration (rather than self-completion) is being used due to low literacy rates within this population and limited comprehension of health-related written information, even among those able to read (20). SCID responses are independently scored by the study physician and an independent physician. Disagreements are resolved by discussion with a psychiatrist (MF). Women with depression are

offered counselling and, when appropriate, anti-depressant medication and follow-up at SMRU. Women with severe symptoms or active suicidal ideation are admitted for treatment and observation.

Table 1. Timeline of data collection

Time	Time		ression	Demographic	Medical	Obstetri	Infant	Infant
Time			RHS-15 [†]	& social	factors	c factors	factors	bonding
Preg	nancy							
T1	1 st trimester (EGA <14)	Х	Full	Х				
T2	2 nd trimester (EGA 18-26)	Х	DT					
T3	3 rd trimester (EGA 28-38)	Х	DT	Х				
Post-	partum							
T4	1m post-partum	X	DT		Χ	Χ	Χ	Х
T5	3m post-partum						Χ	
T6	6m post-partum	X	DT				Х	Х
T7	9m post-partum						Х	
T8	12m post-partum	X	DT		Χ		Х	Х

[†]At T1 the full RHS-15 was administered. At subsequent visits only the distress thermometer (DT) component of the RHS-15 was administered.

Quality assurance and control

The study team consists of SMRU physicians, midwives and counsellors. Midwives and counsellors are fluent in Burmese, Sgaw Karen and English and are themselves members of the local migrant community, and therefore sensitive to the needs of the population. Prior to recruitment the study lead (GF) received training from the American Psychiatry Association in conducting SCID interviews. Counsellors and midwives underwent training in conducting interviews and counselling methods prior to the study. During the first month all questionnaires and interviews were conducted with the study lead until counsellors and midwives were able to perform them unassisted. Thereafter, GF co-conducted interviews at one site per day to ensure quality.

Sample size

A convenience sample of all women attending SMRU ANC in their first trimester of pregnancy during the recruitment period was used. Based on previous studies in this setting, we assumed a high participation rate and approximately 15% loss to follow-up (21). Our target sample size of 500 was based on an assumed approximate overall depression prevalence of 20% and 80% power (with two-

sided 95% confidence intervals) to detect associations of approximately 2.5-fold in magnitude and to run multiple regression analyses with up to four independent variables (22).

Data security and management

All data are de-identified entered into a password-protected Microsoft Excel database accessible only to SMRU study staff. Source questionnaires are stored securely at SMRU ANC sites until follow-up is complete, whereupon they are stored at the SMRU head office.

FINDINGS TO DATE

Between October 2015 and April 2016, 627 eligible women attended SMRU ANC. Of these, 591 were approached and 568 (90.6% of all eligible; 96.1% of those approached) women agreed to participate. **Figure 2** shows the flow of participants through the study from recruitment (T1) through to T3. Follow-up for T4 through T8 is still on-going. Women who were eligible but missed due to language or staffing constraints did not differ significantly from those included by age, ethnicity or educational level. Of the 568 women who completed T1, 84.7% completed T2 and 81.2% completed T3. Some women who did not attend at T2 returned at T3. The most common reason for participants not returning for follow-up was abortion in early pregnancy.

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Figure 2. Flow of participants through study from recruitment to T3

Demographic characteristics

At enrolment, mean age was 26.6 years (**table 2**). Mean EGA (sd) at enrolment was 9.6 (2.3) weeks. Sgaw Karen was the predominant ethnicity and language. Mean years of education was 4.7 years, and almost half (45.4%) of participants attended school for less than three years. The majority were employed in agricultural work (39.2%) or were not in paid employment (35.7%).

Table 2. Demographic characteristics of study participants at T1 (n=568)

	All		La	bour migrant si	tes	Refugee	camp
	All (n=568)	Missing	MKT (n=163)	WPA (n=155)	p value ^a MKT vs WPA	MLA (n=250)	p value ^a Ref vs mig
			(11–103)	(11-133)	IVINI VS VVFA	(11-230)	iver vs iiiig
Age							
Mean (sd)	26.56 (6.51)	0	26.07 (6.33)	26.88 (6.68)	0.264	26.68 (6.53)	0.697
Median (range)	25 (18-50)		25 (18-45)	18-44		18-50	
Interview language, n (%)							

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Di uma o o o	220 (42.4)	0	01 (55.0)	97 (62.6)		F1 /20 4\			
Burmese	239 (42.1) 280 (49.3)	U	91 (55.8) 64 (39.3)	, ,		51 (20.4) 174 (69.6)			
Sgaw Karen				42 (27.1)					
Poe Karen	43 (7.6)		7 (4.3)	13 (8.4)	0.053	23 (9.2)	40.001		
Other	6 (1.1)		1 (0.6)	3 (1.9)	0.052	2 (0.8)	<0.001		
thnicity, n (%)	4.64 (20.4)		77 (47 2)	02 (52 0)		2 (0.0)			
Burman	161 (28.4)	0	77 (47.2)	82 (52.9)		2 (0.8)			
gaw Karen	278 (48.9)		61 (37.4)	41 (26.5)		176 (70.4)			
oe Karen	66 (11.6)		19 (11.7)	24 (15.5)		23 (9.2)			
Burman Muslim	44 (7.8)		0 (0)	1 (0.7)		43 (17.2)			
Other	19 (3.4)		6 (3.7)	7 (4.5)	0.205	6 (2.4)	<0.001		
Religion , n (%)									
Buddhist	408 (71.8)	0	152 (93.2)	147 (94.8)		109 (43.6)			
Christian	115 (20.3)		11 (6.8)	7 (4.5)		97 (38.8)			
Muslim	45 (7.9)		0 (0)	1 (0.7)	0.402	44 (17.6)	<0.001		
Marital status , n (%)									
Married/co-habiting	566 (99.6)	0	163 (100.0)	154 (99.3)	0.487	249 (99.6)	1.000		
Years of education									
Mean (sd)	4.66 (4.18)	107	3.69 (3.63)	4.38 (3.76)	0.149	5.37 (4.55)	<0.001		
Jnder 3 years, n (%)	255 (45.4)		100 (61.7)	60 (39.0)		95 (38.6)			
B to 6 years, n (%)	164 (29.2)	6	35 (21.6)	61 (39.6)		68 (27.6)			
' to 10 years, n (%)	119 (21.2)		26 (16.1)	23 (14.9)		70 (28.5)			
					<0.001		0.001		
Over 10 years, n (%)	24 (4.3)		1 (0.6)	10 (6.5)	<0.001	13 (5.3)	0.001		
Type of school, n (%)									
Myanmar , ,	245 (53.4)	116	66 (53.2)	89 (76.7)		90 (41.1)			
, Thai	9 (2.0)		7 (5.7)	0 (0)		2 (0.9)			
NGO/faith-based	89 (19.4)		9 (7.3)	3 (2.6)		77 (35.2)			
lone	116 (25.3)		42 (33.9)	24 (20.7)	<0.001	50 (22.8)	<0.001		
anguages spoken, n (%)	110 (20.0)		:= (55.5)	= : (==::/	10.002	33 (22.3)	10.002		
L language	211 (46.2)	111	53 (42.7)	58 (50.4)		100 (45.9)			
2-3 languages	192 (42.0)	111	56 (45.2)	44 (38.3)		92 (42.2)			
or more languages	54 (11.8)		15 (12.1)	13 (11.3)	0.479	26 (11.9)	0.992		
iterate (self-report), n (%)	392 (69.0)	0	98 (60.1)	106 (68.4)	0.479	188 (75.2)	0.992		
interate (sen-report), ii (%)	392 (09.0)	U	96 (00.1)	100 (08.4)	0.125	100 (73.2)	0.005		
	212 (20.2)	21	110 (72 0)	76 (56 2)		17 (6.0)			
Agriculture NGO	212 (39.2)	31	119 (73.9)	76 (56.3)		17 (6.9)			
	59 (10.9)		2 (1.2)	5 (3.7)		52 (21.2)			
Selling	50 (9.2)		12 (7.5)	17 (12.6)		21 (8.6)			
Other	27 (5.0)		3 (1.9)	6 (4.4)	0.024	18 (7.4)	ZO 001		
Housework	193 (35.7)		25 (15.5)	31 (23.0)	0.024	137 (55.9)	<0.001		
substance use, n (%)	25 (4.4)	_	1 (0 0)	10 /11 ()	40.001	6 (2.4)	0.030		
Alcohol	25 (4.4)	0	1 (0.6)	18 (11.6)	<0.001	6 (2.4)	0.039		
Smoking	56 (9.9)	0	17 (10.4)	10 (6.5)	0.203	29 (11.6)	0.217		
Chewing tobacco	27 (4.8)	0	23 (14.1)	0 (0)	<0.001	4 (1.6)	0.001		
Chewing betel	251 (44.2)	0	53 (32.5)	66 (42.6)	0.064	132 (52.8)	<0.001		
east depression (self-report),	4.47 (2.5.0)	_	2 (4 22)	25 (46.3)	.0.001	420 (40 0)	10.001		
(%)	147 (26.0)	2	2 (1.23)	25 (16.3)	<0.001	120 (48.0)	<0.001		
ousehold size							_		
lean (sd)	4.62 (2.27)	4	3.83 (2.02)	3.97 (1.91)	0.529	5.54 (2.31)	<0.001		
ountry now living, n (%)									
Nyanmar	113 (24.5)	108	36 (28.8)	74 (63.2)	_	3 (1.4)	_		
hailand	348 (75.5)		89 (71.2)	43 (36.8)	<0.001	216 (98.6)	<0.001		
ears in current location									
Median (range)	9 (1-39)	114	3 (1-33)	10 (1-39)		10 (1-30)			
£1 year, n (%)	65 (14.3)		36 (29.3)	20 (17.5)		9 (4.1)			
5 years, n (%)	157 (34.6)	ī	74 (60.2)	40 (35.1)		43 (19.8)	I		

Planned pregnancy, n (%)	310 (68.3)	114	85 (68.0)	71 (64.0)	0.513	154 (70.6)	0.299
Telephone, n (%)	329 (57.9)	0	87 (53.4)	71 (45.8)	0.177	171 (68.4)	<0.001

^a p values calculated using two-group t-tests for continuous data, Chi-squared tests for categorical data and Fisher's exact test for categorical data with cell counts <5.

