

ORIGINAL ARTICLE

Belief About Medicine Use Among Pregnant and Breastfeeding Women in Malaysia: Translation and Validation of Pregnancy-specific Statements (PSS) and Breastfeeding-specific Statements (BSS) Tools

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ABSTRACT

Introduction: Medication use among pregnant and breastfeeding women is common. The willingness to take medications may be influenced by the individuals' beliefs towards medication use. Pregnancy-Specific Statements (PSS) and Breastfeeding-Specific Statements (BSS) were suggested as tools to assess pregnant and breastfeeding women's beliefs on this matter. This study aims to adapt, translate and validate these tools in Malay version for the Malaysian population. **Methods:** Phase 1 involved the development and translation of study instruments, and Phase 2 involved a pilot study. The questionnaires comprise four sections: 1) Section A comprising demographics information using closed-ended and open-ended questions; 2) Section B: BMQ-General; 3) Section C: BMQ-PSS; and 4) Section D: BMQ-BSS using Likert scale questions. A reliability test was conducted on sections C and D items. **Results:** Two survey tools, BMQ-PSS and BMQ-BSS, had undergone adaptation and translation into the Malay language. BMQ-PSS had a good internal consistency and reached acceptable reliability. Cronbach's alpha reported for BMQ-PSS (P1-P9) was 0.644. However, BMQ-BSS only achieved acceptable reliability with the deletion of two items from the questionnaires (B2 and B3). The Cronbach's alpha reported for BMQ-BSS (B1-B7) was 0.415 and with deletion of B2 and B3 resulted in an alpha value of 0.696. **Conclusion:** BMQ-PSS was shown to have good reliability while BMQ-BSS may require modifications before it can be used for the public. Further face and content validation steps can be performed using a bigger sample size before the tools can be used in a large-scale study.

Keywords: Belief about medicine; Pregnancy; Breastfeeding; Drug use; BMQ

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INTRODUCTION

Medication use during pregnancy is inevitable in some cases, and even for those without chronic diseases, such as to treat acute conditions like nausea and headaches. Studies conducted in various countries report that between 54.4% and 90% of pregnant women consume medication, with 27% to 93% being prescribed at least one drug (excluding vitamins and minerals) (1–5). One multinational study found that 81.2% of pregnant women used at least one prescribed or over-the-counter (OTC) medication at any time during pregnancy (3), while another reported that almost 90% of pregnant women in the United States (US) consume at least one medication (6). The prevalence of prescribed medication use during pregnancy is reported to be as high as 89.9% in France (4) and 81.4% in Malaysia (5), where drug safety information is limited.

Having a healthy child is the utmost priority for a pregnant woman. Therefore, despite some of them needing pharmacological treatment to maintain their health condition, they are usually concerned with the potential harm of the medications to the fetus. The choice of seeking medical help and action of taking medication is highly dependent on the individuals' belief about medicine use (7–9). The negative belief regarding the use of medicine during pregnancy suggests that pregnant women perceive the potential risks from medicine use to be greater than the potential benefits. Several studies reported that most pregnant women overestimate the baseline teratogenic risks of pharmacotherapy during pregnancy (7–11). Risk perception among pregnant women has become one of the clinical challenges, especially for pregnant women with chronic conditions, since neglecting medication intake may also pose a risk to maternal health and fetal well-being (11–14).

A systematic review by Saha et al. found that medication is commonly used among postpartum women but due to limitations of the study, the prevalence of medication

use in postpartum women in different countries is not comparable (15). The study also reported that medication use among breastfeeding mothers was associated with a lower initiation and duration of breastfeeding (15). However, limited studies were being conducted among pregnant and breastfeeding mothers in Malaysia to determine their beliefs about medicine use. One particular study among Malaysian pregnant women was conducted by Alani et. al., which found that over fifty percent of the participants held negative beliefs regarding medication use during pregnancy (5). However, it is important to note that the tool utilized in this study was borrowed from a different population and may not have been validated for our specific context. This underscores the necessity for a validated measurement tool tailored to our own population’s perspectives. The absence of a standardized measurement tool makes it challenging to accurately gauge the beliefs of pregnant women concerning the use of medication. Due to this knowledge gap, healthcare providers may not be able to understand the concerns and are unable to provide counselling sessions tailored to their concerns.

Understanding the need for more information regarding the belief about medicine use among pregnant and breastfeeding women, the objectives of this study are: 1) to develop, translate, and validate beliefs about medicine use instruments for pregnant women (BMQ-Pregnancy Specific Statements) in Malay version, 2) to develop, translate, and validate beliefs about medicine use instruments for breastfeeding women (BMQ-Breastfeeding Specific Statements) in Malay version and 3) to perform pilot study and internal consistency reliability test for these tools.

