
PUBLIC HEALTH RESEARCH

Development and Validation of a Questionnaire to Predict Intention to Comply to Iron Supplement during Pregnancy

Raudah Abd Rahman¹, Idayu Badilla Idris^{1*}, Zaleha Md Isa¹ and Rahana Abd Rahman²

¹Department of Community Health, Faculty of Medicine, Universiti Kebangsaan Malaysia Medical Centre, Jalan Yaacob Latif, Bandar Tun Razak, 56000 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur, Malaysia.

²Department of Obstetrics and Gynaecology, Faculty of Medicine, Universiti Kebangsaan Malaysia Medical Centre, Jalan Yaacob Latif, Bandar Tun Razak, 56000 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur, Malaysia.

*For reprint and all correspondence: Idayu Badilla Idris, Department of Community Health, Faculty of Medicine, Universiti Kebangsaan Malaysia Medical Centre, Jalan Yaacob Latif, Bandar Tun Razak, 56000 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur, Malaysia.

Email : idayubadilla.idris@gmail.com

ABSTRACT

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Introduction	The World Health Organisation (WHO) has recommended iron supplementation to overcome anaemia in pregnancy. In Malaysia, half of pregnant women with anaemia do not comply to iron supplement. The purpose of this study is to develop, assess psychometric properties (via Exploratory Factor Analysis) and validation (via Confirmatory Factor Analysis) of a questionnaire that evaluates attitude towards adherence to iron supplement based on Theory of Planned Behaviour (TPB).
Methods	Based on the guidelines for construction of the TPB based questionnaire, 18 items were created initially by using the findings from a semi-quantitative survey, literature reviews and experts' opinion. From content validity by 3 experts, 15 items with content validity ratio (CVR) of ≥ 0.99 were retained. From a pilot test for exploratory factor analysis (EFA), total of 12 items were retained, and classified into 3 components and termed as "Attitude", "Subjective Norms" and "Perceived Behaviour Control".
Results	Cronbach Alpha for the 12 items was 0.814, and for each component were 0.844, 0.813 and 0.901 respectively, which indicates acceptable internal consistency. During the Confirmatory Factor Analysis (CFA), a final 10 items were retained.
Conclusions	The construct validity was good where the Fitness Index have achieved the threshold (p-value > 0.05 , RMSEA < 0.08 , CFI > 0.90 and the ChiSq/df ratio < 3.00). The convergent validity and composite reliability were good i.e. Average Variance Extracted (AVE) ≥ 0.50 , and Composite Reliability (CR) ≥ 0.60 respectively. As a conclusion, this newly developed questionnaire was validated and potentially reliable in assessing attitude and predicting adherence to iron supplement among pregnant women specifically in Malaysia.
Keywords	Theory of Planned Behaviour - adherence to iron supplement - questionnaire - development - Exploratory Factor Analysis - Confirmatory Factor Analysis.

Questionnaire to Predict Intention to Comply to Iron Supplement

INTRODUCTION

The World Health Organization (WHO) has recommended pregnant women to take 30-60 mg iron and 400µg folate daily during pregnancy and during postpartum period.¹ Despite the implementation of iron supplementation programme, anaemia in pregnancy is still common in Malaysia. Anaemia affected 32 million of pregnant women worldwide.² Previous studies conducted in several states in Malaysia showed that the prevalence of anaemia in pregnancy was 33% in one of the cities in Selangor,³ 43.6% in a city in Perak⁴ and 57.4% in a rural area in Terengganu.⁵

Poor compliance to iron supplement was found to be the main obstacle to achieve improvement of prevention and control of anaemia in pregnancy,⁶ which is high among pregnant women with anaemia in many developing countries such as in Africa^{7, 8} and in India.⁹ In Malaysia, approximately half of pregnant women did not adhere to daily iron supplement intake.¹⁰

Theory of Planned Behaviour is one of the commonest theories used to assess attitude and to predict individual's intention to perform particular behavior.^{11, 12} Theory of Planned Behaviour is the extension of the Theory of Reasoned Action, by adding perceived behaviour control.¹³ According to the Theory of Planned Behaviour, the intention to change behaviour is determined by attitude, subjective norms and perceived control belief.^{13, 14} The attitude is determined by behavioural belief comprising of favourable or unfavourable beliefs towards the behaviour of interest. Meanwhile, subjective norm is determined by normative belief which is defined as social pressure, perception and action by other people that influence individuals to perform the behaviour. The perceived behavioural control is finally determined by control belief which refers to belief in the ability to perform the behavior.¹¹ In this study, the behaviour of interest is compliance to daily iron supplement.

