Research article

The Glycemic Response and Satisfaction toward Diabetes–Specific Nutrition Formula: A Randomized Crossover Study in Healthy Subjects

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ABSTRACT

The purpose of this research was to use maltodextrin and resistance maltodextrin from tapioca planted in Thailand as the main ingredient for carbohydrates in a diabetes-specific nutrition formula known as diabetic formula 1, and employing a Thai innovation. This study aimed to determine glycemic index (GI) and satisfaction levels of the diabetic formula 1 among 12 healthy consumers using a randomized crossover design. Participants consumed the diabetic formula 1 and a glucose solution as reference at the same amount of 50g. After the consumption period, blood samples were collected at timed intervals over a two-hour period. Satisfaction score was measured using the Visual Analog Scale. Results showed that the postprandial plasma glucose (PPG) of diabetic formula 1 increased from fasting levels but was significantly lower than for the glucose solution starting from 15 through 90 min. The incremental area under the curve (IAUC) of blood glucose was significantly lower for diabetic formula 1 than for the glucose solution. Our clinical results showed that diabetic formula 1 had a low GI at 16.5 ± 7.6. For satisfaction, although every aspect of the visual analogue scale had a passing grade (>50), subjects rated 'poor' for the diabetic formula 1 in terms of taste, aftertaste and palatability. Therefore, the diabetic formula 1 needs further development to raise consumer acceptance.

Key words: Glycemic Index, Diabetes-Specific Nutrition Formula, Satisfaction

Received: 7 September 2020 Accepted: 16 Febuary 2021 Available online: 7 April 2021

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บทความวิจัย

การตอบสนองของระดับน้ำตาลในเลือด และความพึงพอใจต่ออาหารทางการแพทย์สำหรับผู้ป่วยเบาหวาน: การศึกษาแบบสุ่มสลับไขว้ในคนปกติ

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บทคัดย่อ

งานวิจัยนี้เป็นการใช้ maltodextrin และ resistance maltodextrin ที่ผลิตจากมันสำปะหลังที่ปลูกในประเทศไทยเป็นส่วนผสมหลักของคาร์โบไฮเดรตในอาหารทางการแพทย์สำหรับผู้ป่วยเบาหวานชื่อว่า อาหารเบาหวานสูตร 1 ผลิตด้วยนวัตกรรมใหม่ของคนไทย การศึกษาครั้งนี้มีวัตถุประสงค์เพื่อวิเคราะห์ค่าดัชนีน้ำตาลและความพึงพอใจของผู้บริโภคต่ออาหารเบาหวานสูตร 1 ในอาสาสมัครสุขภาพดี 12 คนโดยศึกษาแบบสุ่มสลับไขว้ อาสาสมัครดื่มอาหารเบาหวานสูตร 1 และสารละลายกลูโคส (สารละลายอ้างอิง) โดยมีคาร์โบไฮเดรต 50 กรัมเท่ากัน หลังบริโภคทำการเก็บตัวอย่างเลือดเป็นระยะตลอด 2 ชั่วโมง และประเมินความพึงพอใจต่ออาหารเบาหวานสูตร 1 ด้วยแบบทดสอบ Visual Analog Scale ผลการศึกษาพบว่า ระดับน้ำตาลในเลือดหลังดื่มอาหารเบาหวานสูตร 1 เพิ่มสูงขึ้นจากระดับน้ำตาลขณะอดอาหารแต่ต่ำกว่าของสารละลายกลูโคสอย่างมีนัยสำคัญตั้งแต่นาทีที่ 15 ถึงนาทีที่ 90 โดยมีพื้นที่ใต้กราฟที่เพิ่มขึ้นของระดับน้ำตาลในเลือดต่ำกว่าสารละลายกลูโคสอย่างมีนัยสำคัญ ผลการศึกษาทางคลินิกพบว่า อาหารเบาหวานสูตร 1 มีค่าดัชนีน้ำตาลต่ำเท่ากับ 16.5 ± 7.6 สำหรับคะแนนความพึงพอใจ แม้ว่าทุกด้านจะมีคะแนนผ่านเกณฑ์ (> 50) แต่มีกลุ่มตัวอย่างบางคนให้คะแนนระดับต่ำต่อรสชาติ รสชาติคงค้างในลำคอ และความอร่อย ซึ่งเป็นปัจจัยสำคัญ ดังนั้นจึงต้องพัฒนาอาหารเบาหวานสูตร 1 ต่อไปเพื่อให้ได้รับการยอมรับจากผู้บริโภคมากที่สุด

