## **Original Article**

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# Development and validation of breastfeeding and dietary education package for women with gestational diabetes mellitus

Farhanah Ahmad Shuhaimi, Syahrul Bariah Abdul Hamid, Nurul Ainfarhanah Md Yazid

### Abstract:

**BACKGROUND:** Recent findings show that a longer breastfeeding duration and proper dietary management could lower the risk of postnatal diabetes. An excellent and interactive education module on breastfeeding and diet may effectively improve breastfeeding practices and dietary knowledge among women with gestational diabetes mellitus (GDM). Therefore, this study delves into developing and validating the content of Breastfeeding and Dietary Education Package (BFDEP) for women with GDM.

**METHOD:** The development of the module involved three phases: need assessment, module development, and validation. Six experts deployed a content validity index (CVI) to evaluate three areas of the module, including objectives, structure or presentation, and relevance. Sixteen women with GDM were involved in the face validation process by assessing the "literacy presentation," "illustrations," "material is sufficiently specific," and "quality of information."

**RESULTS:** Generally, I-CVI, S-CVI/Ave, and S-CVI/UA of the objectives, structure or presentation, and relevance revealed an excellent level of content validity. No alteration was needed for the domains of objective and relevance (S-CVI/Ave: 1.0, S-CVI/UA: 1.0). However, a minor revision was required in the structure or presentation domain (S-CVI/Ave: 0.98, S-CVI/UA: 0.90). The experts also thought that some module pages were wordy, and a change of font color was needed. The module was thus modified accordingly. For face validation, "literacy presentation" and "material is sufficiently specific" had a 99% positive response, while "illustrations" and "quality of information" had 100% positive feedback.

**CONCLUSION:** A BFDEP with excellent content validity was developed and can be implemented to improve breastfeeding practices and dietary knowledge among women with GDM.

### Keywords:

Breastfeeding, diabetes, diet, education, gestational, language

### Introduction

Gestational diabetes mellitus (GDM) is a glucose disorder that occurs during pregnancy and ceases after delivery. GDM is caused when hormonal changes during pregnancy trigger insulin to be less effective, and the mother becomes insulin resistant.<sup>[1]</sup> The level of the mother's blood glucose usually

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normalizes after delivery. Still, extensive studies reported that women with a history of GDM were sevenfold higher risk of developing type 2 diabetes mellitus (T2DM) than women with normal pregnancies.<sup>[2]</sup> Based on the Malaysian National Obstetric Registry, in 2010,<sup>[3]</sup>9.9% of 136,856 women had GDM. Indian had documented the highest percentage of GDM (14.39%), followed by Malay (11.37%) and Chinese (10.4%).

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Centre of Dietetics, Faculty of Health Sciences, UiTM Selangor Branch, Puncak Alam, 42300 Puncak Alam, Selangor Darul Ehsan, Malaysia

# Address for correspondence:

Dr. Syahrul Bariah Abdul Hamid, Centre of Dietetics, Faculty of Health Sciences, UiTM Selangor Branch, Puncak Alam, 42300 Puncak Alam, Selangor Darul Ehsan, Malaysia. E-mail: syahrulbariah@ uitm.edu.my

Received: 24-02-2022 Accepted: 28-09-2022 Published: 28-02-2023 A standard preventive strategy for T2DM is focusing on diet modification. However, few GDM guidelines recommend mothers practice breastfeeding, but with minimal evidence.<sup>[4]</sup> Encouragingly, there is growing evidence that breastfeeding<sup>[5,6]</sup> and dietary modifications incorporated with glycemic index concepts<sup>[7,8]</sup> are associated with a reduced long-term risk of chronic diseases in women with a medical history of GDM. This approach was attempted in Malaysia.<sup>[7,9]</sup>

Preliminary findings suggested that breastfeeding and dietary management offer vast health benefits to women with GDM.<sup>[9-11]</sup> However, it was reported that women with GDM had low to moderate breastfeeding knowledge.<sup>[12]</sup> They were also less likely to breastfeed their child than women without GDM.<sup>[13]</sup> Women with GDM in Malaysia had a fair knowledge of incorporating glycemic index concepts in their dietary management, specifically for GDM.<sup>[14]</sup>

These findings suggest that optimal lactation intensity and duration, together with implementing dietary modification, is an early T2DM prevention strategy. Additionally, to date, in Malaysia, no standardized GI-based diet incorporates the breastfeeding education package in preventing the development of postnatal T2DM. Hence, this module serves as an early T2DM prevention strategy by refocusing efforts to support optimal lactation intensity and duration together with implementing dietary modification.