Depression status

At baseline the overall prevalence of depression as diagnosed by the SCID was 25.8% (**Table 3**). There were significant differences in crude prevalence rates of depression between MKT and WPA, and between the migrant sites (MKT and WPA) combined and MLA. Explanations for these differences will be explored through regression analyses.

Table 3. First trimester depression status among study participants by site and by migrant status

	All	La	bour migrant	Refugee camp		
		MKT	WPA	p value	MLA	p value
	(n=568)	(n=163)	(n=155)	MKT vs. WPA	(n=250)	Ref vs. mig
Any depression	146 (25.8)	29 (17.9)	46 (29.7)		71 (28.4)	
Major depression	9 (1.6)	0 (0)	2 (1.3)		7 (2.8)	
Minor depression	35 (6.2)	6 (3.7)	17 (11.0)		12 (4.8)	
Depression NOS	102 (18.0)	23 (14.2)	27 (17.4)		52 (20.8)	
Negative	421 (74.2)	133 (82.1)	109 (70.3)	0.015	179 (71.6)	0.05

STRENGTHS AND LIMITATIONS

To our knowledge, this is the first prospective study of perinatal depression among migrant women in a resource-constrained setting. The active screening for depression will inform the early detection and treatment of this condition and enable affected women to be supported and better interventions to be developed. An improved understanding of the prevalence and risk factors of depression is a cornerstone to addressing the disease burden. Mental disorders are a neglected field in this setting, and the small number of previous studies have focussed on specific subgroups including refugee children (23), Burmese political dissidents living in Bangkok (24), labour migrants workers in Mae Sot (25), and Karenni refugees in northern Thailand (26). None have included pregnant or post-partum women. To our knowledge, this is the first study to include both labour migrants and refugees, enabling direct comparison between these two distinct subgroups of the migrant population. As well as allowing the progression of depression through pregnancy and the post-partum period to be assessed, a significant strength of our cohort design is the collection of

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data on an extensive array of potential risk and associated factors including demographic, social, medical, obstetric and infant factors. Overall, our study contributes to the under-researched field of migrant mental health from LMIC settings (9, 23).

A further strength of our study is that while most studies of mental disorders use screening tools to make mental state assessments, we used a diagnostic interview tool (9). Interviews were conducted by local healthcare staff who are themselves part of the local community. This enabled trust to be established with patients, and ensured high levels of cultural sensitivity. The fact that over 90% of women in this area attend ANC, coupled with our high response rate, means that our sample is representative of the general migrant population (21).

There are also a number of limitations to our study. The absence of mental health expertise in our setting meant that it was not possible to obtain specialist psychiatry input (27, 28). However, by providing experienced local healthcare workers with training in conducting interviews and counselling skills we maximised accuracy as much as possible. Furthermore, in a resource-constrained setting it is more appropriate in the long-term for common mental disorders such as depression to be identified and managed by trained local workers, as specialist mental health professionals are rarely available. By training frontline healthcare staff to conduct these assessments and provide counselling, we ensured that our study promoted local capacity-building, ownership, scalability and sustainability (29).

A further limitation is that face-to-face administration of interviews may have resulted in a social desirability bias and a lower willingness to disclose sensitive information (30). Given the sensitive nature of many of the issues discussed, including depression, suicidal ideation and behaviour, intimate partner violence and trauma history, participants may have felt uncomfortable discussing these and under-reported relevant experiences, especially during a vulnerable period such as pregnancy. However there is a strong oral tradition among the local population, and informal discussions are common and well-accepted (31). We also believe that the sensitivity and local knowledge of the study staff helped to ensure that participants felt comfortable disclosing personal information. Finally, our overall loss to follow-up to date of approximately 20% is higher than our anticipated loss of 15%. This figure might increase in subsequent, post-partum waves. We plan to explore differences between those included and lost in our analyses in order to assess potential implications for generalisability of results.

CONCLUSION

Addressing perinatal depression among migrant communities in LMIC is necessary to promote maternal mental health and address key sustainable development goals including ensuring good health and wellbeing, establishing gender equality and reducing global inequalities both within and among countries. Establishing the prevalence and risk factors for perinatal depression among migrant women on the Thai-Myanmar border will enable the burden of disease to be quantified, and earlier, more effective identification and management of affected women. We expect that observations and recommendations arising from this study will be of importance and relevance to other LMIC settings.

COLLABORATION

The data are not available freely. However, we welcome specific and detailed proposals for collaboration. Enquiries and requests for further information should be made to gracia.fellmeth@dph.ox.ac.uk.

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CONTRIBUTOR STATEMENT

Conceptualisation of the study: GF, RM, VC, EP, MF, RF, PC, FN

Data curation: MMO, YP, MP, NKW, OM, GF, VC, RM

Analysis: GF, RM, EP, VC

Writing: All authors

COMPETING INTERESTS

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All authors declare no conflicts of interest.

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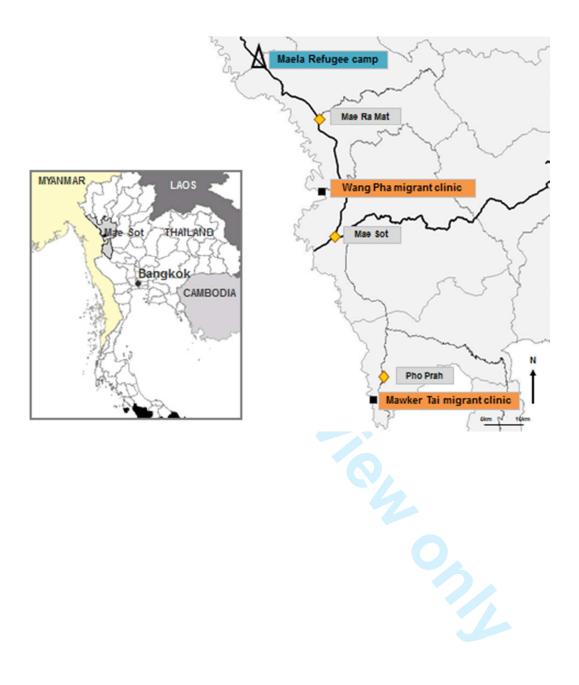
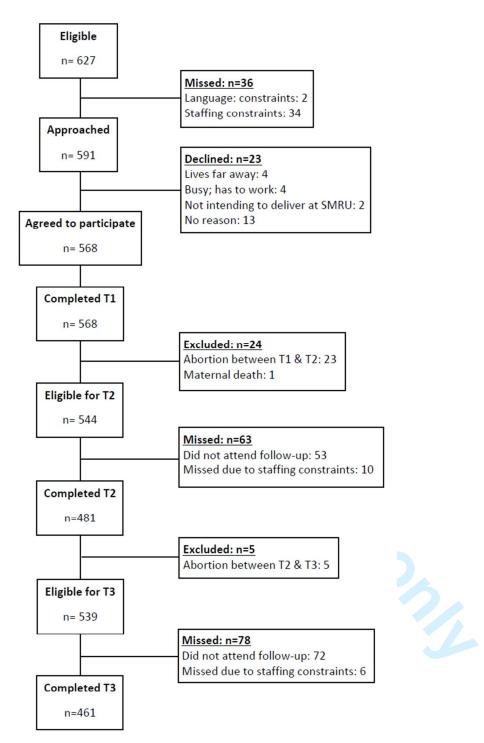


Figure 2. Flow of participants through study from recruitment to T3



STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cohort studies

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any pre-specified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5-6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4-5, 6-7
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	5
		(b) For matched studies, give matching criteria and number of exposed and unexposed	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5-6
Bias	9	Describe any efforts to address potential sources of bias	7 (QA)
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	N/A for cohort profile
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	N/A for cohort profile
		(b) Describe any methods used to examine subgroups and interactions	N/A for cohort profile
		(c) Explain how missing data were addressed	N/A for cohort profile

		(d) If applicable, explain how loss to follow-up was addressed	N/A for cohort
			profile
		(e) Describe any sensitivity analyses	N/A for cohort
			profile
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed	8, figure 2
		eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	8, figure 2
		(c) Consider use of a flow diagram	Figure 2
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential	8, table 2
		confounders	
		(b) Indicate number of participants with missing data for each variable of interest	Table 2
		(c) Summarise follow-up time (eg, average and total amount)	N/A as not complete.
			Planned follow-up
			time stated on page
			5
Outcome data	15*	Report numbers of outcome events or summary measures over time	9, table 3 (baseline
			results)
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence	N/A (cohort profile,
		interval). Make clear which confounders were adjusted for and why they were included	no full results yet)
		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	N/A (results not
			available yet)
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from	10-11
		similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	11

Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on	12
		which the present article is based	

^{*}Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

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.klist item and gives methodolog.
.ailable on the Web sites of PLoS Medicine
.epidem.com/). Information on the STROBE Initiative Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Cohort profile: The Migrant Perinatal Depression Study: a prospective cohort study of perinatal depression on the Thai-Myanmar border

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Title: Cohort profile: The Migrant Perinatal Depression Study: a prospective cohort study of perinatal depression on the Thai-Myanmar border

Short title: Cohort profile: perinatal depression on the Thai-Myanmar border

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Cohort profile: The Migrant Perinatal Depression Study: a prospective cohort study of perinatal depression on the Thai-Myanmar border

ABSTRACT

Purpose: Perinatal depression is a significant contributor to maternal morbidity. Migrant women in resource-poor settings may be at increased risk, yet little research has been conducted in low- and middle-income settings. This prospective cohort study of migrant women on the Thai-Myanmar border aims to establish prevalence of perinatal depression, identify risk factors for perinatal depression and examine associations with infant outcomes.