คำสำคัญ: ค่าดัชนีน้ำตาล, อาหารทางการแพทย์สำหรับผู้ป่วยเบาหวาน, การประเมินความพึงพอใจ

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Introduction

Glycemic Index (GI) is used to classify different foods that elicit varying degrees of postprandial blood glucose. It is defined as the incremental area under the curve (IAUC) thru 2 hours of glucose response after consuming a test food compared to the corresponding IAUC after consuming a carbohydrate-equivalent amount of a reference food (glucose or white bread)[1]. GI can be classified into 3 categories: low (GI $\leq$ 55), medium (GI 55-69), and high (GI $\geq$ 70) relative to pure glucose (GI = 100).

The American Diabetes Association (ADA) (2018)[2] recommends that Type 2 diabetes mellitus (T2DM) patients choose carbohydrates with low glycemic index (GI) and low glycemic load (GL). Many studies have shown that carbohydrate consumption entailing low GI and GL led to HbA1C reductions of –0.2% to –0.5%[3, 4] and to reducing DM-associated complications[5]. Komindr et al.[6] showed that long-term consumption of a low GI diet during diet control, without increasing fiber intake, could improve diabetic control and protein conservation in Type 2 diabetes. Moreover, a low GI diet is believed to help increase satiety and weight loss, improve lipid profiles, and possibly improve insulin sensitivity[7]. Careful glycemic control can reduce DM-associated complications[8, 9]. Consequently, to improve outcomes in terms of postprandial blood glucose and HbA1c, there is significant interest in developing enteral nutrition (EN) formulae specifically designed for patients with hyperglycemia or DM[10].

A systematic review of 19 randomized controlled trials (RCTs), 3 nonrandomized controlled clinical trials (CCTs), and 1 before-after clinical trial revealed that the use of diabetes-specific oral nutrition supports (ONSs) or enteral tube feeding (ETF) consistently resulted in significantly lower postprandial blood glucose, peak blood glucose concentrations, and AUC compared to a standard formula among diabetic patients[11] without evidence of hypoglycemia. This finding suggests that glycemic control may be facilitated by using diabetes-specific enteral formulas compared to standard formulas. A new diabetes-specific nutrition formula with low GI and complete nutrients has been recently developed for diabetic patients, those with impaired fasting glucose or tube feeding, as well as consumers with health concerns. Importantly, its source of dietary fiber from maltodextrin and resistance maltodextrin is derived from tapioca planted in Thailand and employing a Thai innovation.

This study evaluated postprandial blood glucose response between the new diabetes-specific nutrition formula, known as diabetic formula 1 (**Table 1**), and a glucose solution as reference, followed by calculation of the formula's GI, and an evaluation of satisfaction of the formula among healthy adults.

Table 1 Nutrient contents per total serving per day of the new diabetes-specific enteral formula (diabetic formula 1), compared to Thai Recommended Daily Intakes (Thai RDI) 2006 and USDA 2010 dietary guidelines

Nutrients and unit		Guideline RDI	UL		Diabetic formula 1 (1000 mL)	
		Thai RDI 2006	Thai 2006	US 2010	Amount	%Thai RDI
Powder	g	-	-	-	298.8	-
Energy (per 1000 mL, conc. 1.5 kcal/mL)	Kcal	2000	-	-	1500	75
% Distribution of Carbohydrate	%	60	-	-	31.7	
% Distribution of Protein	%	10	-	-	22.4	
% Distribution of Fat	%	30	-	-	45.9	
Protein	g	50	-	-	84	168
Total fat	g	65	-	-	76.5	117.7
Total carbohydrate	g	300	-	-	118.9	39.6
Fructo-oligosaccharide	g	-	-	-	21.2	
Dietary fiber	g	25	-	-		
M – Inositol	mg	-	-	-	861.6	
Taurine	mg	-	-	-	138.6	
L – carnitine	mg	-	-	-	178.4	
Vitamins:						
Total Vitamin A	IU	2664	-	9990	7882.5	295.9
Vitamin D	IU	200	4000	4000	351.7	175.8
Vitamin E	IU	15	-	1000	39.7	264.9
Vitamin K	µg	80	-	-	122.5	153.1
Vitamin C	mg	60	2000	2000	265.0	441.7
Folic acid	µg	200	-	1000	326.3	163.1