This information proves the importance of instilling proper education on breastfeeding and diet management among pregnant women with GDM. This present study aimed to develop and validate Breastfeeding and Dietary Education Package (BFDEP) for pregnant women with GDM. This module was specifically designed to improve breastfeeding and dietary knowledge and practices of suitable women with GDM in Malaysia.

### **Materials and Methods**

The module designation, development, and validation were started in June 2021 and completed in December 2021. This study was conducted in three phases: Phase I: Need assessment, Phase II Development of BFDEP, and Phase III: Content and face validation of the BFDEP. This design and developmental research (DDR) methodology study involved three phases.

The Research Ethics Committee approved this study of Universiti Teknologi MARA with a reference number REC/08/2021 (MR/678).

### Phase 1: Need assessment

In the first phase, the module's content was developed based on current issues in recent literature and guidelines. Literature and guidelines which focused on the population being studied were considered. The Good Clinical Practice management in diabetes in pregnancy, Breastfeeding Support Manual by the Ministry of Health (MoH), and the breastfeeding training course for health professionals and low glycemic index diet during postnatal were referred. In line with these guidelines, the following themes were finalized in phase 1 [Refer to Table 1].

### Phase II: Development of the BFDEP

The Health Belief Model (HBM) was used to design the BFDEP module. The HBM model is based on psychological and behavioral theories that explain human health decision-making and subsequent behavior. It emphasizes two aspects of health-related behavior: 1) the desire to avoid sickness or the idea that a specific health activity would prevent or cure illnesses, and 2) the belief that specific health-related actions will prevent or cure illnesses. The desired outcome of this module is to influence the mother's decision based on their views on the advantages and drawbacks of associated health activities. The previous finding suggested that educational programs based on HBM showed benefits in increasing the participants' knowledge based on the Model constructs over time.<sup>[15]</sup>

The content of the BFDEP was developed based on the Empowerment, Motivation, and Adherence (EMMA) concept.<sup>[16]</sup> According to the EMMA concept, excellent educational material must include three elements: visual and tangible tools (pictures and illustrations), a printed booklet or pamphlet to retain memory by reading educational material at home, and communication by a researcher as an educator. All education materials were written in simple and layman terms to help the comprehension of the targeted audience.<sup>[17]</sup> All education modules were conveyed in the native language, *Bahasa Melayu*. This module consists of four subtopics presented as flipped charts for individual consultation and videos.

# Phase III: Content validation and face validation of the BFDEP

### Content validation by experts

In this study, six interdisciplinary experts were recruited to evaluate the relevance of the BFDEP module. The panel was composed of a science editor, a lecturer, two breastfeeding experts, and two dietitians. The number of experts was determined based on the recommendation by Yusoff (2019) of six to ten experts.<sup>[18]</sup> The experts received an email with the Informed Consent Form, the module storyboard, the four modules, and the Content Validation Index (CVI) via Google Form link. The CVI comprises 18 questionnaires covering objectives, structure, and relevance. The assessments on "objective" were focused on purposes, goals, and