MATERIALS AND METHODS

Study Design

This pilot study was conducted in two phases: Phase 1 involved the development and translation of study instruments to assess belief about medicine use among pregnant and breastfeeding women, and Phase 2 involved face validation by expert panels and content validation via a pilot study (Figure 1). This study was a cross-sectional study using an anonymous self-completed online questionnaire via Google Forms.

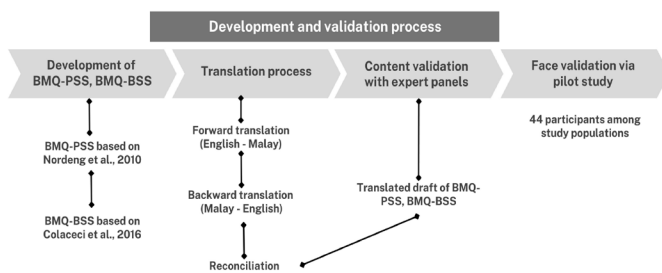


Figure 1 : Flow chart of the study.

Study population and sampling procedure

The study population consisted of women who were pregnant at any gestational age and/or breastfeeding in Malaysia. We included all pregnant and/or breastfeeding women who were willing to participate, at least 18 years old, and literate in English and/or Malay. Respondents who were breastfeeding for more than 24 months were excluded from the study. The sample size required for the large-scale study was calculated using Raosoft sample size calculator. With the expected population of 20,000 pregnant women and breastfeeding women in Malaysia, with 95% confidence interval and 5% margin error, the minimum recommended size of the study population was 377 (16). Referring to Cocks and Torgerson’s approach, a minimum of 9% of the primary trial’s sample size will be allocated to establish the sample size for this pilot study. This allocation enables the construction of a one-sided 80% confidence interval that can effectively rule out a clinically significant difference (17). Therefore, the minimum sample size needed for the pilot study was 34 women.

Study tool

The questionnaires comprise four sections: 1) Section A: Socio-demographics of participants, 2) Section B: Belief about Medicines Questionnaire- General (BMQ-General), 3) Section C: Pregnancy-Specific Statements (PSS), and 4) Section D: Breastfeeding Specific Statements (BSS). Section A included 23 questions related to socio-demographic parameters (including age, ethnicity, highest education level, occupation, marital status), parameters related to their pregnancy or breastfeeding status (i.e. gestational age, duration of breastfeeding), as well as medical and medication history.

Section B (BMQ-General) is used to determine the patients’ beliefs about the use of medicine as a class of treatment for any condition in general. BMQ was first developed by Horne et al. which comprised two sections with a total of 18 questions. The first section was the 10-item BMQ-Specific to evaluate the perception of drugs prescribed to the patients and the second section was the 8-item BMQ-General to evaluate drug perception in general (18). The 8-item BMQ-General was made up of the General-Harm and the General-Overuse, in which only these 8-items were included in this study. The General-Harm assessed the beliefs about the harmfulness of medicines while the General-Overuse addressed the concept of over-prescription of medicines by doctors who placed too much trust in medicines (18). These items were scored on a 5-points Likert scale (1: Strongly agree, 2: Agree, 3: Uncertain, 4: Disagree, 5: Strongly disagree). A higher score suggested a positive belief towards medication and possessed a lesser concern for overuse and harmfulness of the medications. The other components of the BMQ will be irrelevant in this study since the items are

constructed to be more specific in evaluating beliefs about using medication for a certain particular disease.

Tan et al. conducted a study to validate BMQ questionnaires in the Malay version among hypertensive patients in Malaysia and written permission was granted from Tan et al. for the adoption of the Malay versions of BMQ-General for this study. The internal consistency of the components of BMQ General-Overuse and BMQ General-Harm was measured using Cronbach alpha values, which were reported as 0.624 and 0.756, respectively (19).

The translation and validation process involved two survey tools, which were Pregnancy-Specific Statements (BMQ-PSS) for pregnant women and BMQ-Breastfeeding Specific Statements (BMQ-BSS) for breastfeeding women. BMQ-PSS were specifically developed to establish women's perceptions about medication use during pregnancy by Nordeng et al. (20). The PSS consisted of nine items which were comprised of statements to evaluate concerns and benefits medication may possess to unborn babies and mothers as well as the usage of natural remedies among pregnant women. The items were scored on a 5-points Likert scale (1: Strongly agree, 2: Agree, 3: Uncertain, 4: Disagree, 5: Strongly disagree). A higher score suggested a positive belief in medication use during pregnancy. To the best of our knowledge, the PSS had not yet been translated into Malay and validated. Written permission for the adaptation of the PSS was granted from Nordeng et al. for the translation of this tool.