Participants: Participating women are labour migrants and refugees living on the Thai-Myanmar border. A total of 568 women were recruited in their first trimester of pregnancy and are being followed up to one year post-partum.

Findings to date: At baseline, women in our study had a median age of 25 years, the predominant ethnicity was Sgaw Karen (48.9%), agriculture was the main employment sector (39.2%) and educational attainment was low with a median of four years of education. In the first trimester of pregnancy, a quarter (25.8%; 95% CI 22.3-29.5) of all women were depressed as diagnosed by the Structured Clinical Interview for the Diagnosis of DSM-IV Disorders.

Future plans: Follow-up is on-going and expected to continue until January 2018. The prevalence of depression at later stages of pregnancy and during the first post-partum year will be identified and associations between depression status and demographic, social, migration-related, medical, obstetric and infant factors will be quantified.

Registration: This study is registered on <u>ClinicalTrials.gov</u> with identifier number NCT02790905 (https://clinicaltrials.gov/show/NCT02790905).

STRENGTHS AND LIMITATIONS OF THIS STUDY

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- To our knowledge this is the first prospective study of perinatal depression among migrant women in a low-income setting, and our study contributes significantly to the underresearched field of migrant mental health.
- This study will provide the first quantification of disease burden of perinatal depression and identification of associated factors on the Thai-Myanmar border.
- Findings will enable improved detection of perinatal depression as well as earlier and better management of affected women.
- Interviews were carried out by general clinicians rather than psychiatrists. This short-coming
 was the result of an absence of psychiatric expertise in this setting. However, the use of
 generalists including local healthcare workers is a strength for the long-term sustainability of
 identifying and managing mental disorders in this population.
- There was a 26.1% loss to follow-up at the third trimester in this highly-mobile population.
 Statistical analyses will be conducted to explore differences between those lost and those who completed the study.

INTRODUCTION

Perinatal depression – a depressive episode occurring during pregnancy or up to twelve months post-partum – is a significant contributor to maternal morbidity (1, 2). Globally, the burden falls disproportionately upon those living in poverty. In high-income countries, the period prevalence of depression has been estimated at 18.4% in pregnancy and 19.2% postnatally (3). In low- and middle-income countries (LMIC), prevalence estimates are estimated at 25.3% in pregnancy and 19.0% postnatally (2). Point prevalence estimates from meta-analyses have found rates ranging from 7.4% to 12.8% in individual trimesters of pregnancy and a peak of 12.9% in the third month post-partum (3, 4). However, these meta-analyses are limited to studies from high-income settings, and comparable estimates from LMIC are lacking.

The consequences of perinatal depression are significant. Affected women are at risk of chronic and recurrent depression, and the ability to work and provide care may be impaired. Depression in pregnancy has been linked to negative health behaviours such as substance misuse and poor uptake of antenatal care (3). Infants of depressed mothers are at increased risk of preterm birth, low birthweight, stunting in later childhood and poor neurodevelopmental and behavioural outcomes which may persist into adolescence and affect functional outcomes (5-7).

Migrant women, whom we define as those who have left their place of origin regardless of circumstances, are at particular risk of perinatal depression (8, 9). Stressors within their family, occupational and social circumstances – many of which may have contributed to their decision to migrate – continue to impact upon migrant populations in their place of settlement (8, 9). Women who resettle within LMIC are at especially high risk (10). However, despite the bulk of global migration flows occurring in low- and middle-income regions, the evidence on migrant mental health remains heavily skewed towards high-income destinations. A systematic review of perinatal mental disorders among migrant women identified 41 studies, of which 37 were conducted in high-income countries, four in middle-income countries and none in low-income countries (10). There is thus an urgent need for improved understanding and detection of perinatal depression in LMIC to enable quantification of the disease burden and effective management of the condition (2).

The Thai-Myanmar border area is home to an estimated 200,000 labour migrants and 145,000 refugees from Myanmar (11, 12). The prevalence of perinatal depression within this setting has not previously been examined. A prospective cohort study of pregnant migrant women in this low-income setting was set up with the following objectives: 1) to determine the prevalence of perinatal depression; 2) to identify differences in prevalence at various stages of pregnancy and the post-partum period; 3) to identify demographic, social, medical and obstetric factors associated with perinatal depression; and 4) to examine associations between maternal depression and neurodevelopmental outcomes of infants. In this paper, we describe the design, recruitment and characteristics of the cohort.

COHORT DESCRIPTION

Setting

The study was carried out at Shoklo Malaria Research Unit (SMRU) in Mae Sot, Tak Province, Thailand. SMRU is a field station of the Mahidol-Oxford Tropical Medicine Research Unit (MORU), a research collaboration between Mahidol University (Thailand) and the University of Oxford (UK). SMRU has carried out research and provided maternity services on the Thai-Myanmar border area since 1986. Its clinics are located along the Thai side of the border, 30-60 kilometres north and south of Mae Sot. Care is provided to refugee women and infants in Maela camp (MLA) and to rural labour migrants at Mawker Tai (MKT) and Wang Pha (WPA) (figure 1).

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Figure 1. Map of study area showing refugee (Δ) and migrant clinics (■) (Credit: Dr Verena Carrara, SMRU)

Population

Refugees live in camps on the Thai side of the border. MLA is the largest refugee camp with a population of 37,000 (13). Within the refugee camp, non-governmental organisations (NGO) provide health care, education, food rations and housing, and the United Nations High Commissioner for Refugees (UNHCR) manages repatriation and resettlement programmes (13). Though the refugee camps provide a degree of security, opportunities for work and freedom of movement are severely limited. By contrast, labour migrants are a highly mobile population, residing in rural villages on both sides of the border and often many making daily commutes across the border for work. Labour migrants in this setting work predominantly in the agricultural sector and are paid minimal daily wages (11, 12). Many labour migrants lack official documentation rendering them vulnerable to fines, arrest and deportation by the Thai authorities, and excluding them from accessing healthcare, social care and education (11, 12). In this paper, we use the term 'migrant' to include both refugee and labour migrant populations.

Eligibility and recruitment

This prospective cohort study includes first trimester pregnant migrant women attending SMRU antenatal clinics (ANC) at MLA, MKT and WPA. Women were eligible if they were aged 18 years or over, their estimated gestational age (EGA) as determined by ultrasound dating scan was less than 14 weeks, they had a viable pregnancy, planned to deliver at SMRU and were willing and able to participate. Eligible women were approached by a member of the study team whilst waiting to be seen at ANC. Recruitment took place between October 2015 and April 2016. Follow-up assessments will take place regularly until twelve months post-partum and will be complete in January 2018. Further follow-up is subject to funding.

Ethics and consent

At recruitment, study staff provided eligible women with verbal and written explanations of the study. It was explained that participation was voluntary, that non-participation would not affect care and that consent could be withdrawn at any time. Women who agreed to participate provided

consent in the form of a signature or thumbprint for those with low literacy. Participants are offered a small gift (of approximate value £1 GBP) at each visit and any travel costs incurred are reimbursed. Ethics approval was granted by the University of Oxford Tropical Research Ethics Committee (OxTREC 28-15), Mahidol University Faculty of Tropical Medicine Ethics Committee (TMEC 15-045) and the Tak Border Community Advisory Board (T-CAB 6/2/2015) (14).

Instruments

Depression status is being ascertained using the depression items of the *Structured Clinical Interview for the Diagnosis of DSM-IV Disorders* (SCID), a widely used, semi-structured diagnostic tool (15). The SCID was translated into Burmese and Sgaw Karen by two SMRU clinicians fluent in Burmese, Karen and English. Back-translation was carried out by two further SMRU clinicians who had not seen the original English version. Original and back-translated English versions were compared to ensure semantic equivalence had been maintained. DSM-IV criteria were applied to SCID responses to establish diagnoses of Major Depressive Disorder, Minor Depressive Disorder and Depressive Disorder Not Otherwise Specified (NOS). The diagnostic category of Depressive Disorder NOS was included to capture the substantial proportion of women with symptoms of depression that were clinically significant but which did not meet the DSM-IV criteria for major or minor depression.

At inclusion in trimester one (T1), the *Refugee Health Screener-15* (RHS-15) was also administered. The RHS-15 screens for psychological and somatic symptoms of depression, anxiety and post-traumatic stress disorder (16). The RHS-15 consists of fourteen Likert-type response items and a distress thermometer which asks respondents to rate their distress on a visual scale of one to ten. Burmese and Sgaw Karen versions of the RHS-15 were acquired from the RHS-15 authors (17).

Data on demographic, social and migration data were collected using questionnaires. Medical and obstetric data will be obtained from participants' computerised medical records following delivery. Infant measurements including length and weight are being conducted using standardised instruments. Infant development is being assessed using the Shoklo Developmental Test, a locally-developed neurological examination designed for field-use in resource-constrained settings (18, 19). The Shoklo Developmental Test has good correlation with the Griffiths Developmental Scales and has been used in our setting to evaluate the neurodevelopment of infants born to children with malaria in pregnancy and in on-going studies of neonatal jaundice (18, 20-23). Mothers' bonding with infants is being assessed with the Mother-to-Infant Bonding Scale (24).

