

Development and Validation of an Educational Booklet for The Healthy Eating Management of Diabetes Mellitus During Ramadan Fasting

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ABSTRACT

Background: *iabetics who decide on Ramadan fasting are at risk of complications such as hypoglycemia, hyperglycemia, ketosis, or dehydration. The strategy for prevention is to provide education about managing DM with healthy food intake, medication, and exercise during Ramadan fasting. Therefore, it is essential to develop the media to implement education.*

Research Methods: *This research was a research and development method. The model used in developing an educational booklet consists of four stages: define, design, develop, and disseminate. The feasibility of growing media was analyzed by the content validity index (CVI) using I-CV and S-CVI to assess whether the item is relevant or not relevant to the index CVI>0,80.*

Research Result: *Define is the first stage to analyze the need for media development; based on the results of an online survey of nutritionists, as many as 71% mentioned that there were no specific educational media on healthy eating management for DM during Ramadan fasting. Design and development of educational media include literature studies on healthy eating during Ramadan fasting for DM, containing food menus during Ramadan fasting—subsequent dissemination by assessment from experts and target subjects. The assessing subject's content validity index (CVI) was carried out using the I-CV and S-CVI. The average value of I-CV is 0.875, and the average value of S-CVI is 0.875, meaning that all parts of the content are relevant in providing information about healthy eating for DM during Ramadan fasting. The reliability test by the target subject obtained Cronbach's alpha value of 0.850 was reliable.*

Conclusion: *This booklet can be used as an educational medium for pre-Ramadan education. Then, the researchers developed this booklet by considering and improving the booklet design, which was stated to be appropriate.*

BACKGROUND

Ramadan fasting is obligatory for all Muslims, except for children who have not yet reached puberty, the elderly, pregnant women, nursing mothers, and travelers. Alternatively, those who have physical or mental health problems; therefore, they are unable to fast (Ahmed SH, 2020). Furthermore, people with diabetes also may decide to avoid fasting. However, many Muslims with DM choose to fast during Ramadan for religious, cultural, or social reasons (IDF-DAR, 2016). International Diabetes Federation (IDF), in collaboration with the Diabetes and Ramadan International Alliance (2016), noted that more than 148 million people worldwide are diagnosed with DM, and more than 116 million people choose to fast during Ramadan. It is estimated that

by 2024, the number of people with diabetes will reduce in countries with a predominantly Muslim population (Tootee & Larijani, 2021).

People with diabetes who choose to fast during Ramadan without monitoring blood glucose control, taking the correct medication consumption, managing food intake, and proper exercise regularly could lead to health problems, including hypoglycemia, hyperglycemia, ketosis, and dehydration (Benaji et al., 2006) (Alsafadi et al., 2011), (IDF-DAR, 2016) (Ahmed et al., 2020) (Omar et al., 2020) (Tootee & Larijani, 2021), changes in anthropometry even though there is no alteration in energy intake (Azizi, 2013) (Alsafadi et al., 2011), lipid profile, blood pressure (Ahmed et al., 2020), hypovolemia and thrombosis (Maideen et al., 2019) (Al-Arouj et al., 2010). The incidence of hypoglycemia during fasting increased four times (10.8%) than without fasting (2.7%) (Santosa, 2014). These health problems are caused by changes in energy consumption, eating schedules, long periods without eating, lack of fluid intake, inappropriate dosages, and medication schedules (Santosa, 2014). This problem can interfere with fasting and endanger the health of people with diabetes.

People with diabetes who decide to fulfill Ramadan fasting become a positive diet therapy. However, they are also at risk of mild hyperglycemia and hypoglycemia before breaking fasting meals (Santosa, 2014). Alfin et al. (2019) stated that Ramadan fasting reduced blood glucose levels with Type 2 DM who received standard health care ($p=0.039$) compared to those who did not perform Ramadan fasting. Like Alsafadi et al. (2011), severe hypoglycemia can occur significantly compared to the months before fasting. Fasting could lead to lower blood glucose levels and decreased insulin secretion, followed by an increase of glucagon and catecholamine hormones, which results in the breakdown of glycogen. After a few hours of fasting, glycogen stores will begin to decrease. As a result of reduced insulin in the circulation, this will lead to the release of fatty acids. Fatty acids can be broken down to produce energy and ketones (Alfin et al., 2019). The results of Indonesia Basic Health Research (2018) show that 85.5% of people with diabetes never monitor their blood glucose levels, and 12.8% never monitor their blood glucose levels regularly, even though monitoring blood glucose during Ramadan fasting is very important to avoid diabetes complications.