BMQ-BSS was first developed by Colaceci et al. to measure the perception regarding medication used and natural product consumption while breastfeeding as well as breastfeeding management (21). Out of 14 questions reported by these authors, only the first seven questions were relevant to the objectives of this study and therefore included in the development of the questionnaires. Thus, they were categorized as 'Breastfeeding-Specific Statements' for this study. The items were scored on a 5-points Likert scale (1: Strongly agree, 2: Agree, 3: Uncertain, 4: Disagree, 5: Strongly disagree). A higher score suggested a positive belief in medication use during pregnancy. Written permission was granted from Colaceci et al. to translate and validate the BSS for this study. The same translation procedure as Section C was performed before continuing with the pilot study.

Forward and backward translation

BMQ-PSS and BMQ-BSS were translated into the Malay language by two researchers who are native speakers of the Malay language and are fluent in English. A complete set of questionnaires comprised of both tools in Malay language was back-translated to English by a certified translator. Reconciliation of

the new set of back translation questionnaires was compared with the original English version of the questionnaires to ensure the accuracy of the Malay translation.

Validity and reliability measurement

A complete set of questionnaires was sent for content and face validation by two experts; one is a clinical pharmacy researcher who has experience in questionnaire development, and another is an obstetrics and gynaecology consultant. An emphasis was given on the terms and wordings used in the questions instead of the questions' relevancy. This is because the tool was already been used and adopted in several populations (5,20,22). Improvements after receiving feedback from experts include the use of several terms in layman's terms and their respective translations of Malay terms such as "over-the-counter medications" and "natural remedies".

A reliability test was performed in a pilot study involving a subset of the study population. Cronbach's alpha was used as a measure of internal consistency reliability, which assesses the extent to which items in a questionnaire consistently measure the same underlying construct. The questionnaire was developed using Google Forms and distributed using an official Facebook page created for this study. The survey link was posted on this page periodically, and participants were also asked to share the link with their connections. The informed consent was obtained before the participants proceeded to the survey.

Statistical analysis

Data were analyzed using SPSS version 27.0 (IBM Corporation, Armonk, NY, USA). A reliability test was run on items in both tools respectively to calculate Cronbach's alpha coefficient, which determines the internal consistency. The questionnaire items with Cronbach's alpha value >0.60 were selected since the value between 0.6 and 0.8 was considered a good result and acceptable (23,24).

Ethical approval

Ethical approval for the commencement of the study was granted by the Human Research Ethics Committee (HREC) Universiti Sains Malaysia with the (USM/JEPeM/21080575).

RESULTS

Participant Characteristics

From a total of 44 participants, the mean age of the participants was 33.25 which was within the range of 28-41 years old. Almost all of the participants were married. A total of 32 respondents (70.5%) of the participants were currently breastfeeding while only 13 (27.3%) of them were pregnant. Details on the general characteristics of the participants are

Table I : General characteristics of participants (N=44)

Characteristics	Respondents, n (%)
Age (mean years ± S.D.)	33.25±3.9
Race	
Malay	43(97.7)
Chinese	1(2.3)
Highest education level	
SPM	3(6.8)
STPM/Matriculation college/ Pre-university	1(2.3)
Bachelor’s degree	20(45.5)
Postgraduate degree	20(45.5)
Previously study or currently studying in healthcare	
Yes	10(22.7)
No	34(77.3)
Currently working	
Yes	29(65.9)
No	15 (34.1)
Working in healthcare	
Yes	9(20.5)
No	25(56.8)
Not relevant	10(22.7)
Current marital status	
Married	43(97.7)
Divorced/ separated	1(2.3)
Husband or partner have a healthcare-related background (study and/or work in healthcare sector)	
Yes	7(15.9)
No	36(81.8)
Not related	1(2.3)

available in Table I.

Characteristics of the pregnant participants are described in Table II. The mean pregnancy week was 23.69 weeks with a range of seven to 37 weeks. Less than half of the participants were pregnant with their first child. Half of the participants claimed to not have any health problems while several participants had mentioned having diabetes. Only a minority of the participants claimed to receive medication prescribed by the doctor for their health condition. Some of the medications prescribed by the doctor were aspirin, metformin, and calcium carbonate. Almost all participants claimed to receive vitamins prescribed by

Table II : Medical and medication history of pregnant participants (N=13)