Forgetfulness and side effects associated with iron supplement such as gastrointestinal upset are the main reasons for non-compliance to iron supplement in pregnant women.^{8, 15} However,

perception on benefit of iron supplement to mother and baby motivates pregnant women to adhere to iron supplement.¹⁵ Exploring attitude on adherence to iron supplement among pregnant women is thus important to ensure the success of programmes for prevention of anaemia among pregnant women.⁶

In a study in China, a questionnaire to evaluate attitude towards iron-fortified soy sauce consumption was developed using both Theory of Planned Behaviour and Health Belief Model.¹⁶ Meanwhile, a study conducted among pregnant women in East Java Indonesia, a questionnaire assessing attitude towards adherence to iron supplement was developed.¹⁷ However, none of questionnaire to evaluate attitude towards adherence to iron supplement among pregnant women was developed in Malaysia before. Therefore, this study will develop and validate a questionnaire based on the Theory of Planned Behaviour to assess attitude towards adherence to iron supplement as well as to predict the intention to comply with daily iron supplements among pregnant women with anaemia in Malaysia.

METHODOLOGY

Development of questionnaire items

The development of the items in this questionnaire was based on several published articles on guidelines for constructing TPB questionnaire.^{18, 19} Development of the questionnaire was started with a semi-quantitative survey using an open-ended questionnaire (Table 1), that was distributed to ten pregnant women to elicit their behavioural belief, normative belief and control belief on adherence to iron supplement.¹¹

The questions for behavioural belief were on advantages and disadvantages of taking daily iron tablet, and the questions for normative belief were based on perception and action of other people surrounding them who would encourage or discourage these pregnant women to take daily iron supplement. Meanwhile, the questions for control belief were on perceptions of the pregnant women's ability to comply with daily iron supplement.

Table 1 Open-ended questions used to elicit behavioural belief, normative belief and control belief towards compliance to iron supplement.

Objective	Questionnaire items
To determine behavioural belief towards compliance to daily iron supplement	What are the benefits of taking daily iron supplement during pregnancy that you believe? What is the risk of taking daily iron supplement during pregnancy that you believe?
To determine normative belief towards compliance to daily iron supplement	What is the perception or act of people surrounding you that motivate you to take daily iron supplement during pregnancy? What is the perception or act of people surrounding you that demotivate you to take daily iron supplement during pregnancy?

To determine control belief towards compliance to daily iron supplement

What are the factors that you believe that will increase your ability to adhere to daily iron tablet intake?

What are the factors that you believe that will decrease your ability to adhere to daily iron tablet intake?

Based on the findings from this survey, as well as extensive findings from literature reviews including getting opinion from three experts who consisted of a Public Health Specialist, an Obstetrician and a Nutritionist. a total of 18 items were finally created. As per the guidelines, interval scale of “1” to “7” is used for each item in this questionnaire, where “1” was extremely disagree and “7” was extremely agree.^{18, 19} The items were developed in both the Malay and English language. Two independent healthcare providers who are able to speak, write and read well in both languages, performed back-to-back translation. Pretesting was then carried out to assess content and face validity.

$$CVR = (n - N/2) / (N/2)$$

Where,

n = the number of experts

N = the number of experts who rated the item as “essential”.

Face validity was performed by eight participants to ensure comprehensibility of the retained items following content validity.²² Corrections such as replacement of jargon and ambiguous words were carried out based on the comments from the participants.

Following face validity, a pilot test was performed on 100 pregnant women with anaemia who attended an antenatal clinic in Petaling Jaya. According to a study by Awang (2012), a minimum of 100 respondents are needed to obtain reliable results for Exploratory Factor Analysis (EFA) to determine psychometric properties of the items. The questionnaire which consists of the retained items from EFA was then distributed to another 100 pregnant women for Confirmatory Factor Analysis (CFA) to determine the final validated items.²³

RESULTS

Content validity

Table 2 KMO and Bartlett's Test

Kaiser-Meyer-Olkin Measure of Sampling Adequacy		0.814
	Approx. Chi-Square	815.463
Bartlett's Test of Sphericity	df	105
	p-value	<0.0001

Next, the EFA using extraction method of Principal Component Analysis with Varimax Rotation was performed. Total Variance Explained which indicates the number of components or domains with Eigenvalues of at least 1.0 ²⁵ that is