Some strategies to create safe and comfortable Ramadan fasting for people with diabetes include education that focuses on Ramadan fasting, pre-Ramadan health checks, balanced nutrition planning, physical activity, and independent blood glucose monitoring (Oliveira et al., 2014), (Maideen et al., 2019) (Tootee & Larijani, 2021). Only as many as 40% of people with diabetes do pre-Ramadan counseling (Alsafadi et al., 2011). Pre-Ramadan nutrition education programs positively impact people with diabetes who choose to fast during Ramadan (Ben et al., 2019). Therefore, researchers developed educational media for people with diabetes to support healthy eating management before and during fasting for people with diabetes that can be used as pre-Ramadan educational media.

MATERIAL AND METHODS

The research method used is Research and Development (R&D). Research and Development (R&D) is a research method to produce specific products and assess the effectiveness of these products. This research was claimed an ethical approval by the Health Research Ethics Committee Ministry of Health Semarang Health Polytechnic No 0140/EA/KEPK/2022.

The model used in developing this booklet product consists of four stages: define, design, develop, and disseminate. The define stage consists of front analysis, task analysis, concept analysis, and object specification. The design phase comprises test construction, media selection, format selection, and initial design. The development stage consists of expert appraisal and developmental testing. The dissemination stage consists of validation assessment and dissemination.

The initial stage is the define stage, which analyzes the requirements for media development. The results of an online survey of nutritionists showed that 71% explained that there were no specific educational media for eating management for people with diabetes who were fasting during Ramadan, and 39% stated that they already had leaflets as educational media related to the dietary management of diabetes. However, they were not read, and the contents needed more detail. This is why this educational media must be developed to motivate people with diabetes to consume adequate and balanced energy and nutritional intake to help control blood glucose during Ramadan fasting. The second stage is the design stage. This stage begins with developing educational materials for people with diabetes to fulfill Ramadan fasting. The next stage is

the development stage, which is the assessment of the experts on the booklet and evaluating the concept of the content and appearance of the booklet. The assessment is based on an instrument that measures the adequacy of assessment items related to the content and appearance of the booklet. The assessment instrument uses a Linkert scale, and the booklet has open questions for comments and suggestions. The product quality assessment checklist form was prepared using a Likert scale (Strongly Agree, Agree, Doubtful, Disagree, and Strongly Disagree). Then, calculate the percentage of validity with the formula of the assessed score divided by the expected score and categorized into 80-100% very valid, 66-79% valid, 56-65% quite valid, and 40-55% less valid. The assessment experts in this study were experts/practitioners with experience in health education media, namely media designers as experts in arranging booklet contents, which works in the health promotion section at the Health Office, and dietitians as material experts. Next, experts conducted product evaluations using the Linkert scale to analyze the media's responses. Then, grouping these assessments into relevant (score 1) for the answers strongly agree, agree, and undecided, while irrelevant (score 0) for the answers disagree and strongly disagree. Next, use the I-CVI and S-CVI to find out the average rating of all components using the content validity index (CVI) (Yusoff, 2019). I-CVI (level content validity index): For each item, I-CVI is calculated by the number of assessing subjects who evaluate the item as relevant or irrelevant with a CVI index > 0.80 sufficient for content validity. S-CVI (scale-level content validity index): average proportion of items evaluated as relevant and highly relevant by subject experts. The final stage of this research is the dissemination stage, which is the validation test stage of the target. The assessment carried out at this stage is on the clarity of written information, text size, color, image illustrations, motivation to understand the material, and product satisfaction assessment to be used as educational media. Product assessment results for the target subject were processed using SPSS. The validity of the question items was tested using the Pearson Product Moment correlation test with a significance level of 5%.

RESULTS

The booklet has dimensions of 155x214 mm with 23 pages. The front is a cover page and table of contents, while the back is a bibliography and back cover page. The contents of the booklet consist of 10 parts, including an introduction, metabolic changes during fasting, consequences of fasting DM patients, grouping and considerations in performing Ramadan fasting, self-checking blood glucose, principles of food regulation, the composition of macronutrients in food, Ramadan plates, carbohydrate settings, meal recommendations, and sample menus. The display of the booklet compiled by the author is presented in Figure 1.