Table 1 Nutrient contents per total serving per day of the new diabetes-specific enteral formula (diabetic formula 1), compared to Thai Recommended Daily Intakes (Thai RDI) 2006 and USDA 2010 dietary guidelines (continued)

Nutrients and unit		Guideline RDI	UL		Diabetic formula 1 (1000 mL)	
		Thai RDI 2006	Thai 2006	US 2010	Amount	%Thai RDI
Thiamine (Vitamin B1)	mg	1.5	-	-	1.5	99.6
Riboflavin (Vitamin B2)	mg	1.7	-	-	1.5	87.9
Vitamin B6	mg	2	-	100	1.5	74.7
Vitamin B12	µg	2	-	-	4.8	239.0
Niacin	mg	20	-	35	16.4	82.2
Choline	mg	-	-	3500	448.8	-
Biotin	µg	150	-	-	244.7	163.1
Pantothenic acid	mg	6	-	-	8.1	134.5
Minerals:						
Sodium	mg	2400	2400	2300	1131.9	47.2
Potassium	mg	3500	-	-	2059.9	58.9
Chloride	mg	3400	-	3600	1305.2	38.4
Calcium	mg	800	2500	2000	815.7	101.9
Phosphorus	mg	800	-	4000	815.7	101.9
Magnesium	mg	350	-	350	326.3	93.2
Iodine	µg	150	-	1100	122.5	81.7
Manganese	mg	3.5	-	11	1.5	42.7
Copper	mg	2	-	10	16.4	821.7
Zinc	mg	15	-	40	12.3	81.7
Iron	mg	15	-	45	15.2	101.6
Selenium	µg	70	-	400	57.1	81.5
Chromium	µg	130	-	-	163.1	125.5
Molybdenum	µg	160	-	2000	61.3	38.3

Materials and methods

Subjects: A randomized crossover study design with 1 week wash-out period was conducted among 12 healthy subjects based on the recommendation of WHO/FAO[12]. The inclusion criteria for healthy individuals were: age between 20 - 70 years old; body mass index between 18.5 - 22.9 kg/m^2; normal blood test results for glucose, lipid profiles, liver and renal functions; and no consumption of supplemental vitamins, minerals or any other supplements. Subjects who were allergic to cow's milk protein or who habitually smoked were excluded. The study protocol was approved by the Ethical Clearance Committee on Human Rights Related to Researchers Involving Human Subjects, Faculty of Medicine at Ramathibodi Hospital, Bangkok, Thailand.

Test food: Weight and nutrient contents of diabetic formula 1 and the glucose solution are shown in **Table 2**.

Table 2 Weight and nutrient contents of 50-gram available carbohydrate portions of test foods

Test food	Portion size (g)	Energy (kcal)	Protein (g)	Fat (g)	Available carbohydrate (g)	Sugar (g)	Fiber (g)
Reference food (glucose solution)	50 g glucose 150 mL	200	0.0	0.0	**50.0**	50.0	0.0
Dibetic formula 1 (1.5 kcal/mL)	126.2 g powder 430 mL	638.87	36.03	32.75	**50.0**	-	5.88

Experimental procedures: All study participants were advised to consume a weight maintaining diet for diabetic patients and strictly maintain their normal activities 2 weeks prior to the study and throughout the study. On the day before the testing day, they were requested to consume a standard menu of their own choice. Study participants were asked to have their meals as usual and then fast overnight for between 8 – 10 hours. The subjects were also requested to record their dietary intakes for 2 days before the test day. Thereafter, their records were recalled and assessed on the test day to adjust their intakes. On the morning of the test day, the subjects arrived at around 7 – 8 a.m. They were given 10 minutes to rest prior to the beginning of the study's procedures. Body composition, weight, height and blood pressure were assessed before blood collection. Venous blood samples of approximately 10 mL were drawn from each participants. The study participants were then randomly assigned to either a reference food or a test food together with 150 mL of water to consume within 10 minutes. After consumption, 10 mL blood samples were drawn again at 15, 30, 45, 60, 90, and 120 minutes.

