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Factors contributing to urinary aflatoxin M_1 occurrence among residents in Hulu Langat district, Malaysia

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ABSTRACT

Introduction: Chronic exposure to aflatoxin can lead to complications such as liver failure and cancer. There are many factors that affect aflatoxin occurrence. This study aimed to assess the association between sociodemographic factors and the knowledge, attitude and practice towards aflatoxin with urinary aflatoxin M_1 occurrence among residents in Hulu Langat district, Malaysia. **Methods:** This was a cross-sectional study conducted among healthy Malaysian adults aged 18 to 60 years residing in Hulu Langat district, Malaysia. Socio-demographic background and the knowledge, attitude and practice of respondents towards aflatoxin were assessed through questionnaires. Non-fasting urine sample (15 ml) was collected in the morning and urinary aflatoxin M_1 level was quantified. **Results:** Of the 444 healthy Malaysian adults, 199 urine samples were detected with aflatoxin M_1. From 37 positive samples with aflatoxin M_1 level above detection limit (0.64 ng/ml), mean value was 1.23±0.91 ng/ml (range = 0.65-5.34 ng/ml). Urinary aflatoxin M_1 occurrence was significantly different across ethnicity, age group, monthly household income, attitude and practice towards aflatoxin. Binomial logistic regression confirmed ethnicity and monthly household income as factors contributing to urinary aflatoxin M_1 occurrence. Chinese were 3.20 times more likely to have aflatoxin exposure than non-Chinese. Detected urinary aflatoxin M_1 was more common among household with a monthly income above RM1,500. **Conclusion:** The results provided an insight to explain the variation in aflatoxin occurrence among the population.

Keywords: aflatoxin, attitude, ethnicity, household income, practice

INTRODUCTION

Aflatoxins are highly toxic secondary metabolites produced by the *Aspergillus* species fungi (Reddy, Farhana & Salleh, 2011). They are mainly present in foods, including grains, nuts and legumes,

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eggs, and dairy products, which are not properly stored. This toxic compound produced by fungi and moulds are chemically stable and unable to be destroyed through food processing (Bezerra da Rocha *et al.*, 2014). Chronic exposure to aflatoxin can lead to aflatoxicosis and cause serious health threats, such as hepatic cirrhosis and carcinoma, as reported in Asia and Africa (Bosetti, Turati & La Vecchia, 2014).

Storage, environmental and ecological conditions are the main contributors to the growth and development of fungus in foods and feeds (Hussein & Brasel, 2001). Warm and humid climates prevailing in the tropical and sub-tropical developing countries have been shown to favour the production of aflatoxin by fungus (Leong *et al.*, 2011). As one of the countries that experiences tropical climate (Abdullah, Nawawi & Othman, 1998), Malaysia has a higher risk of experiencing aflatoxicosis if storage and production process of foods and feeds are poorly managed.

The outbreak of aflatoxicosis in Malaysia was first recorded in 1960, whereby over 50 pigs from two farms in Malacca died upon consuming aflatoxin-contaminated feeds (Lim & Yeap, 1966). In October 1988, 13 children of Chinese ethnicity aged 2.5-11 years died of acute hepatic encephalopathy in Perak, Malaysia. The deaths of these children were confirmed due to the intake of a type of Chinese noodle, *Loh See Fun*, which had been contaminated by aflatoxin (Lye *et al.*, 1995). Based on existing data, dietary aflatoxin exposure may contribute up to 17.3% towards liver cancer occurrence in Malaysia (Chin, Abdullah & Sugita-Konishi, 2012). Although the figure may not seem big, its potential adverse effects cannot be ignored.

Aflatoxin M_1 (AFM_1) is a sensitive biomarker of human exposure to aflatoxins since it can be detected in urine sample (Jager *et al.*, 2016). With a biological half-life of about one day, the urinary excretion of AFM_1 reflects the actual dietary aflatoxin exposure for the past 1-2 days (Cheng *et al.*, 1997; Kensler *et al.*, 2010). It has been widely used to monitor aflatoxin exposure among various populations including children, lactating women, and the general population (Ali *et al.*, 2017; Chen *et al.*, 2018; Gebreegziabher, Tsegaye & Stoecker, 2016). In the liver, AFM_1 is metabolised from aflatoxin B_1 (Marchese *et al.*, 2018), which is the most toxic aflatoxin and of greatest significance (Pearce *et al.*, 2015). However, the potency of AFM_1 is only approximately one order of magnitude lower than that of AFB_1 (Prandini *et al.*, 2009).