Table 1: Summary of main contents for Breastfeeding and Die	arv Education Package BFDEP
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Торіс	Learning Approach	Content					
"Diet Sihat Buat Bonda"	Flipped chart and brochure	Educate on the pathophysiology of GDM, dietary management of GDM, and menu planning for women with GDM					
		Integrate the dietary management for GDM with the glycemic index (GI) concept. Introduce food based on GI categories					
"Titisan Rahmat Bonda"	Video and brochure	Educate about breast anatomy and how human milk is produced. The comparison of breastfeeding versus formula milk					
		Benefits of breastfeeding for the mother and baby					
		Explain the physiology of how breastfeeding can reduce the risk of diabetes in the future					
		Preparation to start the breastfeeding journey					
"Susu Badan Semudah 1,2,3."	Flipped chart and video	Educate mothers regarding foremilk versus hindmilk					
		Signs when the baby had received enough milk, signs when the baby did not receive enough mill					
		Breastfeeding position for normal and caesarean section delivery					
		Common problems related to breastfeeding					
		Facts and myths related to breastfeeding					
		Breastfeeding position and attachment delivered through a video					
"Diet Sihat	Flipped chart and brochure	Educate mother on postnatal diet					
Semasa Pantang"		Facts and myths related to food consumption during the postnatal period					
		Postnatal menu planning					
		Preparation of breastfeeding for working mothers					

targets. The area of "structure" was assessed for organization, consistency, strategy, and sufficiency. The "relevance" area was assessed for impact, significance, motivation, and interest. Each item was rated as follows: 0 for strongly disagree, 1 for partially agree, and 2 for strongly agree.<sup>[19]</sup>

The item was proposed for acceptance with a CVI of 0.80 or higher.<sup>[20]</sup> The item was deemed appropriate if the CVI was higher than 0.79, and the item needed revision if the CVI was between 0.70 and 0.79. The item was eliminated if the CVI was less than 0.70.<sup>[21]</sup> Table 2 shows the formulas I-CVI, S-CVI/Ave, and S-CVI. A comment section was made available for the experts to suggest improvements for each module based on their perceptions. All comments were taken into consideration for the modification of the module content.

### *Face validation by the target audience*

The content used for the target audience was similar to that presented to the experts, but the module storyboard was excluded. The face validity questionnaire consisted of 27 items that focused on the "literacy presentation," "illustrations," "material is sufficiently specific," and "quality of information" indicated with "yes" or "no."<sup>[17]</sup> The item was deemed validated for face validation when a minimum of 75% positive response was obtained.<sup>[22]</sup> A total of 16 women with GDM were invited to participate in the face validation process. The validation process was measured and confirmed by a study in Iran.<sup>[23]</sup> The inclusion criteria were women free from other severe health conditions except being diagnosed with GDM, and able to understand and communicate in the Malay language. These subjects were contacted through the Malaysian Facebook Breastfeeding Support Groups. All

# Table 2: The formula of I-CVI, S-CVI/Ave, and S-CVI/

UA	
	The formula of I-CVI, S-CVI/Ave, and S-CVI/UA
*I-CVI	Agreed item/number of experts
#S-CVI/	Sum of I-CVI score/number of items
Ave	Sum of proportion relevance rating/number of experts
^UA	Universal Agreement (UA) score was 1 when the item achieved 100% experts in agreement. Otherwise, the UA score was given as 0.
#S-CVI/UA	Sum of UA scores/number of items

\*I-CVI=Item-level Content Validity Index, \*S-CVI/Ave=Sum Content Validity Index/Average, ^UA=Universal agreement

subjects were given a Google Form link that consisted of the four modules and questionnaires.

### **Statistical analysis**

For the content validation by experts, the calculations of I-CVI, S-CVI, S-CVI/UA, and S-CVI/Ave were manually performed.<sup>[24]</sup> Meanwhile, for the face validation among the targeted audience, a descriptive statistical test was used to analyze and present most of the sociodemographic data and the face validation questionnaire. The items must obtain at least 75% positive responses to ensure validity among the targeted audience. All numerical data were presented in mean and standard deviation.