Characteristics	Respondents, n (%)
Pregnancy (mean weeks ± S.D.)	23.69 ± 9.8
Number of children previously given birth to	
0 - 1	11 (84.6)
2 - 4	2 (15.4)
Have existing medical problems	5 (38.5)
Taking prescribed medications	3 (23.1)
Being prescribed vitamins by the doctor	12(92.3)
Vitamins prescribed by the doctor*	
Folic acid	9(69.2)
Multivitamin	4(30.8)
Vitamin B complex	5(38.5)
Vitamin D	2(15.4)
Minerals	3(23.1)
Iron supplement	4(30.8)
Omega 3 and Omega 6	1(7.7)
Taking vitamins as instructed**	10(76.9)
Have taken additional vitamin/minerals beside from the vitamin given by doctor (as stated above)	6(46.2)
Additional vitamins/minerals taken*	
Folic acid	2(15.4)
Calcium	1(7.7)
Multivitamin	3(23.1)
Vitamin E	1(7.7)
Vitamin B complex	2(15.4)
Vitamin D	1(7.7)
Iron supplement	2(15.4)
Omega 3 and Omega 6	2(15.4)
Initiation of folic acid consumption	
First trimester	12(92.3)
Second Trimester	1(7.7)

* one participant may have more than one answer; % valid percent

** the question proceeded only if the participant chose ‘yes’ on the previous question

their doctors for their health conditions stated above and/or for pregnancy. Folic acid was prescribed to more than half of the participants by their doctor and the majority of the participants agreed had taken the vitamins as instructed. Less than half of the participants had taken additional vitamins besides the vitamin given by the doctor. Most of the participants reported had been taking folic acid starting the first trimester. None of the participants claimed to be taking herbal products during pregnancy. Meanwhile, only one

participant claimed to take an over-the-counter antacid medication, which she had good compliance toward it.

Validation of BMQ-PSS

Table III presented the results from PSS component of the questionnaires. Reliability analysis was carried out on the perceived task values scale comprising nine items from BMQ-PSS (P1-P9). Scale means from each item ranged between 1.85 + 1.14 and 3.92 + 1.04. Cronbach's alpha reported was 0.644 which proved that the questionnaire had reached acceptable reliability. Most items were presented as reliable for retention, which causes a decrease in the alpha if deleted. However, there were two exceptions to this which include the deletion of items P3 (*'I have a higher threshold for using medicines when I'm pregnant than when I'm not pregnant. As much as possible, I would refrain from using it'*) and P9 (*'Pregnant women should not use natural remedies without the consent of a doctor'*), which would result in an increase of the alpha to 0.645 and 0.648 respectively. As such, the removal of these items may be considered in a large-scale study.

Of a total of 32 participants who were currently breastfeeding, almost half of them had just started breastfeeding in less than 6 months (Table IV). From a total of four participants who had health problems, only one of them had received medication prescribed by a doctor for her health problem, which was a salbutamol sulfate inhaler. Only three participants

claimed to be taking over-the-counter medications including paracetamol and cetirizine. Some of the participants took supplementary vitamins including vitamin B complex and vitamin C. A quarter (25%) of participants reported taking milk booster products that include several local products and some of them also consumed pennywort powder supplement, dates milk, and home remedies as milk booster. The majority of the participants did not take any herbal products during labour while two of them had taken virgin coconut oil during labour. Only one participant claimed to have taken herbal remedies during breastfeeding, but stopped it after one month of use.

Validation of BMQ-BSS

Reliability analysis was carried out on the perceived task values scale comprising seven items from BMQ-BSS (B1-B7) (Table V). The mean score of the items ranged between 1.88 + 1.10 and 3.56 + 0.95. Cronbach's alpha reported was 0.415 which indicates the questionnaire had not yet reached acceptable reliability. Hence, item B2 was removed which resulted in an increase of the alpha to $\alpha=0.572$. This Cronbach's alpha has not yet reached acceptable reliability so item B3 was further removed to increase the alpha value. The resulting Cronbach's alpha was 0.696 which showed the questionnaire had reached acceptable reliability. According to this value, most items presented are worthy of retention, which causes a decrease of the alpha if deleted except for item B1 which may result in

Table III : The internal consistency of the items in the BMQ-PSS (N= 13)

Item	Questions	Mean score \pm s.d	Scale mean if item deleted	Scale variance if item deleted	Cronbach's alpha if item deleted
P1	All medicines can be harmful for the fetus.	3.92 \pm 1.04	21.69	25.90	0.582
P2	When I am ill, I would have taken a medicine if I am not pregnant. However, if I am pregnant, I believe it is better for the fetus that I refrain from using medicine.	3.15 \pm 1.35	22.46	24.60	0.587
P3	I have a higher threshold for using medicines when I'm pregnant than when I'm not pregnant. As much as possible, I would refrain from using it.	2.46 \pm 1.27	23.15	27.98	0.645
P4	Thanks to treatment with medicines during pregnancy, lives of many unborn children are saved each year.	2.46 \pm 1.20	23.15	26.64	0.613
P5	It is better for the fetus that I use medicines and get well than to have an untreated illness during pregnancy.	1.85 \pm 1.14	23.77	27.53	0.625
P6	Doctors prescribe too many medicines to pregnant women.	3.46 \pm 1.27	22.15	26.14	0.610
P7	Natural remedies can generally be used by pregnant women.	3.00 \pm 1.29	22.62	26.59	0.622
P8	Pregnant women should preferably use natural remedies during pregnancy.	3.15 \pm 1.14	22.46	26.94	0.614
P9	Pregnant women should not use natural remedies without the consent of a doctor.	2.15 \pm 1.41	23.46	27.27	0.648