Anthropometric and blood pressure assessments: Height, weight, body composition, and blood pressure assessments were carried out at every visit. Height was asked from the subject. Weight and body composition, consisting of percent of body fat, percent of total body water, muscle mass, and the visceral fat rating, were measured using body composition monitor Model: TANITA BC-543, TANITA England. Body mass index (BMI) was calculated as weight in kilograms divided by the square of height in meters. Blood pressure, consisting of systolic blood pressure, diastolic blood pressure, and pulse, was measured by using 3 Series® Upper Arm Blood Pressure Monitor, Model: BP7100, OMRON Healthcare.

Laboratory testing: All laboratory tests were analyzed at National Healthcare Systems Co., Ltd. (N Health), Bangkok, Thailand. Plasma glucose, blood Urea Nitrogen (BUN), creatinine (plus eGFR), cholesterol, triglyceride, HDL- and LDL- cholesterol, aspartate aminotransferase (AST), and alanine aminotransferase (ALT) were determined by the automated Alinity m Instrument, Abbott Molecular. Complete Blood Count was determined by Sysmex XN-1000™ Hematology Analyzer.

Satisfaction testing: Subjects were requested to assess their satisfaction after consuming the diabetic formula 1 using a validated Visual Analog Scale (VAS)[13]. The VAS, 100 mm in length with words anchored at each end, expressed the most positive (100) and the most negative (0) rating with a score of 50 being considered as a "passing grade"[14]. Each measurement was thoroughly explained by a researcher. Thereafter, each subject marked the line based on their senses. Satisfaction testing aimed to assess product acceptance, including texture, smell, taste, aftertaste and palatability after diabetic formula 1 consumption.

Statistical analysis: Statistical analysis was performed using SPSS for Windows, Version 18 (SPSS Inc., 2004 Chicago, USA). All data were analyzed for normal distribution by Kolmogorov-Smirnova test. The results were expressed as mean ± SD. The comparison of postprandial plasma glucose (PPG) between time points was analyzed by repeated-measures ANOVA. The incremental area under the curve (IAUC) of blood glucose was compared by paired student t-test. The difference was considered statistically significant if p-value <0.05.

Results and discussion

Twelve healthy subjects (8 males and 4 females) were recruited. Their mean values (± SD) for age, body mass index, and fasting plasma glucose were 23.7 ± 4.2 yrs, 21.4 ± 1.8 kg/m^2, and 78.5 ± 6.6 mg/dL, respectively. Their mean values for lipid profile, liver and renal functions were in the normal range. No adverse events or protocol deviations were reported (**Table 3**). Mean levels of PPG after consuming diabetic formula 1 and the glucose solution both increased from fasting levels. However, diabetic formula 1 had significantly lower mean values for postprandial plasma

glucose (PPG) than the glucose solution starting from 15 through 90 minutes (**Table 4**). Furthermore, no individual subject showed any sign of hypoglycemia. **Figure 1** shows the mean changes in plasma glucose concentrations from fasting baseline concentrations for both test foods. Results shown in **Table 4** indicate that the diabetic formula 1 had significantly lower IAUC glucose response compared to the glucose solution. Our clinical study also revealed that the diabetic formula 1 had a low GI at 16.5 ± 7.6. This result could be explained by the properties of this product. According to starch digestibility, 60% of carbohydrate was comprised of resistant maltodextrin (Cal-DM) from Thai cassava plants, scFOS, fructose, maltitol, and isomaltulose, which are slowly digestible carbohydrates (SDC). This results in prolonged glucose release from the lumen of the small intestine into the blood stream, with blunted glycaemia and, therefore, a lower insulin requirement[15]. Our study's result is similar to that of Gourineni et al., 2019[16]. They compared glycemic response of SDC (SUSTRA^{TM} 2434 slowly digestible carbohydrate from tapioca flour and corn starch) in water, SCD drink-mix powder reconstituted in skim milk, a control drink-mix reconstituted in skim milk (without SDC), and dextrose in water (placebo), all of which contained 50 grams of carbohydrate for 14 healthy subjects. They found that SDC and SDC drink-mix had low GI (27.0 and 30.0 respectively). A meta-analysis and systematic review of randomized control trial (RCT) demonstrated positive effects of low GI diet on fasting blood glucose (FBG) and HbA1c (short-term and long-term biomarker of glucose metabolism, respectively) in T2DM[17]. Moreover, diabetic formula 1 had complete nutrients and micronutrients in accordance with Thai RDI, which can help to maintain organ systems. Hence, the diabetic formula 1 has a potential to benefit T2DM and obese patients, as it demonstrated a lower GI.