Validation process

Content validity is an assessment of the adequacy of items to represent domains of interest.²⁰ In this study, content validity was performed by three experts who were a Public Health Specialist, an Obstetrician and a Nutritionist. Each expert has rated each item as “essential”, “useful but not essential” or “not necessary” based on the appropriateness, accuracy and ambiguity of each item. Content validity ratio (CVR), which is the value of the valid content of each item, was subsequently calculated based on Lawshe’s formula ²¹. The formula is as follows:

Since the experts were less than five people, only items with content validity ratio (CVR) of at least 0.99 or items that were rated as “essential” by all experts, were retained.²¹ From this procedure, the total number of items that were retained was 15 items.

Exploratory Factor Analysis

Prior to analysis, all negative statements were reversely scored i.e. the score of 1,2,3,4,5,6,7 was changed to score of 7,6,5,4,3,2,1 respectively.^{18, 19}

In order to proceed with exploratory factor analysis (EFA), Kaiser-Meyer-Olkin (KMO) Measure of Sampling Adequacy was checked and it should be at least 0.60 with significant value of Bartlett's Test of Sphericity (p-value <0.05).²⁴ In this analysis, both KMO measure of Sampling Adequacy and Bartlett’s Test of Sphericity have met the criteria as shown in Table 2.

shown in Table 3. According to the study by Streiner (1994), the acceptable Total Variance Explained should be at least 60%. In this study, the Total Variance Explained was 62.3%.

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Table 3 Total Variance Explained

Component	Initial Eigenvalues			Rotation Sums of Spread Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	5.822	38.816	38.816	4.229	28.191	28.191
2	2.066	13.776	52.592	3.054	20.361	48.553
3	1.457	9.713	62.305	2.063	13.752	62.305

Extraction Method: Principal Component Analysis

The Scree Plot as shown in Figure 1 indicates three (3) dimensions or components for the latent construct of this questionnaire. In the Scree Plot, the point began to become a fairly straight line at Component 3. This suggests that the 15 items in

this questionnaire were classified into three (3) components or domains which are also similar with the number of components with Eigenvalues of less than 1.0 as shown in Table 3.