Table IV : Medical and medication history of breastfeeding participants (N=32)

Characteristics	Respondents, n (%)
Duration started breastfeeding	
Less than 6 months	14(43.8)
6-12 months	7(21.9)
13-18 months	4(12.5)
19-24 months	4(12.5)
More than 24 months	3(9.4)
Number of children previously given birth to	
0 - 1	10 (31.3)
2 - 3	18(56.3)
4 - 6	4(12.5)
Have existing medical problems	4 (12.5)
Taking prescribed medications	1 (12.5)
Vitamins prescribed by doctor*	
Folic acid	2(6.3)
Iron supplement	2(6.3)
Have taken additional vitamin/minerals apart from the vitamin given by the doctor (as stated above)	13(40.6)
Additional vitamins/minerals taken*	
Folic acid	3(9.4)
Vitamin B complex	4(12.5)
Vitamin C	4(12.5)
Multivitamin	2(6.3)
Iron supplement	3(9.4)
Omega 3 and Omega 6	3(9.4)
Calcium	2(6.3)
Initiation of folic acid consumption	
Before pregnancy	6(18.8)
First trimester	13(40.6)
Third trimester	1(3.1)
Did not consume	12(37.5)
Have taken any herbal products during pregnancy	4(12.5)
Currently taking any over-the-counter medications	3(9.4)
Currently taking or have consumed any milk booster products or products that claimed to increase breast-milk during breastfeeding	8(25.0)
Have taken any herbal products/remedies during labour	2(6.3)
Have taken any herbal remedies during breastfeeding	1(3.1)

* one participant may have more than one answer; % valid percent

** the question proceeded only if the participant chose 'yes' on the previous question

an increase of the alpha to $\alpha=0.816$ if deleted. As such, removal of these items can be considered but further removal of item B1 may result in too few items left in the questionnaire.

DISCUSSION

The study described the adaptation, translation and validation of the English version of the BMQ tools for pregnant (BMQ-PSS) and breastfeeding women (BMQ-BSS). The translation process for PSS and BSS was smooth except for items P2 and P3 from the PSS section. The terms for natural products, herbal remedies, and natural remedies may possess a similar meaning in the English language but may have a different meaning when translated into the Malay language. Depending on the respondents' education status, these terms may be understood differently. Hence, the term "ubat-ubatan semula jadi" was used to ensure the accuracy of the translation due to cultural adaptation.

Data were obtained from 44 either pregnant or breastfeeding women or both. Since the questionnaires were distributed online through social media, it was quite difficult to achieve a higher number of respondents. Hence, it may also result in bias of the educational level, in which this study involved a majority of the respondents with bachelor's degrees and postgraduate degrees. Similarly, the residential state of the participants was randomly distributed throughout Malaysia since the questionnaire was distributed online and accessible equally to all states.

Generally, the pregnant participants were healthy and only several of them had health medical problems, which related to a small number of them receiving prescribed medications. The majority of the participants were prescribed folic acid and some of them also took it as an additional vitamin if it was not prescribed by the doctor. Folic acid is exceptionally important during early pregnancy when the development of the baby's brain and spinal cord is taking place. Therefore, folic acid is proven to help prevent major birth defects such as neural tube defects and spina bifida (25,26).

The reliability test for PSS concluded a reliable internal consistency with Cronbach's alpha reported was 0.644. The deletion of items P3 and P9 gave slightly higher alpha values. Item P3 states 'I have a higher threshold for using medicines when I'm pregnant than when I'm not pregnant. As much as possible, I would refrain from using it'. This statement bears almost similar meaning to item P2, which states 'When I am ill, I would have taken a medicine if I am not pregnant. However, if I am pregnant, I believe it is better for the fetus that I refrain from using medicine'. Pregnant women in Belgium and the study population believed that they had a higher threshold for using medication during pregnancy, particularly because they tend to be

Table V : The internal consistency of the items in the BMQ-BSS (N=32)