Figure 1. Booklet View

Educational materials were developed by the recommendations for Diabetes and Ramadan Practical Guidelines 2021 by the International Diabetes Federation (IDF) and Guidelines for the Management of Type 2 DM in Adult Individuals in the Month of Ramadan (Perkeni, 2015). The educational material is accompanied by an example of a menu composition adjusted with Indonesian local food. The research team took the images in the booklet, and the cartoon illustrations were obtained from the Canva app. The booklet was developed in Indonesian with layouts and illustrations to adapt to Indonesian culture.

The initial part of the booklet contains material on the importance of managing meals during Ramadan fasting for people with diabetes, including the purpose of managing meals, followed by changes in metabolism that occur during fasting to illustrate that there is regulation of glucose use. Furthermore, it contains material on complications for people with diabetes during Ramadan fasting. The following page contains groupings and considerations for people with diabetes in carrying out Ramadan fasting. In this section, the criteria for people with diabetes who are allowed to fast are given in three categories: moderate/low, high, and very high risk. The higher and the very high risk are advised not to perform Ramadan fasting. The next page gives the importance of independent blood glucose examination during Ramadan fasting to frequently monitor hypoglycemia risk. The booklet material also contains ten principles of eating management for people with diabetes who are fasting during Ramadan. This principle contains the importance of consulting a doctor and dietitians in deciding to fast during Ramadan, the importance of consuming sufficient energy and balanced carbohydrates at dawn and breaking the fast, the importance of a balanced proportion of macronutrients, the selection of food sources of carbohydrates that are recommended, choosing healthy distractions, using the "Ramadan Plate" to ensure the source of nutrients to be consumed, meal schedules, adequate fluids, and physical activity recommendations.

The following booklet material is the composition of macronutrients as recommended carbohydrates, proteins, and fats sources. Furthermore, the illustration of the "Ramadan Plate" serves as a guide and illustrates the adequacy of the types of nutritional sources consumed. Next, the importance of regulating carbohydrates consumed, starting from the type, amount, and schedule, to help control blood

glucose during Ramadan. The booklet is equipped with recommendations for eating at dawn and when breaking the fast and ends by displaying a sample 9-day menu along with a division of fluid consumption, which can be used as a guide to the daily menu during Ramadan fasting for people with diabetes.

This booklet has been assessed by material and media experts. The material expert is a senior dietitian who has experience in nutritional services in DM with the latest undergraduate education to provide an assessment of the contents of the booklet material. The results of the material expert's assessment are presented in Table 1. In general, the material content assessment is stated to be very valid and can be used without revision, according to the material expert.

Table 1. Material Expert Assessment Results

No	Components	Percentage	Criteria of Validity	Recommendations
1	Booklet content quality	80%	Very valid	General assessment: usable without revision Suggestion: Fluid management during Ramadan fasting needs to be considered for Nephropathy DM
2	Quality of presentation	80%	Very valid	
3	Language quality	80%	Very valid	

Media experts are health promotion staff who have experience in educational media and health promotion both in print and through social media to evaluate the appearance of the booklet. The results of the expert assessments are presented in Table 2. In general, the assessment of media experts indicated that the booklet could be used with revisions with some improvements to the font size of the table of contents. The spacing between paragraphs needs headings, subheadings, and their contents; health information needs to be highlighted and menu images enlarged. Media experts also assessed that the booklet size was appropriate and stated it was convenient for educational media.

Table 2. Media Expert Assessment Results

No	Components	Percentage	Criteria of Validity	Recommendations
1	Booklet size	80%	Very valid	<ol style="list-style-type: none"> 1. General assessment: can be used with revision 2. Improvement suggestions: 3. The writing font is adjusted on each page and is set for headings, subheadings, body, and notes 4. The font size in the table of contents is enlarged, and the image is shifted to the right 5. The space between paragraphs is still too narrow 6. Food ingredient's Glycemic Index (GI) value is not very clear 7. Health information is more compacted and highlighted 8. The sample menu image is enlarged.
2	Booklet cover design	60%	Quite valid	
3	Coten illustration	80%	Very valid	
4	Booklet content design	56%	Quite valid	
5	Practicality	100%	Very valid	

After repairs are made to the booklet, the booklet is assessed by the experts. The results of the qualitative assessment are presented in Table 3 below. The experts assessed that the material's content was good but needed improvements in the booklet design, namely the typeface, font color, and design that needed to be uniform, mixed, and matched to look consistent.