Procedure

A study timeline is shown in **Table 1**. Data is being collected at eight time points: in the first (T1), second (T2) and third (T3) trimesters of pregnancy and at one (T4), three (T5), six (T6), nine (T7) and twelve (T8) months post-partum. Questionnaires and interviews are conducted by study staff in a private room in Sgaw Karen or Burmese according to women's preference. Verbal administration (rather than self-completion) is being used due to low literacy rates within this population and limited comprehension of health-related written information, even among those able to read (25). SCID responses are independently scored by the study physician and an independent physician. Disagreements are resolved by discussion with a psychiatrist (MF). Women with depression are offered counselling and, when appropriate, anti-depressant medication and follow-up at SMRU. Women with severe symptoms or active suicidal ideation are admitted for treatment and observation.

Table 1. Timeline of data collection

Time	Time		ression RHS-15 [†]	Demographic & social	Medical factors	Obstetric factors	Infant factors	Infant bonding
Pregnan	су	SCID						
T1	1 st trimester (EGA <14)	Х	Full	X				
T2	2 nd trimester (EGA 18-26)	Х	DT					
T3	3 rd trimester (EGA 28-38)	X	DT	X				
Post-par	tum							
T4	1m post-partum	Х	DT		X	Х	Χ	Х
T5	3m post-partum						Χ	
T6	6m post-partum	X	DT				Χ	Х
T7	9m post-partum						Χ	
T8	12m post-partum	Х	DT		Х		Χ	Х

[†]At T1 the full RHS-15 was administered. At subsequent visits only the distress thermometer (DT) component of the RHS-15 was administered.

Quality assurance and control

The study team consists of SMRU physicians, midwives and counsellors. Midwives and counsellors are fluent in Burmese, Sgaw Karen and English and are themselves members of the local migrant community, and therefore sensitive to the needs of the population. Prior to recruitment the study lead (GF) received training from the American Psychiatry Association in conducting SCID interviews. Counsellors and midwives underwent training in conducting interviews and counselling methods prior to the study. During the first month all questionnaires and interviews were conducted with the

study lead until counsellors and midwives were able to perform them unassisted. Thereafter, GF coconducted interviews at one site per day to ensure quality.

Sample size

A convenience sample of all women attending SMRU ANC in their first trimester of pregnancy during the recruitment period was used. Based on previous studies in this setting, we assumed a high participation rate and approximately 15% loss to follow-up (26). Our target sample size of 500 was based on an assumed approximate overall depression prevalence of 20% and 80% power (with two-sided 95% confidence intervals) to detect associations of approximately 2.5-fold in magnitude and to run multiple regression analyses with up to four independent variables (27).

Data security and management

All data are de-identified entered into a password-protected Microsoft Excel database accessible only to SMRU study staff. Source questionnaires are stored securely at SMRU ANC sites until follow-up is complete, whereupon they are stored at the SMRU head office.

FINDINGS TO DATE

Between October 2015 and April 2016, 627 eligible women attended SMRU ANC. Of these, 591 were approached and 568 (90.6% of all eligible; 96.1% of those approached) women agreed to participate. **Figure 2** shows the flow of participants through the study from recruitment (T1) through to T3. Follow-up for T4 through T8 is still on-going. Women who were eligible but missed due to language or staffing constraints did not differ significantly from those included by age, ethnicity or educational level. Of the 568 women who completed T1, 84.7% completed T2 and 81.2% completed T3. Some women who did not attend at T2 returned at T3. The most common reason for participants not returning for follow-up was abortion in early pregnancy.

Figure 2. Flow of participants through study from recruitment to T3

Demographic characteristics

At enrolment, the median age was 25 years (**table 2**). Mean EGA (sd) at enrolment was 9.6 (2.3) weeks. Sgaw Karen was the predominant ethnicity and language among refugees, while Burman ethnicity and Burmese language were predominant among labour migrant women. The median years of education was 4 years, and almost half (45.4%) of all participants had attended school for under three years. The main employment sector was agricultural work (39.2%), though over a third of participants were not in paid employment (35.7%).

Table 2. Demographic characteristics of study participants at T1 (n=568)

	Au.		La	bour migrant si	tes	Refugee	camp
	All	Missing	MKT	WPA	p value ^a	MLA	p value ^a
	(n=568)		(n=163)	(n=155)	MKT vs WPA	(n=250)	Ref vs mig
Demographic							
Age, med [range]	25 [18-50]	0	25 [18-45]	26 [18-44]	0.50	25 [18-50]	0.98
Ethnicity, n (%)							
Burman	161 (28.4)	0	77 (47.2)	82 (52.9)	0.21	2 (0.8)	<0.01
Sgaw Karen	278 (48.9)		61 (37.4)	41 (26.5)		176 (70.4)	
Poe Karen	66 (11.6)		19 (11.7)	24 (15.5)		23 (9.2)	
Burman Muslim	44 (7.8)		0 (0)	1 (0.7)		43 (17.2)	
Other	19 (3.4)		6 (3.7)	7 (4.5)		6 (2.4)	
Religion, n (%)							
Buddhist	408 (71.8)	0	152 (93.2)	147 (94.8)		109 (43.6)	
Christian	115 (20.3)		11 (6.8)	7 (4.5)		97 (38.8)	
Muslim	45 (7.9)		0 (0)	1 (0.7)	0.40	44 (17.6)	<0.01
Marital status, n (%)							
Married/co-habiting	566 (99.6)	0	163 (100.0)	154 (99.3)	0.49	249 (99.6)	1.00
Education and language							
Yrs of education, med [range]	4 [0-18]	78	3 [0-12]	4 [0-15]	0.42	5 [0-18]	0.02
Yrs of education, n (%)							
Under 3 years, n (%)	255 (45.4)	6	100 (61.7)	60 (39.0)	<0.01	95 (38.6)	<0.01
3 to 6 years, n (%)	164 (29.2)		35 (21.6)	61 (39.6)		68 (27.6)	
7 to 10 years, n (%)	119 (21.2)		26 (16.1)	23 (14.9)		70 (28.5)	
Over 10 years, n (%)	24 (4.3)		1 (0.6)	10 (6.5)		13 (5.3)	
Type of school, n (%)							
Myanmar school	245 (53.4)	116	66 (53.2)	89 (76.7)	<0.01	90 (41.1)	<0.01
Thai school	9 (2.0)		7 (5.7)	0 (0)		2 (0.9)	
NGO/faith-based school	89 (19.4)		9 (7.3)	3 (2.6)		77 (35.2)	
None	116 (25.3)		42 (33.9)	24 (20.7)		50 (22.8)	
Literate (self-report), n (%)	392 (69.0)	0	98 (60.1)	106 (68.4)	0.13	188 (75.2)	<0.01
Interview language, n (%)							
Burmese	239 (42.1)	0	91 (55.8)	97 (62.6)	0.05	51 (20.4)	<0.01
Sgaw Karen	280 (49.3)		64 (39.3)	42 (27.1)		174 (69.6)	
Poe Karen	43 (7.6)		7 (4.3)	13 (8.4)		23 (9.2)	
Other	6 (1.1)		1 (0.6)	3 (1.9)		2 (0.8)	
Languages spoken, n (%)							
1 language	211 (46.2)	82	53 (42.7)	58 (50.4)	0.48	100 (45.9)	0.99
2-3 languages	192 (42.0)		56 (45.2)	44 (38.3)		92 (42.2)	
4 or more languages	54 (11.8)		15 (12.1)	13 (11.3)		26 (11.9)	
Economic							
Employment sector, n (%)							
Agriculture	212 (39.2)	2	119 (73.9)	76 (56.3)	0.02	17 (6.9)	<0.01
NGO	59 (10.9)		2 (1.2)	5 (3.7)		52 (21.2)	
Selling	50 (9.2)		12 (7.5)	17 (12.6)		21 (8.6)	

3 (1.9)

25 (15.5)

3 [1-14]

87 (53.4)

1 (0.6)

17 (10.4)

23 (14.1)

53 (32.5)

1 [0-5]

85 (68.0)

2 (1.23)

36 (28.8)

89 (71.2)

3 [1-33]

36 (42.4)

74 (60.2)

6(4.4)

31 (23.0)

4 [2-12]

71 (45.8)

18 (11.6)

10 (6.5)

0 (0)

66 (42.6)

1 [0-8]

71 (64.0)

25 (16.3)

74 (63.2)

43 (36.8)

10 [1-39]

19 (29.7)

41 (47.7)

0.51

0.18

<0.01

0.20

<0.01

0.06

0.43

0.51

<0.01

<0.01

<0.01

0.11

0.07

18 (7.4)

137 (55.9)

5 [1-13]

171 (68.4)

6 (2.4)

29 (11.6)

4 (1.6)

132 (52.8)

1 [0-7]

154 (70.6)

120 (48.0)

3 (1.4)

216 (98.6)

10 [1-30]

9 (17.0)

43 (49.4)

<0.01

<0.01

0.04

0.22

<0.01

<0.01

<0.01

0.30

<0.01

<0.01

<0.01

<0.01

0.38

27 (5.0)

193 (35.7)

4 [1-14]

329 (57.9)

25 (4.4)

56 (9.9)

27 (4.8)

251 (44.2)

1 [0-8]

310 (68.3)

147 (26.0)

113 (24.5)

348 (75.5)

9 [1-39]

64 (31.7)

158 (53.4)

4

0

0

0

0

0

113

114

2

108

272

Other

Housework

Lifestyle

Alcohol

Smoking

Obstetric

Household size, med [range]

Telephone ownership, n (%)

Substance use, n (%)

Chewing tobacco

Parity, med [range]

Planned pregnancy, n (%)

History of depression, n (%)

Country now living, n (%)

Years in current location

Chewing betel

Psychosocial

Migration

Myanmar

Median [range]

≤1 year, n (%)

≤5 years, n (%)

Thailand

1 2 3

4

5

6

7

8

9

10

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^a p-values calculat	ed using two-gr	oup t-tests	for cor	ntinuous	data,	Chi-squar	ed tests for	categoric	al data and
Fisher's exact test	for categorical	data with o	ell cour	nts <5.					