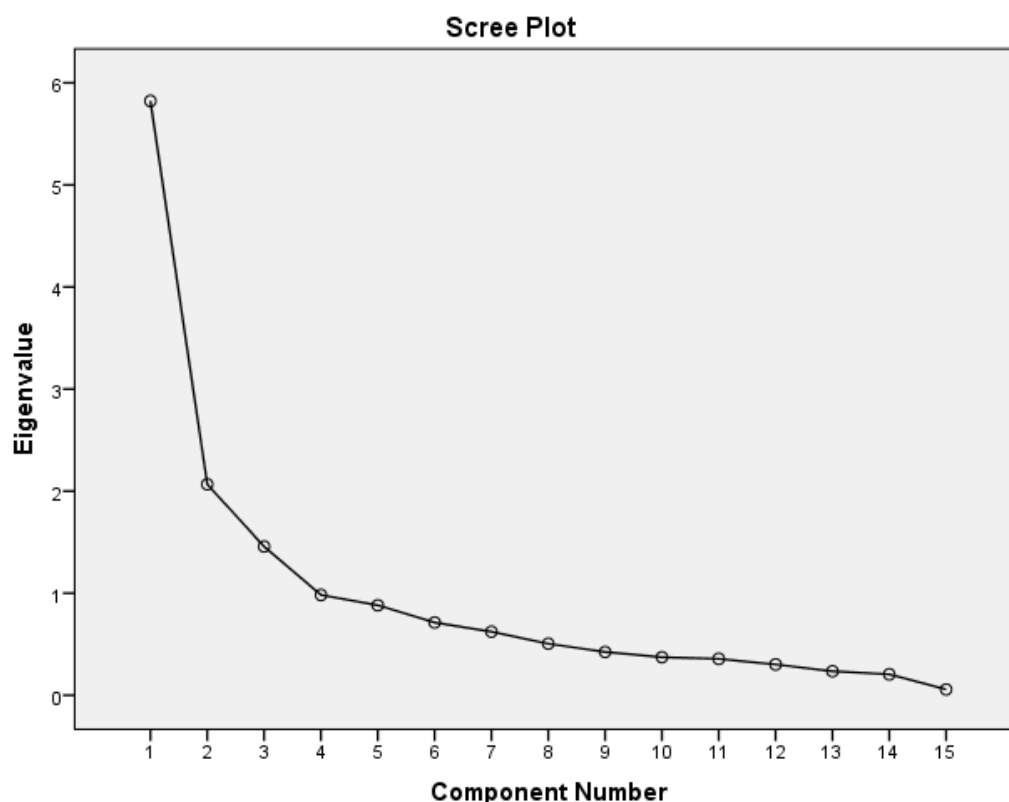


Figure 1 Scree Plot of Eigenvalue and Component Number

Finally, Dimension Reduction was performed to determine which items belonged to the respective components or domains.²⁵ The mean and standard deviation of all retained items and Rotated Component Matrix findings from the Dimension Reduction is shown in Table 4. In terms of Rotated

Component Matrix findings, only items with factor loading of at least 0.6 were retained for further analysis.²⁶ At this level, three (3) items with redundant or poor factor loading (<0.6), i.e. item Q6, Q9 and Q12 were deleted (Table 4).

Table 4 Mean, standard deviation of items and Rotated Component Matrix

Item	Item statement	Mean (SD)	Component		
			1	2	3
Q1	I am determined to take daily iron tablet throughout pregnancy	6.08 (0.895)	0.739		
Q3	I believed that taking daily iron tablet throughout pregnancy is beneficial	6.27 (0.763)	0.723		

Q5	I believed that by taking daily iron tablet during pregnancy, my haemoglobin (Hb) level will improve	6.08 (0.774)	0.611	
Q6	I believed that by maintaining normal level of haemoglobin (Hb), this will save my life	6.24 (0.793)		Deleted
Q7	I believed that by taking daily iron tablet during pregnancy, the growth of my baby will be normal	6.28 (0.740)	0.775	
Q8	I need to take daily iron tablet during pregnancy even if it may cause side effects such as vomiting or stomach discomfort	5.74 (0.824)	0.732	
Q15	I am confident to become compliant to daily iron tablet throughout pregnancy	5.98 (0.816)	0.707	
Q2	People around me believed that daily iron tablet intake during pregnancy is harmful	6.41 (0.818)		0.802
Q4	People around me believed that compliance to daily iron tablet throughout pregnancy is unnecessary	6.31 (0.884)		0.802
Q9	People around me encouraged me to be compliant to daily iron tablet throughout pregnancy	6.02 (0.864)		Deleted
Q10	People around me always remind me to take daily iron tablet during pregnancy	6.27 (0.886)		0.633
Q11	People around me do not bother whether I am compliant to daily iron tablet throughout pregnancy or not	6.25 (0.845)		0.803
Q12	People around me are also compliant to daily iron tablet throughout their pregnancy	6.17 (0.792)		Deleted
Q13	Being compliant to daily iron tablet throughout pregnancy is difficult for me	5.90 (0.785)		0.936
Q14	It is up to me whether to become compliant to daily iron tablet or not	5.88 (0.808)		0.951

SD=standard deviation

From Dimension Reduction, the final retained items were 12. Subsequently, internal reliability for the 12 retained items as well as items in each component or domain were evaluated by determining the Cronbach Alpha value. The Cronbach Alpha value of at least 0.70 indicates good

internal reliability in a scale.²⁷ In this study, the Cronbach alpha for all 12 items was 0.814. Meanwhile, the values of Cronbach alpha for each component or domain are shown in Table 5. The 12 retained items were also renamed as item t1 to t12 as shown in Table 5.

Table 5 Internal Reliability for Each Domain

Component or domain	Number of items per domain	Item	Item statement	Cronbach alpha value
1 (Attitude)	6	t1	I am determined to take daily iron tablet throughout pregnancy	0.844

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		t2	I believed that taking daily iron tablet throughout pregnancy is beneficial	
		t3	I believed that by taking daily iron tablet during pregnancy, my haemoglobin (Hb) level will improve	
		t4	I believed that by taking daily iron tablet during pregnancy, the growth of my baby will be normal	
		t5	I need to take daily iron tablet during pregnancy even if it may cause side effects such as vomiting or stomach discomfort	
		t6	I am confident to become compliant to daily iron tablet throughout pregnancy	
2	4	t7	People around me believed that daily iron tablet intake during pregnancy is harmful	0.813
(Subjective Norms)		t8	People around me believed that compliance to daily iron tablet throughout pregnancy is unnecessary	
		t9	People around me always remind me to take daily iron tablet during pregnancy	
		t10	People around me do not bother whether I am compliant to daily iron tablet throughout pregnancy	
3	2	t11	Being compliant to daily iron tablet throughout pregnancy is difficult for me	0.901
(Perceived Behavioural Control)		t12	It is up to me whether to become compliant to daily iron tablet or not	

Confirmatory Factor Analysis

Finally, Confirmatory Factor Analysis (CFA) was performed on another 100 pregnant women to validate the 12 items using Sequential Equation

Model (SEM).^{26, 27} Figure 2 shows the Fitness Indexes for the whole construct and the factor loading for each item in the questionnaire.