Table 3. Summary of Quality Assessment

No	Page	Recommendations
1	ii-iii	Latin fonts are not clearly visible
2	19-21	Organize the menu samples layout
3	General	The content of the material is good. Font colors and designs need to be uniform so that they look consistent and unified

The assessing subject's content validity index (CVI) was carried out using the I-CV and S-CVI approaches. In questions 2, 3, 6, and 8, the I-CV value was <0.80, but the average I-CV value was 0.875. The average value of S-CVI is 0.875, which implies that all parts of the content are declared relevant in providing information about meal arrangements for people with diabetes who commit to Ramadan fasting. The evaluation results based on the eight components of the questions to the evaluator subject are presented in Table 4.

Table 4. Booklet Evaluation Results

No	Components	Expert 1	Expert 2	Expert 3	Expert 4	I-CV
1	The content of the material presents clear information	1	1	1	1	1
2	The text looks clear	1	1	1	0	0.75
3	Perfect design and color combination	1	1	1	0	0.75
4	The illustrations used are following the material	1	1	1	1	1
5	Illustrations can support understanding the content of the material	1	1	1	1	1
6	Illustrations and texts can motivate and understand material information	1	1	1	0	0.75
7	Products can be used as educational media	1	1	1	1	1
8	Overall, I am satisfied with the product	1	1	1	0	0.75
S-CVI = 0.875						

The target subject, diabetic Muslims, responded positively to the preparation of this booklet. Subjects stated the importance of this booklet being reproduced and distributed. However, some subjects thought the introduction was too much, and the language needed to be more scientific, namely, part of metabolic changes during fasting. The results of the validity test indicate that assessment of the first component produces a value smaller than the r table (> 0.4438) (Table 5), meaning that it is invalid because the subject feels that the use of language is still too scientific so that the information conveyed in the booklet needs direct explanation by the educator. The reliability test results obtained that Cronbach's alpha value of 0.850 was declared good reliability.

Table 5. Booklet Evaluation Results

No	Components	Value of r calculate	Description
1	The content of the material presents clear information	0.374	Not valid
2	The text looks clear	0.843	Valid
3	Perfect design and color combination	0.806	Valid
4	The illustrations used are following the material	0.710	Valid
5	Illustrations can support understanding the content of the material	0.616	Valid
6	Illustrations and texts can motivate and understand material information	0.777	Valid
7	Products can be used as educational media	0.787	Valid
8	Overall, I am satisfied with the product	0.738	Valid

DISCUSSION

Ramadan fasting is obligatory for all grown-up and healthy Muslims. Fasting means refraining from eating, drinking, and engaging in sexual intercourse between dawn and sunset for twenty-nine to thirty days during Ramadan. (Alsafadi et al., 2011; Azizi, 2013; Ahmed, 2020). Metabolic benefits obtained during Ramadan include maintaining muscle mass, improving body composition, optimizing physiological functions, reducing fat mass, and losing weight in overweight and obese people (Ahmed et al., 2020) (Osman et al., 2020) (Daradkeh et al., 2021) as well as controlling blood glucose levels and lipid profiles in people with diabetes who are fasting during Ramadan (Alsafadi et al., 2011) (Alfin et al., 2019).

Islam allows a Muslim with an illness to break his fast or be exempt from fasting. Fasting for Muslims with chronic illnesses may affect their health, or fasting will delay or disrupt recovery or increase the risk of complications (Ahmed et al., 2020).