Depression status

At baseline the overall prevalence of depression as diagnosed by the SCID was 25.8% (**Table 3**). There were significant differences in crude prevalence rates of depression between MKT and WPA, and between the migrant sites (MKT and WPA) combined and MLA. Explanations for these differences will be explored through regression analyses.

Table 3. First trimester depression status among study participants by site and by migrant status

	All	La	abour migrant s	Refugee camp		
	(n=568)	MKT	WPA	p value	MLA	p value
		(n=163)	(n=155)	MKT vs. WPA	(n=250)	Ref vs. mig
Any depression	146 (25.8)	29 (17.9)	46 (29.7)	0.01	71 (28.4)	0.03
Major depression	9 (1.6)	0 (0)	2 (1.3)		7 (2.8)	
Minor depression	37 (6.5)	6 (3.7)	19 (12.3)		12 (4.8)	
Depression NOS	100 (17.6)	23 (14.2)	25 (16.1)		52 (20.8)	
Negative	421 (74.2)	133 (82.1)	109 (70.3)		179 (71.6)	

STRENGTHS AND LIMITATIONS

To our knowledge, this is the first prospective study of perinatal depression among migrant women in a resource-constrained setting. The active screening for depression will inform the early detection and treatment of this condition and enable affected women to be supported and better interventions to be developed. An improved understanding of the prevalence and risk factors of depression is a cornerstone to addressing the disease burden. Mental disorders are a neglected field in this setting, and the small number of previous studies have focussed on specific subgroups including refugee children (28), Burmese political dissidents living in Bangkok (29), labour migrants workers in Mae Sot (30), and Karenni refugees in northern Thailand (31). None have included pregnant or post-partum women. To our knowledge, this is also the first study to include both labour migrants and refugees, enabling direct comparison between these two distinct subgroups of the migrant population. As well as allowing the progression of depression through pregnancy and the post-partum period to be assessed, a significant strength of our cohort design is the collection of data on an extensive array of potential risk and associated factors including demographic, social, medical, obstetric and infant factors. Overall, our study contributes to the under-researched field of migrant mental health from LMIC settings (10, 28).

A further strength of our study is that while most studies of mental disorders use screening tools to make mental state assessments, we used a diagnostic interview tool (10). Interviews were conducted by local healthcare staff who are themselves part of the local community. This enabled trust to be established with patients, and ensured high levels of cultural sensitivity. The fact that over 90% of women in this area attend ANC, coupled with our high response rate, means that our sample is representative of the general migrant population (26). The inclusion of the category of Depression NOS sheds light on an under-reported group of women who experience symptoms of depression that are clinically significant but do not quite meet the criteria for major or minor depression. In order to increase comparability to findings from other settings, our main statistical analyses will be limited to the more commonly reported categories of minor and major depression. However, we will also conduct additional analyses to explore the effects of including the NOS group.

There are also a number of limitations to our study. The absence of mental health expertise in our setting meant that it was not possible to obtain specialist psychiatry input (32, 33). However, by providing experienced local healthcare workers with training in conducting interviews and counselling skills we maximised accuracy as much as possible. Furthermore, in a resource-constrained setting it is more appropriate in the long-term for common mental disorders such as depression to be identified and managed by trained local workers, as specialist mental health

professionals are rarely available. By training frontline healthcare staff to conduct these assessments and provide counselling, we ensured that our study promoted local capacity-building, ownership, scalability and sustainability (34).

A further limitation is that face-to-face administration of interviews may have resulted in a social desirability bias and a lower willingness to disclose sensitive information (35). Given the sensitive nature of many of the issues discussed, including depression, suicidal ideation and behaviour, intimate partner violence and trauma history, participants may have felt uncomfortable discussing these and under-reported relevant experiences, especially during a vulnerable period such as pregnancy. However there is a strong oral tradition among the local population, and informal discussions are common and well-accepted (36). We also believe that the sensitivity and local knowledge of the study staff helped to ensure that participants felt comfortable disclosing personal information.

The repeated administration of the SCID may have affected how women responded. We saw no evidence of questionnaire fatigue, perhaps because women in our setting attend clinic on a fortnightly basis through much of their pregnancy, and thus completing the SCID once per trimester was not perceived as burdensome. However, the repeated SCID interviews may have had a therapeutic effect by enabling participants an opportunity to talk and share any worries. This possibility will be taken into account in the interpretation of prevalence of depression after the baseline assessment.

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Infants' neurodevelopmental outcomes will need to be interpreted with caution as assessments within the first year of life may not be sensitive enough to identify subtle differences between infants. Ideally, the cohort of infants would be followed-up longer-term. Nevertheless it may be possible by twelve months to see trends in the progression of global development. The use of a more widely-used tool such as the Bayley Scales would have been preferable. However, staffing and resource constraints, the length of the full Bayley test and a number of test items being difficult to convey in the local cultural context meant this was not possible (18, 19). The Shoklo Developmental Test has been used extensively in our setting and its strong correlation with the Griffiths Developmental Scale – a standardised neurodevelopmental assessment tool – gives confidence to the results (18, 19).

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Finally, our overall loss to follow-up to date of approximately 20% is higher than our anticipated loss of 15%. This figure may increase in subsequent, post-partum waves. We plan to explore differences between those included and lost in our analyses in order to assess potential implications for generalisability of results.

CONCLUSION

Addressing perinatal depression among migrant communities in LMIC is necessary to promote maternal mental health and address key sustainable development goals including ensuring good health and wellbeing, establishing gender equality and reducing global inequalities both within and among countries. Establishing the prevalence and risk factors for perinatal depression among migrant women on the Thai-Myanmar border will enable the burden of disease to be quantified, and earlier, more effective identification and management of affected women. We expect that observations and recommendations arising from this study will be of importance and relevance to other LMIC settings.

COLLABORATION

The data are not available freely. However, we welcome specific and detailed proposals for collaboration. Enquiries and requests for further information should be made to gracia.fellmeth@dph.ox.ac.uk.

FUNDING DECLARATION

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CONTRIBUTOR STATEMENT

Conceptualisation of the study: GF, RM, VC, EP, MF, RF, PC, FN

Data curation: MMO, YP, MP, NKW, OM, GF, VC, RM

Analysis: GF, RM, EP, VC
Writing: All authors

COMPETING INTERESTS

All authors declare no conflicts of interest.

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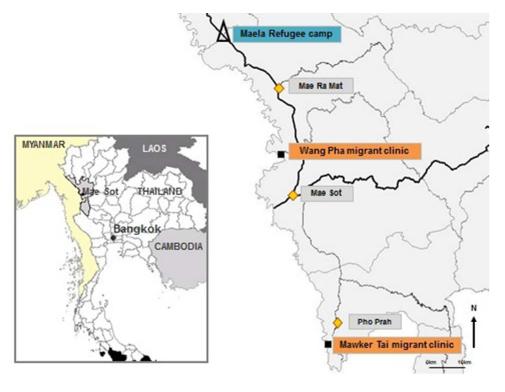


Figure 1. Map of study area showing refugee (Δ) and migrant clinics (\blacksquare) (Credit: Dr Verena Carrara, SMRU) 127x95mm (96 x 96 DPI)

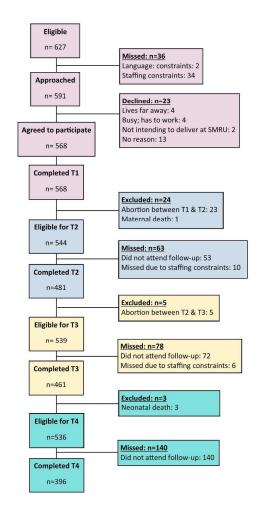


Figure 2. Flow of participants 209x297mm (300 x 300 DPI)

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cohort studies

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any pre-specified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5-6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4-5, 6-7
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	5
		(b) For matched studies, give matching criteria and number of exposed and unexposed	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-6
Data sources/	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe	5-6
measurement		comparability of assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	7 (QA)
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	N/A for cohort profile
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	N/A for cohort profile
		(b) Describe any methods used to examine subgroups and interactions	N/A for cohort profile
		(c) Explain how missing data were addressed	N/A for cohort profile

		(d) If applicable, explain how loss to follow-up was addressed	N/A for cohort profile
		(e) Describe any sensitivity analyses	N/A for cohort profile
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8, figure 2
		(b) Give reasons for non-participation at each stage	8, figure 2
		(c) Consider use of a flow diagram	Figure 2
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8, table 2
		(b) Indicate number of participants with missing data for each variable of interest	Table 2
		(c) Summarise follow-up time (eg, average and total amount)	N/A as not complete Planned follow-up time stated on page
			5
Outcome data	15*	Report numbers of outcome events or summary measures over time	9, table 3 (baseline results)
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N/A (cohort profile, no full results yet)
		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	N/A (results not available yet)
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10-11
Generalisability	21	Discuss the generalisability (external validity) of the study results	11

	1		
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on	12
		which the present article is based	

^{*}Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Cohort profile: The Migrant Perinatal Depression Study: a prospective cohort study of perinatal depression on the Thai-Myanmar border

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Title: Cohort profile: The Migrant Perinatal Depression Study: a prospective cohort study of perinatal depression on the Thai-Myanmar border

Short title: Cohort profile: perinatal depression on the Thai-Myanmar border

Authors:

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Cohort profile: The Migrant Perinatal Depression Study: a prospective cohort study of perinatal depression on the Thai-Myanmar border

ABSTRACT

Purpose: Perinatal depression is a significant contributor to maternal morbidity. Migrant women in resource-poor settings may be at increased risk, yet little research has been conducted in low- and middle-income settings. This prospective cohort study of migrant women on the Thai-Myanmar border aims to establish prevalence of perinatal depression, identify risk factors for perinatal depression and examine associations with infant outcomes.