Satisfaction testing entailed 5 questions on texture, smell, taste, aftertaste, and palatability with a grade of 50 being considered as "passing"[14]. The recommendation for sensory testing was that 1 to 18 subjects should be used for an effective acceptance test[18]. In the present study, the acceptance test was performed with all study participants (n = 12). The satisfaction scores for diabetic formula 1 assessed by VAS scales, including texture, smell, taste, aftertaste, and palatability were 62.8 ± 23.7, 63.5 ± 17.3, 54.8 ± 31.3, 52.0 ± 26.4 and 52.1 ± 30.6, respectively. However, some participants rated the diabetic formula 1 as 'poor', in terms of taste (16.7%), aftertaste (8.3%) and palatability (25%), which are important factors. Their comments included that the formula's texture and taste were powdery and not very sweet and giving a greasy feeling during drinking (**Tables 5 and 6**). Hence, diabetic formula 1 should be further developed to improve satisfaction and then be evaluated in healthy and T2DM patients in the future.

Table 3 Baseline characteristics of study participants (n=12)

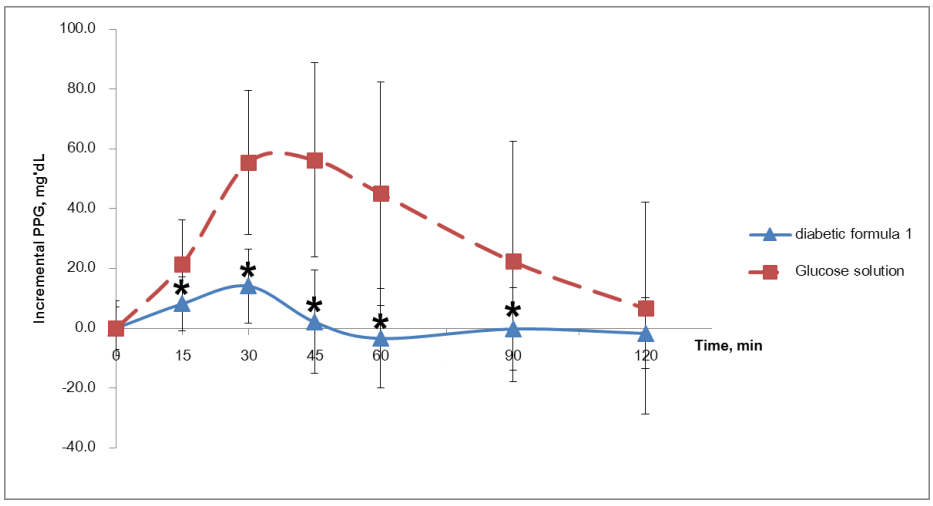
Parameters	Mean ± SD	Normal range
Sex (Males : Females)	8 : 4	-
Age (yrs)	23.7 ± 4.2 *	-
Body Mass Index (BMI) (kg/m^2)	21.4 ± 1.8	18.5 – 22.9
% Body Fat (%)	17.6 ± 4.8	M 15-25, F24-36
% Total Body Water (TBW) (%)	59.9 ± 4.8	-
Muscle mass (kg)	49.1 ± 10.6	-
Visceral fat rating	3.8 ± 2.6	$\leq$ 12
Systolic blood pressure (mmHg)	110.9 ± 10.5	< 120
Diastolic blood pressure (mmHg)	71.5 ± 9.8	< 80
Pulse (beats/min)	83.5 ± 5.9	-
Fasting blood glucose (mg/dL)	78.5 ± 6.6	70 - 99
Hemoglobin (g/dL)	14.4 ± 1.7	M 14-18, F 12-15
Blood Urea Nitrogen (BUN) (mg/dL)	12.4 ± 2.9	8 - 23
Creatinine (mg/dL)	1.0 ± 0.2	M 0.7-1.2, F 0.5-0.9
eGFR (mL/min/1.73^2) (Thai)	109.0 ± 12.4	$\geq$ 90
Total cholesterols (mg/dL)	178.6 ± 26.6	< 200
High Density Lipoprotein – cholesterol (HDL-c) (mg/dL)	57.2 ± 10.6	> 50
Low Density Lipoprotein – cholesterol (LDL-c) (mg/dL)	118.9 ± 23.3	< 130
Triglyceride (mg/dL)	85.0 ± 47.3	< 150
Aspartate Aminotransferas (AST) (U/L)	21.4 ± 7.8	0 – 32
Alanine Aminotransferase (ALT) (U/L)	18.8 ± 9.5	0 – 33