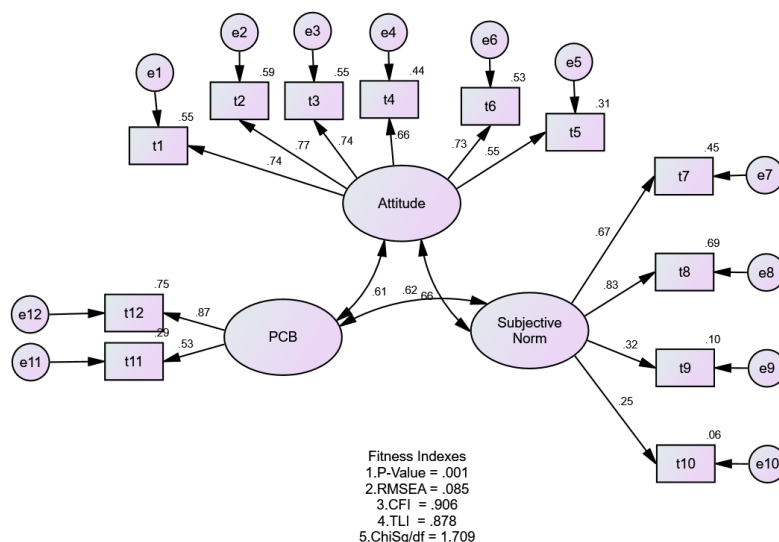


Figure 2 CFA results for the 12 items

According to Harrington (2009), items with low factor loading (<0.50) as shown in item t9 and t10, should be removed. Therefore, there were ten items remained, in which six items were from the

“Attitude” domain, and another two items from both “Subjective Norms” and “Perceived Behaviour Control” domain respectively (Figure 3).

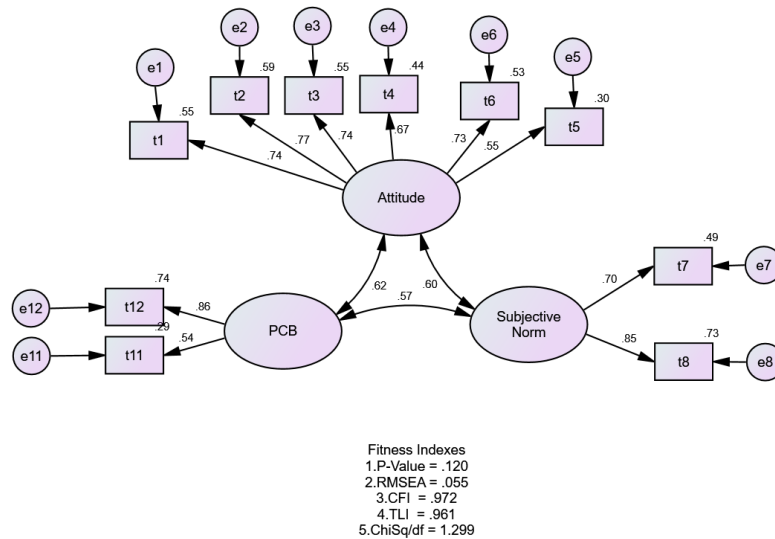


Figure 3 CFA results for the 10 items

Construct Validity

For assessment of Construct Validity, the Fitness Indexes have met the threshold value.²³ Absolute Fit category namely p-value was >0.05 and RMSEA was 0.055 which has achieved the threshold of less than 0.08. The Incremental Fit category namely CFI was 0.972 has also achieved the threshold of greater than 0.90. Similarly, the Parsimonious Fit category namely the ratio of ChiSq/df was 1.299 which has also achieved the threshold of less than 3.00. Thus, this questionnaire has achieved the requirements for all components in the Construct Validity.^{23, 26}