### Results

Objectives, structure, and relevance obtained a CVI of 1.0, 0.98, and 1.0, respectively. This finding indicates an excellent level of agreement between the six experts for content validity [refer to Table 3]. The overall CVI of the four modules was 0.99 and was thus considered validated for their content. Moreover, the experts provided suggestions to improve the modules at the

### Table 3: Ratings on the domains of objectives, structure, and relevance by six experts

tem	Description	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Experts in Agreement	I-CVI <sup>a</sup>	UA
	OBJEC	TIVES: p	urposes	, goals,	or target	ts				
1	Contemplates the proposed objectives	1	1	1	1	1	1	6	1	1
2	Suits the teaching-learning process	1	1	1	1	1	1	6	1	1
3	Clarifies doubts on the addressed objective	1	1	1	1	1	1	6	1	1
4	Provides reflection on the objective	1	1	1	1	1	1	6	1	1
5	Encourages behavior change	1	1	1	1	1	1	6	1	1
								S-CVI/Ave	1	
								S-CVI/UA		1
	Proportion relevance	1	1	1	1	1	1			
Avera	age proportion of items judges as relevance across s	ix exper	s					1		
	STRUCTURE/PRESENTATION: or			ture, st	rategy, c	onsister	ncy, and	sufficiency		
6	Language appropriate to the target audience	1	1	1	1	1	1	6	1	1
7	Language appropriate to the educational material	1	1	1	1	1	1	6	1	1
8	Interactive language, enabling active involvement in the educational process	1	1	1	1	1	1	6	1	1
9	Correct information	1	1	1	1	1	1	6	1	1
10	Objective information	1	1	1	1	1	1	6	1	1
11	Enlightening information	1	1	1	1	1	1			
12	Necessary information	1	1	1	1	1	1			
13	Logical sequence of ideas	1	1	1	1	1	1			
14	Current theme	1	1	1	1	1	1			
15	Appropriate text size	1	1	1	1	1	0	5	0.83	0
								S-CVI/Ave	0.98	
								S-CVI/UA		0.9
	Proportion relevance	1	1	1	1	1	0.9			
Avera	age proportion of items judges as relevance across s	ix exper	s					0.98		
	RELEVANCE: sig	nifican	ce, impac	ct, motiv	vation, a	nd intere	est			
16	Encourage learning	1	1	1	1	1	1	6	1	1
17	Contributes to knowledge in the area	1	1	1	1	1	1	6	1	1
18	Arouses interest in the theme	1	1	1	1	1	1	6	1	1
								S-CVI/Ave	1	
								S-CVI/UA		1
	Proportion relevance	1	1	1	1	1	1			
Avera	age proportion of items judges as relevance across s	ix exper	s					1		

<sup>a</sup>l-CVI (Item-level Content Validity Index). Number of expert panels who agreed with the items by coding them with "1" divided by the total number of the expert panel (*n*=6). <sup>b</sup>UA (Universal agreement). The item that achieved 100% agreement from each expert was assigned as "1"

end of the content validation questionnaire. The experts suggested improvements to the formatting of the text, namely bolding the highlighted word or differentiation through the change of font color. The expert panel also noted that some slides used in the module were too wordy. The module was consequently revised based on the suggestions. Other aspects of evaluation, including purpose, goals, target, organization, structure, strategy, consistency, sufficiency, impact, motivation, and interest, yielded positive responses from the expert panel.

Sixteen pregnant women with GDM were involved in the face validation evaluation. As shown in Figure 1, all four aspects of face validation achieved more than a 75% level of agreement. These findings suggested an excellent level of agreement among women with GDM. As a result, the BFDEP was considered to have achieved face validity for the targeted audience.

### Discussion

In Malaysia, breastfeeding promotion has been actively conveyed since the 1970s through mass media, breastfeeding counseling by health professionals, the school curriculum, availability of baby-friendly hospitals, and breastfeeding support groups.<sup>[25]</sup> However, the national rate of exclusive breastfeeding is still lower than the rate recommended by the WHO.<sup>[26]</sup> Currently, pregnant women in Malaysia are commonly given education on breastfeeding during antenatal appointments. Additionally, the mothers can communicate with lactation counselors, which modes of reaching out to them are provided through information sharing or pamphlets received during antenatal or postnatal follow-ups.<sup>[27]</sup>