People with diabetes are at high risk of experiencing health problems if they fast during Ramadan due to acute metabolic disorders and drug side effects (Alfin et al., 2019; Ahmed et al., 2020). The potential risks associated with Ramadan fasting and DM are disturbances in glycemic control manifested as hypoglycemia and hyperglycemia and metabolic emergencies, such as diabetic ketoacidosis, hyperosmolar hyperglycemic syndrome (HHS), dehydration, renal impairment, hypotension, and thrombosis secondary to hyperglycemia. (Azizi, 2013; Ahmed et al., 2020). Furthermore, cardiometabolic factors such as blood pressure and lipid profile can also be affected by Ramadan fasting. Pre-Ramadan risk stratification is essential for people with diabetes to guide and support people with diabetes to make the right decisions. High to very high-risk patients are advised not to fast, but if people with diabetes choose to fast, it must be supported and closely monitored (Ahmed et al., 2020). People with diabetes who decide to fast during Ramadan should receive proper assessment and counseling 1-2 months before the start of Ramadan (Alsafadi et al., 2011). Pre-Ramadan education has been indicated to enhance the fasting experience of diabetics. Nutrition education programs positively impact the food intake of people with diabetes who choose to fast during Ramadan or insist on fasting during Ramadan (Ben et al., 2019). Pre-Ramadan education in diabetics is associated with greater weight loss and a significant reduction in hypoglycemic events. Health service activities during Ramadan fasting for diabetics consist of pre-Ramadan nutrition education and meal management during Ramadan fasting, which is beneficial for people with diabetes in improving clinical outcomes such as regulating fasting blood glucose levels, triglycerides, and reducing Hemoglobin A1c (HbA1c) levels which significantly lower than those with diabetics who underwent standard care (Omar et al., 2020). Pre-Ramadan assessment is crucial for increasing knowledge, self-empowerment, and medication adjustments to ensure that Ramadan fasting is observed safely (Ahmed et al., 2020). A pre-Ramadan assessment is essential for people with diabetes who intend to fast to evaluate the risks, educate the patient on self-management during Ramadan, and develop a patient-tailored treatment plan that outlines any needed medication adjustments. Ramadan-focused education and better nutrition knowledge during Ramadan are essential elements for safer fasting (Hassanein et al., 2017).

People with diabetes require to feel safe and comfortable during Ramadan fasting through education that focuses on Ramadan fasting, pre-Ramadan assessment, balanced nutrition planning, physical activity, and self-monitoring of blood glucose (Khaled, 2014) (Oliveira et al., 2014), (Maideen et al., 2019) (Tootee & Larijani, 2021) were the background for the preparation of this booklet. Education for people with diabetes focusing on Ramadan is focused on increasing knowledge, management, and self-empowerment in making the right decisions about managing conditions during Ramadan (Hassanein et al., 2017). Healthcare professionals need to be well informed about the effects of Ramadan on people with diabetes, as they should be able to provide the necessary advice and guidance during pre-Ramadan counseling to enable people with diabetes to fast Ramadan safely (Alsafadi et al., 2011). Educational materials were developed by the recommendations for Diabetes and Ramadan Practical Guidelines 2021 by the International Diabetes Federation (IDF) and Guidelines for the Management of Type 2 DM in Adult Individuals in the Month of Ramadan (Perkeni, 2015).

The process of assessing the content and appearance of this booklet involves material experts, media experts, the subject of evaluation, and the target subject. This is similar to research by Oliveira et al. (2014), in which this booklet was developed for experts and target subjects. The results of the product relevance assessment with a CVI value of >0.80 also refer to research by Oliveira et al. (2014). This differs from the explanation (Yusoff, 2019) that the CVI value depends on the number of experts. That is, if there are four experts, then the CVI value that is considered acceptable is CVI>1. The CVI value >0.80 is the

theory of Davis (1992) (Yusoff, 2019), which states that the minimum number of experts is two persons. The CVI value of 0.875 means that the experts considered the information relevant about eating arrangements during Ramadan fasting for people with diabetes. The booklet includes nutritional education on hypoglycemia and hyperglycemia symptoms, meal planning, blood glucose monitoring, taking medications, physical activity, and management of acute complications, including when to break the fast. Besides that, education on consuming a balanced diet, adequate fluid intake, and physical activity is recommended (Alsafadi et al., 2011) (Ben et al., 2019).

This booklet can be used as a medium for pre-Ramadan education by dietitians. Pre-Ramadan counseling for people with diabetes is personalized management. This pre-Ramadan counseling could control the occurrence of hypoglycemia (Ahmed et al., 2020). Given this importance, the researcher then developed this booklet by considering and revising the booklet design, which was announced to be inappropriate. This study has limitations in that the assessment instruments used for the experts and the target subject are the same, which allows for the perception of a relationship between the two. In addition, the food menu sample uses Javanese local cuisine and could limit the implementation of booklets in other regions.

CONCLUSIONS

The experts and target subjects have validated this booklet for its content and relevance. The result is that the information is relevant to eating management during Ramadan fasting for people with diabetes. However, researchers still need to improve on input from the experts, including the design of the booklet for consistent color and written text and the use of language acceptable to ordinary people so that the target can receive the information. Furthermore, the improved booklet could be used as educational media for pre-Ramadan nutrition counseling for people with diabetes.

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