Item	Questions	Mean score \pm s.d	Scale mean if item deleted	Scale variance if item deleted	Cronbach's alpha if item deleted
B1	Many medicines can be used during breastfeeding.	2.03 \pm 0.93	17.56	12.25	0.540
B2	If a breastfeeding mother has pain, it is better that she endures it rather than taking medicines	3.56 \pm 0.95	171.03	2.81	0.5712
B3	If you are taking medicines that could harm your baby, you should temporarily withhold breastfeeding	1.88 \pm 1.10	18.72	11.69	0.544
B4	If you are taking medicines that could harm your baby, you should definitely discontinue breastfeeding	2.28 \pm 1.33	16.88	6.82	0.171
B5	Breastfeeding can be resumed even several weeks after taking medicines	2.63 \pm 0.98	17.97	7.77	0.173
B6	During breastfeeding, natural remedies are more effective than medicines	3.22 \pm 0.87	17.81	8.54	0.238
B7	During breastfeeding, natural remedies are safer than medicines	3.00 \pm 1.08	17.59	6.70	0.046

cautious and worry about the risks of using drugs during pregnancy (11,20). However, in conditions where drug treatment is necessary, this perception may cause more negative outcomes to their health.

Item P9 states 'Pregnant women should not use natural remedies without the consent of a doctor'. This statement might be reflective of the nature of patient-physician relationship in the population. Many women were probably sceptical to disclose their consumption of herbal and complementary medicine towards physicians or other healthcare professionals, for fear to be judged and misinterpreted. Several studies performed among pregnant women in Malaysia had reported a high prevalence of use of herbal preparations for various reasons, which was between 51.4 to 89.2% among pregnant women (27–29) and between 66.2 to 85.5% among post-partum women (30,31). In view of this high prevalence of use of traditional and herbal medicine in this country, retaining this item might provide an insight on the perception of pregnant women towards the use of traditional medicine and natural remedies.

The reliability of PSS conducted by Tefera et al reported a higher Cronbach's alpha value of 0.829 (11). The reason for the variation between these two alpha values may be due to the sample size of this study being too small for pregnant women which were only 13 participants. Meanwhile, the study with a higher alpha value involved 50 participants during the pretest phase (11).

Similar to pregnant participants, the breastfeeding participants were generally healthy; only one participant had received a prescribed medication and only a few of them received prescribed vitamins. According

to the results, the additional vitamins taken by the breastfeeding participants were vitamin B complex and vitamin C. The removal of items B2 and B3 leads to a higher Cronbach's alpha value, in which item B2 states 'If a breastfeeding mother has pain, it is better that she endures it rather than taking medicines', while item B3 states 'If you are taking medicines that could harm your baby, you should temporarily withhold breastfeeding'. The concerns about the harmful effects of medication on infants contribute to the early cessation of breastfeeding (32). This is because of a lack of information and evidence-based sources to guide health care providers in drug selection for patients on breastfeeding. Similar to pregnant women, breastfeeding women and their infants are also rarely included in clinical trials for medication safety. However, most of the frequently used medications are reported to be safe during breastfeeding since only minimal transmission of maternal medications is absorbed in breast milk (15).

The results from this pilot study might indicate a positive belief among breastfeeding women toward the use of medication during this period. However, many were still confused about the safety of using medications while breastfeeding. It may be related to the fact that most of the participants did not have chronic diseases, thus they did not require an ongoing long treatment of medications.

The initial Chronbach's alpha value did not reach acceptable reliability, probably because the questionnaire was not yet validated previously. This section of questionnaires should be re-evaluated by the experts before reusing them for a larger scale study. Additional tests are required including the measures of item-level content validity index (I-CVI), scale-level content validity index based on the average method

(S-CVI/Ave) and scale-level content validity index based on the universal agreement method (S-CVI/UA) (33). Meanwhile, face validity may be evaluated using Cohen's Kappa Index (CKI) (34).

This pilot study has several limitations. Notably, a majority of the participants possess a high level of education, possibly inducing a selection bias favouring individuals with a higher education level as compared to the general population. Additionally, the cohort of pregnant participants is comparatively outnumbered by breastfeeding women. Increasing the sample size within the pilot study for each subgroup of interest is preferable. This would facilitate a more precise evaluation of the reliability of the assessed items and scales, thereby enhancing the validity of the questionnaire tools.

CONCLUSION

Two survey tools to evaluate the beliefs about medicine use, BMQ-PSS and BMQ-BSS, were assessed among a population of pregnant and breastfeeding women. However, given the limitations in terms of the small sample size and the limited variability of the characteristics of the study participants, content and face validation methods can be performed using a larger-scale study with a bigger sample size. These tools hold significant potential to assist healthcare providers in assessing the beliefs of these populations regarding the advantages and risks associated with medication use. Furthermore, they offer an improved method for involving these populations in the decision-making process concerning pharmacotherapy plans that are pertinent to their specific conditions.