Participants: Participating women are labour migrants and refugees living on the Thai-Myanmar border. A total of 568 women were recruited in their first trimester of pregnancy and are being followed up to one year post-partum.

Findings to date: At baseline, women in our study had a median age of 25 years, the predominant ethnicity was Sgaw Karen (48.9%), agriculture was the main employment sector (39.2%) and educational attainment was low with a median of four years of education. In the first trimester of pregnancy, a quarter (25.8%; 95% CI 22.3-29.5) of all women were depressed as diagnosed by the Structured Clinical Interview for the Diagnosis of DSM-IV Disorders.

Future plans: Follow-up is on-going and expected to continue until January 2018. The prevalence of depression at later stages of pregnancy and during the first post-partum year will be identified and associations between depression status and demographic, social, migration-related, medical, obstetric and infant factors will be quantified.

Registration: This study is registered on <u>ClinicalTrials.gov</u> with identifier number NCT02790905 (https://clinicaltrials.gov/show/NCT02790905).

STRENGTHS AND LIMITATIONS OF THIS STUDY

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- To our knowledge this is the first prospective study of perinatal depression among migrant women in a low-income setting, and our study contributes significantly to the underresearched field of migrant mental health.
- This study will provide the first quantification of disease burden of perinatal depression and identification of associated factors on the Thai-Myanmar border.
- Findings will enable improved detection of perinatal depression as well as earlier and better management of affected women.
- Interviews were carried out by general clinicians rather than psychiatrists. This short-coming
 was the result of an absence of psychiatric expertise in this setting. However, the use of
 generalists including local healthcare workers is a strength for the long-term sustainability of
 identifying and managing mental disorders in this population.
- There was a 26.1% loss to follow-up at the third trimester in this highly-mobile population.
 Statistical analyses will be conducted to explore differences between those lost and those who completed the study.

INTRODUCTION

Perinatal depression – a depressive episode occurring during pregnancy or up to twelve months post-partum – is a significant contributor to maternal morbidity (1, 2). Globally, the burden falls disproportionately upon those living in poverty. In high-income countries, the period prevalence of depression has been estimated at 18.4% in pregnancy and 19.2% postnatally (3). In low- and middle-income countries (LMIC), prevalence estimates are estimated at 25.3% in pregnancy and 19.0% postnatally (2). Point prevalence estimates from meta-analyses have found rates ranging from 7.4% to 12.8% in individual trimesters of pregnancy and a peak of 12.9% in the third month post-partum (3, 4). However, these meta-analyses are limited to studies from high-income settings, and comparable estimates from LMIC are lacking.

The consequences of perinatal depression are significant. Affected women are at risk of chronic and recurrent depression, and the ability to work and provide care may be impaired. Depression in pregnancy has been linked to negative health behaviours such as substance misuse and poor uptake of antenatal care (3). Infants of depressed mothers are at increased risk of preterm birth, low birthweight, stunting in later childhood and poor neurodevelopmental and behavioural outcomes which may persist into adolescence and affect functional outcomes (5-7).

Migrant women, whom we define as those who have left their place of origin regardless of circumstances, are at particular risk of perinatal depression (8, 9). Stressors within their family, occupational and social circumstances – many of which may have contributed to their decision to migrate – continue to impact upon migrant populations in their place of settlement (8, 9). Women who resettle within LMIC are at especially high risk (10). However, despite the bulk of global migration flows occurring in low- and middle-income regions, the evidence on migrant mental health remains heavily skewed towards high-income destinations. A systematic review of perinatal mental disorders among migrant women identified 41 studies, of which 37 were conducted in high-income countries, four in middle-income countries and none in low-income countries (10). There is thus an urgent need for improved understanding and detection of perinatal depression in LMIC to enable quantification of the disease burden and effective management of the condition (2).

The Thai-Myanmar border area is home to an estimated 200,000 labour migrants and 145,000 refugees from Myanmar (11, 12). The prevalence of perinatal depression within this setting has not previously been examined. A prospective cohort study of pregnant migrant women in this low-income setting was set up with the following objectives: 1) to determine the prevalence of perinatal depression; 2) to identify differences in prevalence at various stages of pregnancy and the post-partum period; 3) to identify demographic, social, medical and obstetric factors associated with perinatal depression; and 4) to examine associations between maternal depression and neurodevelopmental outcomes of infants. In this paper, we describe the design, recruitment and characteristics of the cohort.

COHORT DESCRIPTION

Setting

The study was carried out at Shoklo Malaria Research Unit (SMRU) in Mae Sot, Tak Province, Thailand. SMRU is a field station of the Mahidol-Oxford Tropical Medicine Research Unit (MORU), a research collaboration between Mahidol University (Thailand) and the University of Oxford (UK). SMRU has carried out research and provided maternity services on the Thai-Myanmar border area since 1986. Its clinics are located along the Thai side of the border, 30-60 kilometres north and south of Mae Sot. Care is provided to refugee women and infants in Maela camp (MLA) and to rural labour migrants at Mawker Tai (MKT) and Wang Pha (WPA) (figure 1).

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Figure 1. Map of study area showing refugee (Δ) and migrant clinics (■) (Credit: Dr Verena Carrara, SMRU)

Population

Refugees live in camps on the Thai side of the border. MLA is the largest refugee camp with a population of 37,000 (13). Within the refugee camp, non-governmental organisations (NGO) provide health care, education, food rations and housing, and the United Nations High Commissioner for Refugees (UNHCR) manages repatriation and resettlement programmes (13). Though the refugee camps provide a degree of security, opportunities for work and freedom of movement are severely limited. By contrast, labour migrants are a highly mobile population, residing in rural villages on both sides of the border and often many making daily commutes across the border for work. Labour migrants in this setting work predominantly in the agricultural sector and are paid minimal daily wages (11, 12). Many labour migrants lack official documentation rendering them vulnerable to fines, arrest and deportation by the Thai authorities, and excluding them from accessing healthcare, social care and education (11, 12). In this paper, we use the term 'migrant' to include both refugee and labour migrant populations.

Eligibility and recruitment

This prospective cohort study includes first trimester pregnant migrant women attending SMRU antenatal clinics (ANC) at MLA, MKT and WPA. Women were eligible if they were aged 18 years or over, their estimated gestational age (EGA) as determined by ultrasound dating scan was less than 14 weeks, they had a viable pregnancy, planned to deliver at SMRU and were willing and able to participate. Eligible women were approached by a member of the study team whilst waiting to be seen at ANC. Recruitment took place between October 2015 and April 2016. Follow-up assessments will take place regularly until twelve months post-partum and will be complete in January 2018. Further follow-up is subject to funding.

Ethics and consent

At recruitment, study staff provided eligible women with verbal and written explanations of the study. It was explained that participation was voluntary, that non-participation would not affect care and that consent could be withdrawn at any time. Women who agreed to participate provided

consent in the form of a signature or thumbprint for those with low literacy. Participants are offered a small gift (of approximate value £1 GBP) at each visit and any travel costs incurred are reimbursed. Ethics approval was granted by the University of Oxford Tropical Research Ethics Committee (OxTREC 28-15), Mahidol University Faculty of Tropical Medicine Ethics Committee (TMEC 15-045) and the Tak Border Community Advisory Board (T-CAB 6/2/2015) (14).

Instruments

Depression status is being ascertained using the depression items of the *Structured Clinical Interview for the Diagnosis of DSM-IV Disorders* (SCID), a widely used, semi-structured diagnostic tool (15). The SCID was translated into Burmese and Sgaw Karen by two SMRU clinicians fluent in Burmese, Karen and English. Back-translation was carried out by two further SMRU clinicians who had not seen the original English version. Original and back-translated English versions were compared to ensure semantic equivalence had been maintained. DSM-IV criteria were applied to SCID responses to establish diagnoses of Major Depressive Disorder, Minor Depressive Disorder and Depressive Disorder Not Otherwise Specified (NOS). The diagnostic category of Depressive Disorder NOS was included to capture the substantial proportion of women with symptoms of depression that were clinically significant but which did not meet the DSM-IV criteria for major or minor depression.

At inclusion in trimester one (T1), the *Refugee Health Screener-15* (RHS-15) was also administered. The RHS-15 screens for psychological and somatic symptoms of depression, anxiety and post-traumatic stress disorder (16). The RHS-15 consists of fourteen Likert-type response items and a distress thermometer which asks respondents to rate their distress on a visual scale of one to ten. Burmese and Sgaw Karen versions of the RHS-15 were acquired from the RHS-15 authors (17).

Data on demographic, social and migration data were collected using questionnaires. Medical and obstetric data will be obtained from participants' computerised medical records following delivery. Infant measurements including length and weight are being conducted using standardised instruments. Infant development is being assessed using the Shoklo Developmental Test, a locally-developed neurological examination designed for field-use in resource-constrained settings (18, 19). The Shoklo Developmental Test has good correlation with the Griffiths Developmental Scales and has been used in our setting to evaluate the neurodevelopment of infants born to children with malaria in pregnancy and in on-going studies of neonatal jaundice (18, 20-23). Mothers' developing relationships with their infants is being assessed with the Mother-to-Infant Bonding Scale (24).