* Means ± SD

Table 4 Postprandial Glucose Response, (mg/dL) in 12 healthy subjects consuming the new diabetics-specific enteral formula (diabetic formula 1) and a glucose solution (reference food)

Glucose Response	Test Food			
	Glucose solution		Formula 1	
	Mean	SD	Mean	SD
Time (min):				
0	82.9	7.0	83.0	9.3
15	103.1	14.8	90.2*	9.0
30	138.4	24.1	97.3*	12.3
45	142.6	32.4	86.9*	17.3
60	133.3	37.4	81.3*	16.6
90	111.1	40.3	84.3*	13.8
120	93.8	35.4	83.5	11.8
IAUC-glucose (mg.min/dL)	4338.3	2616.2	672.7*	445.2
Glycemic index (GI)	100	-	16.5	7.6

* Significantly different from glucose solution at the same time point by independent t-test, p<0.05



* Significantly different from glucose solution at the same time point by independent t-test, p<0.05

Figure 1 Plasma glucose concentration at various times from fasting baseline until 120 min after consuming the new diabetes-specific nutrition formula known as diabetic formula 1 and a glucose solution in healthy subjects (n=12).

Table 5 Satisfaction scores of 12 healthy subjects after consuming the new diabetics-specific enteral formula (diabetic formula 1) using Visual Analog Scale (VAS) score

Parameters	Score (mean ± SD)	Level of score (n (%))				
		Poor (0-20)	Fair (20.1-40)	Average (40.1-60)	Good (60.1-80)	Excellent (80.1-100)
1. Texture	62.8 ± 23.7	0	3 (25)	3 (25)	2 (16.7)	**4 (33.3)**
2. Smell	63.5 ± 17.3	0	1 (8.3)	**5 (41.7)**	4 (33.3)	2 (16.7)
3. Taste	54.8 ± 31.1	2 (16.7)	3 (25)	2 (16.7)	1 (8.3)	**4 (33.3)**
4. Aftertaste	52.0 ± 26.4	1 (8.3)	4 (33.3)	2 (16.7)	4 (33.3)	1 (8.3)
5. Palatability	52.1 ± 30.6	3 (25)	1 (8.3)	1 (8.3)	**5 (41.7)**	2 (16.7)

VAS (0-100): Score " 0 " expressed the most negative, Score " 100 " expressed the most positive

Table 6 Participant's comments on satisfaction of the new diabetics-specific enteral formula (diabetic formula 1)

Parameters	Comments
1. Texture	- The appearance of the food looks a bit coarse, unlike fine milk. - Feels too powdery, like eating flour stirred with water. The texture is not very fine. - Feeling like there is powder in the throat which makes it difficult to swallow
2. Smell	The smell of good food.
3. Taste	- Too sweet, feeling greasy when drinking. Should adjust the taste to be less sweet. - Feels the taste was like spoiled soybean milk.
4. Aftertaste	There is bitterness in the mouth and throat.
5. Palatability	No comment

Conclusions

This study showed that diabetic formula 1 had significantly lower mean values of postprandial plasma glucose than a glucose solution starting from 15 through 90 minutes, smaller incremental area under the curve of glucose through 2 hours. The glycemic index of diabetic formula 1 was 16.5 and satisfaction score was 52. However, some study participants

rated the diet as poor (25.0%), fair (8.3%), and average (8.3%). Since texture and taste are important attributes, diabetic formula 1 should be further developed to increase consumer acceptance. Further development should focus on the formula's texture and taste, and then be reevaluated in both healthy and T2DM individuals for acceptability.

Acknowledgement

The author gratefully acknowledges STEM (Science, Technology, Engineering, and Mathematics), (NSTADA) 2017 and NIA for supporting research funds.

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