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REFERENCES

1. Daw JR, Hanley GE, Greyson DL, Morgan SG. Prescription drug use during pregnancy in developed countries: a systematic review. *Pharmacoepidemiol Drug Saf.* 2011;20:895–902.
2. Colaceci S, Giusti A, De Angelis A, Della Barba MI, De Vincenti AY, Vellone E, et al. Medications, "Natural" Products, and Pharmacovigilance during Breastfeeding: A Mixed-Methods Study on Womens Opinions. *J Hum Lact.* 2016;32(2):324–32.
3. Lupattelli A, Picinardi M, Einarson A, Nordeng H. Health literacy and its association with perception of teratogenic risks and health behavior during pregnancy. *Patient Educ Couns [Internet].*

- 2014;96(2):171–8. Available from: <http://dx.doi.org/10.1016/j.pec.2014.04.014>
4. Bérard A, Abbas-Chorfa F, Kassai B, Vial T, Nguyen KA, Sheehy O, et al. The French pregnancy cohort: Medication use during pregnancy in the French population. *PLoS One.* 2019;14(7):1–18.
5. Alani AHDA, Hassan BAR, Suhaimi AM, Mohammed AH. Use, awareness, knowledge and beliefs of medication during pregnancy in Malaysia. *Osong Public Heal Res Perspect.* 2021;11(6):373–9.
6. Mitchell AA, Gilboa SM, Werler MM, Kelley KE, Louik C, Hernández-Díaz S. Medication use during pregnancy, with particular focus on prescription drugs: 1976-2008. *Am J Obstet Gynecol.* 2011;205(1):51.e1-51.e8.
7. Nyholm RS, Andersen JT, Vermehren C, Kaae S. Perceptions of medicine use among pregnant women: an interview-based study. *Int J Clin Pharm [Internet].* 2019;41(4):1021–30. Available from: <https://doi.org/10.1007/s11096-019-00840-4>
8. Wolgast E, Lindh-Åstrand L, Lilliecreutz C. Women's perceptions of medication use during pregnancy and breastfeeding—A Swedish cross-sectional questionnaire study. *Acta Obstet Gynecol Scand.* 2019;98(7):856–64.
9. Widnes SF, Schjøtt J. Risk perception regarding drug use in pregnancy. *Am J Obstet Gynecol [Internet].* 2017;216(4):375–8. Available from: <http://dx.doi.org/10.1016/j.ajog.2016.12.007>
10. Walfisch A, Sermer C, Matok I, Einarson A, Koren G. Perception of Teratogenic Risk and the Rated Likelihood of Pregnancy Termination: Association with Maternal Depression. *Can J Psychiatry.* 2011;56(12):761–7.
11. Tefera YG, Gebresillassie BM, Getnet Mersha A, Belachew SA. Beliefs and Risk Awareness on Medications Among Pregnant Women Attending the Antenatal Care Unit in Ethiopia University Hospital. *Overestimating the Risks Is Another Dread.* *Front Public Heal.* 2020 Mar;8:28.
12. Toh S, Li Q, Cheetham TC, Cooper WO, Davis RL, Dublin S, et al. Prevalence and trends in the use of antipsychotic medications during pregnancy in the U.S., 2001-2007: A population-based study of 585,615 deliveries. *Arch Womens Ment Heal.* 2013;16(2):149–57.
13. Juch H, Lupattelli A, Ystrom E, Verheyen S, Nordeng H. Medication adherence among pregnant women with hypothyroidism—missed opportunities to improve reproductive health? A cross-sectional, web-based study. *Patient Educ Couns [Internet].* 2016;99(10):1699–707. Available from: <http://dx.doi.org/10.1016/j.pec.2016.04.006>
14. Yakuwa N, Nakajima K, Koinuma S, Goto M, Suzuki T, Ito N, et al. Perception of pregnant Japanese women regarding the teratogenic risk of medication exposure during pregnancy and the effect of counseling through the Japan drug