Procedure

A study timeline is shown in **Table 1**. Data is being collected at eight time points: in the first (T1), second (T2) and third (T3) trimesters of pregnancy and at one (T4), three (T5), six (T6), nine (T7) and twelve (T8) months post-partum. Questionnaires and interviews are conducted by study staff in a private room in Sgaw Karen or Burmese according to women's preference. Verbal administration (rather than self-completion) is being used due to low literacy rates within this population and limited comprehension of health-related written information, even among those able to read (25). SCID responses are independently scored by the study physician and an independent physician. Disagreements are resolved by discussion with a psychiatrist (MF). Women with depression are offered counselling and, when appropriate, anti-depressant medication and follow-up at SMRU. Women with severe symptoms or active suicidal ideation are admitted for treatment and observation.

Table 1. Timeline of data collection

Time		Dep SCID	ression RHS-15 [†]	Demographic & social	Medical factors	Obstetric factors	Infant factors	Infant bonding
Pregnan	су							
T1	1 st trimester (EGA <14)	Х	Full	X				
T2	2 nd trimester (EGA 18-26)	Х	DT					
T3	3 rd trimester (EGA 28-38)	X	DT	X				
Post-par	tum							
T4	1m post-partum	Х	DT		X	Х	Χ	Х
T5	3m post-partum						Χ	
T6	6m post-partum	X	DT				Χ	Х
T7	9m post-partum						Χ	
T8	12m post-partum	Х	DT		Х		Χ	Х

[†]At T1 the full RHS-15 was administered. At subsequent visits only the distress thermometer (DT) component of the RHS-15 was administered.

Quality assurance and control

The study team consists of SMRU physicians, midwives and counsellors. Midwives and counsellors are fluent in Burmese, Sgaw Karen and English and are themselves members of the local migrant community, and therefore sensitive to the needs of the population. Prior to recruitment the study lead (GF) received training from the American Psychiatry Association in conducting SCID interviews. Counsellors and midwives underwent training in conducting interviews and counselling methods prior to the study. During the first month all questionnaires and interviews were conducted with the

study lead until counsellors and midwives were able to perform them unassisted. Thereafter, GF coconducted interviews at one site per day to ensure quality.

Sample size

A convenience sample of all women attending SMRU ANC in their first trimester of pregnancy during the recruitment period was used. Based on previous studies in this setting, we assumed a high participation rate and approximately 15% loss to follow-up (26). Our target sample size of 500 was based on an assumed approximate overall depression prevalence of 20% and 80% power (with two-sided 95% confidence intervals) to detect associations of approximately 2.5-fold in magnitude and to run multiple regression analyses with up to four independent variables (27).

Data security and management

All data are de-identified entered into a password-protected Microsoft Excel database accessible only to SMRU study staff. Source questionnaires are stored securely at SMRU ANC sites until follow-up is complete, whereupon they are stored at the SMRU head office.

FINDINGS TO DATE

Between October 2015 and April 2016, 627 eligible women attended SMRU ANC. Of these, 591 were approached and 568 (90.6% of all eligible; 96.1% of those approached) women agreed to participate. **Figure 2** shows the flow of participants through the study from recruitment (T1) through to T3. Follow-up for T4 through T8 is still on-going. Women who were eligible but missed due to language or staffing constraints did not differ significantly from those included by age, ethnicity or educational level. Of the 568 women who completed T1, 84.7% completed T2 and 81.2% completed T3. Some women who did not attend at T2 returned at T3. The most common reason for participants not returning for follow-up was abortion in early pregnancy.

Figure 2. Flow of participants through study from recruitment to T3

Demographic characteristics

At enrolment, the median age was 25 years (**table 2**). Mean EGA (sd) at enrolment was 9.6 (2.3) weeks. Sgaw Karen was the predominant ethnicity and language among refugees, while Burman ethnicity and Burmese language were predominant among labour migrant women. The median years of education was 4 years, and almost half (45.4%) of all participants had attended school for under three years. The main employment sector was agricultural work (39.2%), though over a third of participants were not in paid employment (35.7%).

Table 2. Demographic characteristics of study participants at T1 (n=568)

Table 2. Demogra		1	· · · · · · · · · · · · · · · · · · ·	bour migrant si	tes	Refugee	camp
	All	Missing	MKT	WPA	p value ^a	MLA	p value ^a
	(n=568)		(n=163)	(n=155)	MKT vs WPA	(n=250)	Ref vs mig
Demographic							
Age, med [range]	25 [18-50]	0	25 [18-45]	26 [18-44]	0.50	25 [18-50]	0.98
Ethnicity, n (%)		_					
Burman	161 (28.4)	0	77 (47.2)	82 (52.9)	0.21	2 (0.8)	<0.01
Sgaw Karen	278 (48.9)		61 (37.4)	41 (26.5)		176 (70.4)	
Poe Karen	66 (11.6)		19 (11.7)	24 (15.5)		23 (9.2)	
Burman Muslim	44 (7.8)		0 (0)	1 (0.7)		43 (17.2)	
Other	19 (3.4)		6 (3.7)	7 (4.5)		6 (2.4)	
Religion, n (%)							
Buddhist	408 (71.8)	0	152 (93.2)	147 (94.8)		109 (43.6)	
Christian	115 (20.3)		11 (6.8)	7 (4.5)		97 (38.8)	
Muslim	45 (7.9)		0 (0)	1 (0.7)	0.40	44 (17.6)	<0.01
Marital status, n (%)							
Married/co-habiting	566 (99.6)	0	163 (100.0)	154 (99.3)	0.49	249 (99.6)	1.00
Education and language							
Yrs of education, med [range]	4 [0-18]	78	3 [0-12]	4 [0-15]	0.42	5 [0-18]	0.02
Yrs of education, n (%)							
Under 3 years, n (%)	255 (45.4)	6	100 (61.7)	60 (39.0)	<0.01	95 (38.6)	<0.01
3 to 6 years, n (%)	164 (29.2)		35 (21.6)	61 (39.6)		68 (27.6)	
7 to 10 years, n (%)	119 (21.2)		26 (16.1)	23 (14.9)		70 (28.5)	
Over 10 years, n (%)	24 (4.3)		1 (0.6)	10 (6.5)		13 (5.3)	
Type of school, n (%)							
Myanmar school	245 (53.4)	116	66 (53.2)	89 (76.7)	<0.01	90 (41.1)	<0.01
Thai school	9 (2.0)		7 (5.7)	0 (0)		2 (0.9)	
NGO/faith-based school	89 (19.4)		9 (7.3)	3 (2.6)		77 (35.2)	
None	116 (25.3)		42 (33.9)	24 (20.7)		50 (22.8)	
Literate (self-report), n (%)	392 (69.0)	0	98 (60.1)	106 (68.4)	0.13	188 (75.2)	<0.01
Interview language, n (%)							
Burmese	239 (42.1)	0	91 (55.8)	97 (62.6)	0.05	51 (20.4)	<0.01
Sgaw Karen	280 (49.3)		64 (39.3)	42 (27.1)		174 (69.6)	
Poe Karen	43 (7.6)		7 (4.3)	13 (8.4)		23 (9.2)	
Other	6 (1.1)		1 (0.6)	3 (1.9)		2 (0.8)	
Languages spoken, n (%)							
1 language	211 (46.2)	82	53 (42.7)	58 (50.4)	0.48	100 (45.9)	0.99
2-3 languages	192 (42.0)		56 (45.2)	44 (38.3)		92 (42.2)	
4 or more languages	54 (11.8)		15 (12.1)	13 (11.3)		26 (11.9)	
Economic							
Employment sector, n (%)			,				
Agriculture	212 (39.2)	2	119 (73.9)	76 (56.3)	0.02	17 (6.9)	<0.01
NGO	59 (10.9)		2 (1.2)	5 (3.7)		52 (21.2)	
Selling	50 (9.2)		12 (7.5)	17 (12.6)		21 (8.6)	

3 (1.9)

25 (15.5)

3 [1-14]

87 (53.4)

1 (0.6)

17 (10.4)

23 (14.1)

53 (32.5)

1 [0-5]

85 (68.0)

2 (1.23)

36 (28.8)

89 (71.2)

3 [1-33]

36 (42.4)

74 (60.2)

6(4.4)

31 (23.0)

4 [2-12]

71 (45.8)

18 (11.6)

10 (6.5)

0 (0)

66 (42.6)

1 [0-8]

71 (64.0)

25 (16.3)

74 (63.2)

43 (36.8)

10 [1-39]

19 (29.7)

41 (47.7)

0.51

0.18

<0.01

0.20

<0.01

0.06

0.43

0.51

<0.01

<0.01

<0.01

0.11

0.07

18 (7.4)

137 (55.9)

5 [1-13]

171 (68.4)

6 (2.4)

29 (11.6)

4 (1.6)

132 (52.8)

1 [0-7]

154 (70.6)

120 (48.0)

3 (1.4)

216 (98.6)

10 [1-30]

9 (17.0)

43 (49.4)

<0.01

<0.01

0.04

0.22

<0.01

<0.01

<0.01

0.30

<0.01

<0.01

<0.01

<0.01

0.38

27 (5.0)

193 (35.7)

4 [1-14]

329 (57.9)

25 (4.4)

56 (9.9)

27 (4.8)

251 (44.2)

1 [0-8]

310 (68.3)

147 (26.0)

113 (24.5)

348 (75.5)

9 [1-39]

64 (31.7)

158 (53.4)

4

0

0

0

0

0

113

114

2

108

272

Other

Housework

Lifestyle

Alcohol

Smoking

Obstetric

Household size, med [range]

Telephone ownership, n (%)

Substance use, n (%)

Chewing tobacco

Parity, med [range]

Planned pregnancy, n (%)

History of depression, n (%)

Country now living, n (%)

Years in current location

Chewing betel

Psychosocial

Migration

Myanmar

Median [range]

≤1 year, n (%)

≤5 years, n (%)

Thailand

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^a p-values calculat	ed using two-gr	oup t-tests	for co	ntinuous	data,	Chi-squar	ed tests for	categorical	data and
Fisher's exact test	for categorical	data with d	ell cou	nts <5.					