Several factors have been shown to affect aflatoxin level in humans. For example, a field study conducted among rural Ghanaians reported significant associations between education level, ethic group, and number of households with AFB_1-albumin level (Jolly *et al.*, 2006). In Malaysia, Leong *et al.* (2012) found that Chinese and older people were more likely to be exposed to aflatoxin. The current study previously demonstrated that the consumption of eggs and dairy products were positively associated with urinary AFM_1 (Siti Husna, Rosita & Mohd Redzwan, 2018). However, the relationships between factors such as knowledge, attitude, and practice (KAP) with aflatoxin that may lead to the increase in urinary AFM_1 occurrence have not been thoroughly examined. In this paper, we explored the associations between sociodemographic factors and KAP towards aflatoxin with urinary AFM_1 occurrence among residents in Hulu Langat district, Malaysia.

MATERIALS AND METHODS

Study design and population

This was a cross-sectional study conducted among adults aged 18 to 60

years residing in six subdistricts of Hulu Langat, Malaysia, including Beranang, Cheras, Hulu Langat, Hulu Semenyih, Semenyih, and Kajang. Ethical approval was granted by the Ethics Committee for Research Involving Human Subjects, Universiti Putra Malaysia (JKEUPM) (Project number: FPSK (EXP16) P047). Written informed consent was obtained from respondents prior to the study. Respondents were required to complete a set of questionnaires. A non-fasting urine sample was collected in the morning and stored at -80˚C until further analysis.

Respondents were recruited using multistage sampling design. In the first stage, all subdistricts within Hulu Langat were divided into three categories based on their development status (countryside, developing, and developed areas). In the second stage, systematic random sampling was applied to select 2-8 residential areas from each category. Lastly, residents of the selected residential areas were randomly approached and screened to recruit for eligible respondents in the study.

There were 455 out of 468 respondents who met the following inclusion criteria: (1) in good health; (2) not taking any medications or supplements; (3) not smoking; (4) not following a restricted diet; and (5) not pregnant and not in postpartum period. Eleven respondents were further excluded from the study due to missing questionnaires (n=5), out of age range (n=2), and unreturned urine containers (n=4). Thus, the response rate of this study was 94.9%.

Socio-demographic factors

Socio-demographic factors including gender, age, education level, marital status, monthly personal income, and monthly household income were assessed via a self-administered close-ended questionnaire.

KAP towards aflatoxin

The KAP towards aflatoxin and its contamination in foods and feeds were assessed using a questionnaire adapted from a Ghanaian study (Jolly *et al.*, 2006). Prior to data collection, pre-testing was carried out on 31 respondents from Serdang, Selangor who met the inclusion and exclusion criteria. Based on pre-testing results, all the questions from Jolly *et al.* (2006) were retained.

The knowledge domain consisted of eight multiple choice items. Each item provided 'correct', 'wrong', and 'do not know' options. Each 'correct' answer was scored one, whereas 'wrong' and 'do not know' scored zero. The total score of knowledge ranged from 0 to 8. The cut-off value was determined based on the calculated median value to classify knowledge level into low (≤1.00) and high (>1.00).

There were four items in the attitude domain, defined as respondent's awareness and belief towards aflatoxin and its contamination in foods and feeds. The degree of agreement was indicated based on a four Likert scale (1=strongly disagree, 2=disagree, 3=agree, 4=strongly agree), with a total score ranging from 4 to 16. The median value calculated statistically was used as a cut-off point to differentiate negative (≤11.00) and positive (>11.00) attitudes.

A total of five items was listed in the practice domain focusing on the practices in gaining information related to aflatoxin and controlling aflatoxin contamination in food products. Respondents were asked to describe the frequency of experiencing the listed situations based on five categories: 1=never, 2=seldom, 3=sometimes, 4=frequently, 5=always. Only one question *'I avoid buying expensive food products to save money'* had reverse scoring as it was a negative statement. The total scores ranged from

5 to 25 and it was classified into poor (≤13.00) and good (>13.00) practices.