Convergent Validity and Composite Reliability

During assessment of Convergent Validity of this questionnaire, Average Variance Extracted (AVE) was calculated. Convergent validity is accepted if AVE value accomplishes the threshold of 0.50. Likewise, Composite Reliability is fulfilled if Composite Reliability (CR) value is at least 0.60 (Table 8). The formula of AVE and CR are as follows:

$$AVE = \frac{\sum K^2}{n}$$

$$CR = \frac{(\sum K)^2}{(\sum K)^2 + (\sum 1 - K^2)}$$

K_i is factor loading of each item
 n is number of items in the model

Table 8 AVE and CR for each component in the model

Domain	Item	Factor loading	CR	AVE
Attitudes	t1	0.74	0.60	0.50
	t2	0.77		
	t3	0.74		
	t4	0.67		
	t5	0.55		
	t6	0.73		
Subjective norms	t7	0.70	0.66	0.61
	t8	0.85		
Perceived behavioural control	t11	0.54	0.66	0.52
	t12	0.86		

The AVE and CR results for each domain in this questionnaire have achieved the accepted threshold value. This indicates that this

questionnaire has fulfilled the requirement for Convergent Validity and Composite Validity²³.

DISCUSSION

This study was performed to develop, assess the psychometric properties as well as validate a questionnaire that assess the attitude of pregnant women on iron supplementation and to predict their intention to comply to iron supplement in Malaysia based on Theory of Planned Behaviour. Theory of Planned Behaviour (TPB) was chosen as benchmark as it is the most frequently used theory to predict certain behavior.^{11, 13} In this study, the theory was used to evaluate attitudes of pregnant women towards health-related behaviour and predicted their compliance to treatment i.e. iron supplement^{28, 29} using this questionnaire.

In this study, the questionnaire adequately and appropriately covers the salient belief i.e. behavioural belief, normative belief and control belief according to the Theory of Planned Behaviour construct. Fifteen out of 18 items were rated as “essential” by all the selected experts. This was achieved after commencement of comprehensive literature review, discussion with experts, and open-ended questionnaire that was distributed to pregnant women.

In term of psychometric properties from the Exploratory Factor Analysis findings, the items were divided into three components or domains which correspond to the Theory of Planned Behaviour construct, which are attitude, subjective norms and perceived behaviour control.¹³ A study that was conducted in Indonesia to evaluate attitude and predict intention to comply to iron supplement among pregnant women based on the Theory of Planned Behaviour was published, yet the psychometric properties and reliability of the items in the questionnaire used was uncertain¹⁷. Meanwhile, in a study predicting intention to comply to iron-fortified soy sauce among pregnant women using combination of Theory of Planned Behaviour (TPB) and Health Belief Model (HBM), the items in the questionnaire that was used, have been divided into 10 domains which represent three (3) TPB constructs, six (6) HBM constructs and one (1) for knowledge.¹⁶

The questionnaire also showed high consistency. The Cronbach Alpha for the whole latent construct was 0.814. Meanwhile, the internal consistency for “Attitudes”, “Subjective Norms” and “Perceived Behavioural Control” domains were 0.844, 0.813 and 0.901 respectively. The latent construct and each component were reliable with Cronbach alpha of more than 0.70²⁷. Reliability of domains of items in a questionnaire assessing intention to comply to iron supplement i.e. iron-fortified soy sauce, based on the Theory of Planned Behaviour (TPB) and Health Belief Model (HBM), was also good, ranging from 0.75 to 0.99.¹⁶

There were twelve items that were retained after completion of the EFA. In the subsequent CFA, another two (2) items with poor factor loading i.e.

<0.5 were removed.²⁰ Hence, the final retained items were ten (10) items. These final items were found to be valid and reliable to determine attitude and predict intention to comply to iron supplement as value of construct validity, convergent validity and composite reliability achieved the threshold level. Unlike in another study, CFA was not performed to assess validation of items in that study.¹⁶

CONCLUSIONS

This newly developed questionnaire which consist of 10 items i.e. 6 items in “Attitude” domain, 2 items in both “Subjective Norms” and “Perceived Behaviour Control” domain respectively, are valid and reliable to assess attitude towards adherence to iron supplement as well as to predict intention to comply to iron supplement among pregnant women in Malaysia setting.

RECOMMENDATION

In future, this questionnaire can be used by researcher or healthcare staff to evaluate attitude towards adherence to iron supplement as well as to predict adherence to iron supplement among pregnant women. Apart from that, this questionnaire also can be used as tool to assess the failure of treatment among pregnant women with anaemia.

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