- information institute in pregnancy. *Reprod Toxicol*. 2018;Aug(79):66–71.
15. Saha MR, Ryan K, Amir LH. Postpartum women's use of medicines and breastfeeding practices: A systematic review. *Int Breastfeed J*. 2015 Oct;10(1):1–10.
 16. Viechtbauer W, Smits L, Kotz D, Budé L, Spigt M, Serroyen J, et al. A simple formula for the calculation of sample size in pilot studies. *J Clin Epidemiol* [Internet]. 2015;68(11):1375–9. Available from: <http://dx.doi.org/10.1016/j.jclinepi.2015.04.014>
 17. Cocks K, Torgerson DJ. Sample size calculations for pilot randomized trials: A confidence interval approach. *J Clin Epidemiol* [Internet]. 2013;66(2):197–201. Available from: <http://dx.doi.org/10.1016/j.jclinepi.2012.09.002>
 18. Horne R, Weinman J, Hankins M. The beliefs about medicines questionnaire: The development and evaluation of a new method for assessing the cognitive representation of medication. *Psychol Heal*. 1999;14(1):1–24.
 19. Tan CS, Hassali MA, Neoh CF, Saleem F, Horne R. Cultural Adaptation and Linguistic Validation of the Beliefs about Medicines Questionnaire in Malaysia. *Value Heal Reg Issues* [Internet]. 2018;15:161–8. Available from: <http://dx.doi.org/10.1016/j.vhri.2017.12.010>
 20. Nordeng H, Koren G, Einarson A. Pregnant women's beliefs about medications - A study among 866 Norwegian women. *Ann Pharmacother*. 2010;44(9):1478–84.
 21. Colaceci S, Giusti A, De Angelis A, Della Barba MI, De Vincenti AY, Vellone E, et al. Medications, "natural" Products, and Pharmacovigilance during Breastfeeding: A Mixed-Methods Study on Womens Opinions. *J Hum Lact*. 2016 May;32(2):324–32.
 22. Zaki NM, Albarraq AA. Use, attitudes and knowledge of medications among pregnant women: A Saudi study. *Saudi Pharm J*. 2014 Nov;22(5):419–28.
 23. Taan S, Hajjar EL. Statistical Analysis: Internal -Consistency, Reliability and Construct Validity. *Int J Quant Qual Res Methods*. 2018;6(1):27–38.
 24. Janssens W, Wijnen K, Patrick De Pelsmacker, Kenhove P Van. Exploratory Factor Analysis. In: *Marketing Research With SPSS* [Internet]. 1st ed. Essex, England: FT Prentice Hall; 2008. p. 245–78. Available from: <http://www.lavoisier.fr/livre/notice.asp?ouvrage=1377458>
 25. Imbard A, Benoist JF, Blom HJ. Neural Tube Defects, Folic Acid and Methylation. *Int J Environ Res Public Health*. 2013 Sep;10(9):4352–89.
 26. Burke N, Walsh T, Geary M. Antenatal Prevention of Neural Tube Defects. In: Narasimhan KL, editor. *Neural Tube Defects- Role of Folate, Prevention Strategies and Genetics* [Internet]. 1st ed. Croatia: InTeach; 2012. p. 91–8. Available from: <https://www.intechopen.com/books/advanced-biometric-technologies/liveness-detection-in-biometrics>
 27. Yusof J, Mahdy ZA, Noor RM. Use of complementary and alternative medicine in pregnancy and its impact on obstetric outcome. *Complement Ther Clin Pract* [Internet]. 2016;25:155–63. Available from: <http://dx.doi.org/10.1016/j.ctcp.2016.09.005>
 28. Sooi L, Keng SL. Herbal medicines : Malaysian women's knowledge and practice. *Evidence-Based Complement Altern Med*. 2016;2013:438139.
 29. Rahman AA, Sulaiman SA, Ahmad Z, Daud WNW, Hamid AM. Prevalance and pattern of use of herbal medicines during pregnancy in Tumpat District, Kelantan. *Malaysian J Med Sci*. 2008;15(3):40–8.
 30. Ridzuan MH, Ali MF, Tan C-E, Abdul Aziz AF. Traditional and Complementary Medicine Use During Postpartum Period: A Cross-Sectional Analysis at a Rural, Public Maternal and Child Health Clinic in West Malaysia. *Cureus*. 2021;13(6).
 31. Nik Yusof Fuad NF, Ching SM, Awg Dzulkarnain DH, Cheong AT, Zakaria ZA. Complementary alternative medicine use among postpartum mothers in a primary care setting: a cross-sectional study in Malaysia. *BMC Complement Med Ther*. 2020;20(1):197.
 32. McClatchey AK, Shield A, Cheong LH, Ferguson SL, Cooper GM, Kyle GJ. Why does the need for medication become a barrier to breastfeeding? A narrative review. *Women and Birth* [Internet]. 2018;31(5):362–6. Available from: <http://dx.doi.org/10.1016/j.wombi.2017.12.004>
 33. Yusoff MSB. ABC of Content Validation and Content Validity Index Calculation. *Educ Med J*. 2019;11(2):49–54.
 34. Patel N, Desai S. ABC of Face Validity for Questionnaire. *Int J Pharm Sci Rev Res*. 2020;65(1):164–8.