Depression status

At baseline the overall prevalence of depression as diagnosed by the SCID was 25.8% (**Table 3**). There were significant differences in crude prevalence rates of depression between MKT and WPA, and between the migrant sites (MKT and WPA) combined and MLA. Explanations for these differences will be explored through regression analyses.

Table 3. First trimester depression status among study participants by site and by migrant status

	All	La	abour migrant s	Refugee camp		
	(n=568)	MKT	WPA	p value	MLA	p value
	(11=308)	(n=163)	(n=155)	MKT vs. WPA	(n=250)	Ref vs. mig
Any depression	146 (25.8)	29 (17.9)	46 (29.7)	0.01	71 (28.4)	0.03
Major depression	9 (1.6)	0 (0)	2 (1.3)		7 (2.8)	
Minor depression	37 (6.5)	6 (3.7)	19 (12.3)		12 (4.8)	
Depression NOS	100 (17.6)	23 (14.2)	25 (16.1)		52 (20.8)	
Negative	421 (74.2)	133 (82.1)	109 (70.3)		179 (71.6)	

STRENGTHS AND LIMITATIONS

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To our knowledge, this is the first prospective study of perinatal depression among migrant women in a resource-constrained setting. The active screening for depression will inform the early detection and treatment of this condition, enabling affected women to be supported and appropriate interventions to be developed. An improved understanding of the prevalence and risk factors of depression is a cornerstone to addressing the disease burden. Mental disorders are a neglected field in this low-income settings, and the small number of previous studies have focussed on specific subgroups including refugee children (28), Burmese political dissidents living in Bangkok (29), labour migrants workers in Mae Sot (30), and Karenni refugees in northern Thailand (31). None have included pregnant or post-partum women. To our knowledge, this is also the first study to include both labour migrants and refugees, enabling direct comparison between these two distinct subgroups of the migrant population. As well as allowing the progression of depression through pregnancy and the post-partum period to be assessed, a significant strength of our cohort design is the collection of data on an extensive array of potential risk and associated factors including demographic, social, medical, obstetric and infant factors. Overall, our study contributes to the under-researched field of migrant mental health from LMIC settings (10, 28).

A further strength of our study is that while most studies of mental disorders use screening tools to make mental state assessments, we used a diagnostic interview tool (10). Interviews were conducted by local healthcare staff who are themselves part of the local community. This enabled trust to be established with patients, and ensured high levels of cultural sensitivity. The fact that over 90% of women in this area attend ANC, coupled with our high response rate, means that our sample is representative of the general migrant population (26). The inclusion of the category of Depression NOS sheds light on an under-reported group of women who experience symptoms of depression that are clinically significant but do not quite meet the criteria for major or minor depression. In order to increase comparability to findings from other settings, our main statistical analyses will be limited to the more commonly reported categories of minor and major depression. However, we will also conduct additional analyses to explore the effects of including the NOS group.

There are also a number of limitations to our study. The absence of mental health expertise in our setting meant that it was not possible to obtain specialist psychiatry input (32, 33). However, by providing experienced local healthcare workers with training in conducting interviews and counselling skills we maximised accuracy as much as possible. Furthermore, in a resource-constrained setting it is more appropriate in the long-term for common mental disorders such as depression to be identified and managed by trained local workers, as specialist mental health

professionals are rarely available. By training frontline healthcare staff to conduct these assessments and provide counselling, we ensured that our study promoted local capacity-building, ownership, scalability and sustainability (34).

A further limitation is that face-to-face administration of interviews may have resulted in a social desirability bias and a lower willingness to disclose sensitive information (35). Given the sensitive nature of many of the issues discussed, including depression, suicidal ideation and behaviour, intimate partner violence and trauma history, participants may have felt uncomfortable discussing these and under-reported relevant experiences, especially during a vulnerable period such as pregnancy. However there is a strong oral tradition among the local population, and informal discussions are common and well-accepted (36). We also believe that the sensitivity and local knowledge of the study staff helped to ensure that participants felt comfortable disclosing personal information.

The repeated administration of the SCID may have affected how women responded. We saw no evidence of questionnaire fatigue, perhaps because women in our setting attend clinic on a fortnightly basis through much of their pregnancy, and thus completing the SCID once per trimester was not perceived as burdensome. However, the repeated SCID interviews may have had a therapeutic effect by enabling participants an opportunity to talk and share any worries. This possibility will be taken into account in the interpretation of prevalence of depression after the baseline assessment.

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Infants' neurodevelopmental outcomes will need to be interpreted with caution as assessments within the first year of life may not be sensitive enough to identify subtle differences between infants. Ideally, the cohort of infants would be followed-up longer-term. Nevertheless it may be possible by twelve months to see trends in the progression of global development. The use of a more widely-used tool such as the Bayley Scales would have been preferable. However, staffing and resource constraints, the length of the full Bayley test and a number of test items being difficult to convey in the local cultural context meant this was not possible (18, 19). The Shoklo Developmental Test has been used extensively in our setting and its strong correlation with the Griffiths Developmental Scale – a standardised neurodevelopmental assessment tool – gives confidence to the results (18, 19). Should further follow-up become possible, it would be important to consider a wider range of validated instruments to test child outcomes.

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CONCLUSION

Addressing perinatal depression among migrant communities in LMIC is necessary to promote maternal mental health and address key sustainable development goals including ensuring good health and wellbeing, establishing gender equality and reducing global inequalities both within and among countries. Establishing the prevalence and risk factors for perinatal depression among migrant women on the Thai-Myanmar border will enable the burden of disease to be quantified, and earlier, more effective identification and management of affected women. We expect that observations and recommendations arising from this study will be of importance and relevance to other LMIC settings.

COLLABORATION

The data are not available freely. However, we welcome specific and detailed proposals for collaboration. Enquiries and requests for further information should be made to gracia.fellmeth@dph.ox.ac.uk.

FUNDING DECLARATION

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CONTRIBUTOR STATEMENT

Conceptualisation of the study: GF, RM, VC, EP, MF, RF, PC, FN

Data curation: MMO, YP, MP, NKW, OM, GF, VC, RM

Analysis: GF, RM, EP, VC
Writing: All authors

COMPETING INTERESTS

All authors declare no conflicts of interest.

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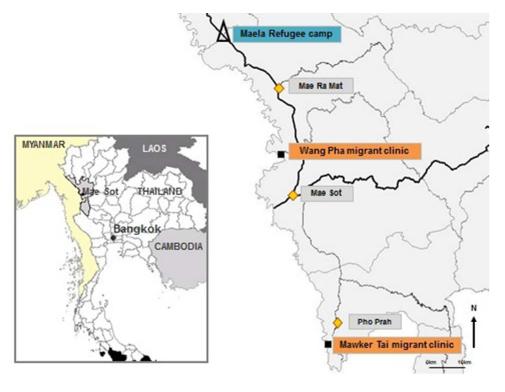


Figure 1. Map of study area showing refugee (Δ) and migrant clinics (\blacksquare) (Credit: Dr Verena Carrara, SMRU) 127x95mm (96 x 96 DPI)

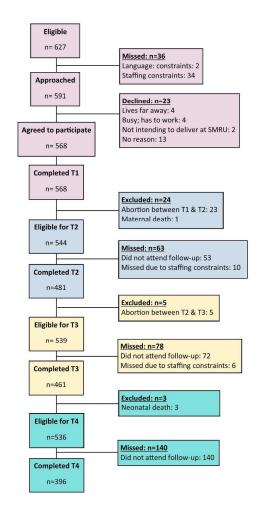


Figure 2. Flow of participants 209x297mm (300 x 300 DPI)

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cohort studies

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any pre-specified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5-6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4-5, 6-7
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	5
		(b) For matched studies, give matching criteria and number of exposed and unexposed	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-6
Data sources/	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe	5-6
measurement		comparability of assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	7 (QA)
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	N/A for cohort profile
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	N/A for cohort profile
		(b) Describe any methods used to examine subgroups and interactions	N/A for cohort profile
		(c) Explain how missing data were addressed	N/A for cohort profile

		(d) If applicable, explain how loss to follow-up was addressed	N/A for cohort profile
		(e) Describe any sensitivity analyses	N/A for cohort profile
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8, figure 2
		(b) Give reasons for non-participation at each stage	8, figure 2
		(c) Consider use of a flow diagram	Figure 2
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8, table 2
		(b) Indicate number of participants with missing data for each variable of interest	Table 2
		(c) Summarise follow-up time (eg, average and total amount)	N/A as not complete Planned follow-up time stated on page
			5
Outcome data	15*	Report numbers of outcome events or summary measures over time	9, table 3 (baseline results)
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N/A (cohort profile, no full results yet)
		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	N/A (results not available yet)
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10-11
Generalisability	21	Discuss the generalisability (external validity) of the study results	11

Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on	12
		which the present article is based	

^{*}Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.