In addition, individualized breastfeeding education was found effectively improve breastfeeding self-efficacy,

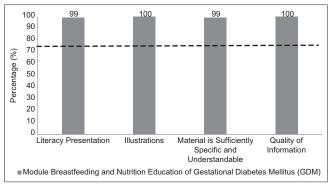


Figure 1: Level of agreement among the target audience for face validity

knowledge, and breastfeeding rates among mothers with GDM from the time of discharge to 6 months postpartum.<sup>[28]</sup> Moreover, a recent study has indicated that breastfeeding intervention programs have effectively increased the rate of exclusive breastfeeding and prolonged the breastfeeding duration, especially among primiparous mothers.<sup>[29]</sup> Therefore, this module was implemented through a one-to-one consultation between a dietitian and a patient.

This study has successfully developed a validated BFDEP module with a mean I-CVI of 0.99 for objective, structure, and relevance. CVI is an empirical method to test the validity of an instrument used for data collection. The CVI method to validate tools is vastly used because of its efficiency, that it saves cost and time, and is easy to implement and administer.<sup>[30]</sup> Extensive studies also applied CVI to validate their research instrument.<sup>[17,24,30,31]</sup>

One of the subtopics in BFDEP is a video clip on breastfeeding position and attachment techniques. The video was presented in an individual session with the counselor, and the mothers were free to ask questions regarding the video during the session. The mothers were then given a link to the video for their reference at home. According to the expert panel in this study, the colored pictures in the slides and videos were engaging in structure and presentation. The panel also found that the video would be beneficial for mothers to understand the topics. Module with a video-based approach can increase the audience's knowledge and skills.<sup>[32]</sup>

Additionally, a few well-designed randomized controlled trials done in Malaysia suggested that incorporating the glycemic index concept in managing women with GDM during pregnancy and postdelivery has resulted in favorable outcomes. These outcomes have included glycemic control, better dietary intake, better postnatal weight management, and significantly lower fasting blood glucose compared to a conventional diet.<sup>[7,8,10,33]</sup> Hence, the dietary management in this module incorporated the concept of the glycemic index during pregnancy and postnatal diet.

This study reports the content expert validity and face validity of the BFDEP module to educate women with GDM. A dietitian shall give the module in an individual session with mothers at Mother and Child health clinic. This module highlights the physiology of lactation, how it helps to reduce the risk of developing postnatal diabetes, and dietary guidance during pregnancy and postnatal. On top of that, Yasuhi and colleagues have suggested that breastfeeding and dietary modifications can be used as a low-cost intervention approach for chronic diseases among women with a history of GDM.<sup>[11]</sup> Therefore, a study of the effectiveness of this module is essential to be conducted in lowering postnatal blood glucose and the development of T2DM.

The strength of the current study is that this module is presented and delivered in the native Malay language using laymen's terms and contains many infographics. The current approach enhances the participants' understanding. The videos incorporated in the module were completely voiced in Malay to accommodate the majority Malay-speaking population in Malaysia.<sup>[34]</sup> Moreover, the use of medical terminologies without clear definitions may complicate the understanding of contents by readers. Therefore, this module was designed to incorporate common terms known to all levels of society. This module was also tailored to the needs of mothers with a caesarean section for a suggestion of appropriate breastfeeding positions. Nevertheless, the availability of the module in one language is also a possible limitation. However, this may not be the main issue as the Malay Language is the official language in Malaysia.

### Conclusion

This current study has developed a module specifically for breastfeeding and dietary interventions to reduce the risk of developing postnatal T2DM among women with GDM. The module has undergone a validation process by a 6 six-expert member panel and face validation by 16 targeted audiences. The module was found to have good content validity, where all three areas achieved an appropriate scoring. In addition, five aspects of face validation reached more than 75% level of agreement. In conclusion, this validated module can be used to improve breastfeeding and dietary knowledge and practices among women with GDM. This module has the potential to benefit women with a history of GDM by lowering the risk of T2DM and other chronic diseases.

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### **Conflicts of interest**

There are no conflicts of interest.

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