Urinary AFM_1 analysis

The analysis of urinary AFM_1 has been described previously (Siti Husna *et al.*, 2018). Briefly, morning urine samples (15 ml) were collected and kept frozen at -80˚C until further analysis. Prior to the analysis, urine samples were centrifuged at 3000×*g* for five minutes and supernatants were collected. The AFM_1 level was quantified using Helica Aflatoxin M_1 ELISA kit (Helica Biosystem, Inc., Santa Ana, CA). The absorbance was measured at 450 nm using a microplate reader (SIRIO S Microplate Reader, RADIM, Italy). The limit of detection was 0.064 ng/ml and the recovery range was 73.0% to 88.0%. The concentration of urinary AFM_1 was corrected for variations in urine dilution among individual samples and expressed in ng/ml.

Statistical analysis

Data were analysed using IBM SPSS Statistics version 22. Non-parametric tests were used since data were not normally distributed. Chi-square test for association was carried out to determine the relationships between independent variables and urinary AFM_1 occurrence; whereas binomial logistic regression was run to identify the possible predictors that were found to be significant in bivariate analysis. Statistical significance was set at $p<0.05$.

RESULTS

Urinary AFM_1 level

Table 1 describes the urinary AFM_1 level of respondents. Of the 444 urine samples, 44.8% (n=199) had detectable urinary AFM_1 biomarker, which was an AFM_1 concentration of >0. From the positive samples, only 37 samples (18.6%) contained a urinary AFM_1 level above the detection limit of 0.64 ng/ml. Data from these 37 samples were further analysed. Urinary AFM_1 level of respondents ranged from 0.65 to 5.34 ng/ml, with a mean of 1.23±0.91 ng/ml and median of 0.89 ng/ml.

Table 1. Descriptive statistics of urinary AFM_1 level among respondents (n=37)

	Urinary AFM_1 level (ng/ml)
Mean±standard deviation	1.23±0.91
Median	0.89
Range	0.65 – 5.34
Percentile	
25th	0.76
50th	0.89
75th	1.20
95th	3.19

Associations between sociodemographic factors and urinary AFM_1 occurrence

When sociodemographic factors were examined based on the presence or absence of urinary AFM_1 biomarker, the biomarker was significantly different across ethnicity, age, and monthly household income (Table 2). However, no significant difference was found between urinary AFM_1 level with gender, marital status, education level, and monthly personal income. Respondents of Chinese ethnicity had a higher urinary AFM_1 occurrence compared to non-Chinese. More respondents aged 18 to 24 years had detectable urinary AFM_1 level, but the effect size of the association was small with a *Phi* value of 0.09. Those who had a household income of >RM1,500 monthly were more likely to have detectable urinary AFM_1 biomarker as compared to those with ≤RM1,500 in monthly household income.

Table 2. Associations between sociodemographic factors and urinary AFM_1 occurrence among respondents (n=444)

Sociodemographic factors	*AFM₁, n (%)*		*χ²*	*Phi*	*p-value*
	Positive	*Negative*			
Gender			0.06	0.01	0.81
Male	90 (45.5)	108 (54.5)			
Female	109 (44.3)	137 (55.7)			
Marital status			1.69	0.06	0.19
Single/ divorce/ others	153 (46.6)	175 (53.4)			
Married	46 (39.7)	70 (60.3)			
Ethnicity			56.77	0.36	0.01**
Chinese	134 (63.5)	77 (36.5)			
Non-Chinese	65 (27.9)	168 (72.1)			
Age group†			3.92	0.09	0.05*
18 - 24 years old	113 (49.3)	116 (50.7)			
25 - 60 years old	86 (40.0)	129 (60.0)			
Education level			0.25	-0.02	0.62
None/ primary	51 (42.9)	68 (57.1)			
Secondary/ tertiary	148 (45.5)	177 (54.5)			
Monthly personal income‡			0.10	0.02	0.75
≤ RM1,500	136 (45.3)	164 (54.7)			
> RM1,500	63 (43.8)	81 (56.3)			
Monthly household income‡			32.70	-0.27	0.01**
≤ RM1,500	31 (23.8)	99 (76.2)			
> RM1,500	168 (53.5)	146 (46.5)			

*p<0.05; **p<0.01 from Chi-square test for association
†Classification of age based on median=24 years old
‡Classification of income based on Malaysian Economic Planning Unit (Malaysian Economic Planning Unit, 2012)

Associations between KAP towards aflatoxin with urinary AFM_1 occurrence

Significant differences were demonstrated between attitude and practice, instead of knowledge, towards aflatoxin with urinary AFM_1 occurrence as presented in Table 3. Regardless of education level, more than half of the respondents (52.0%) did not have knowledge about aflatoxins and were not aware of aflatoxin contamination in products. Similarly, less than half of the respondents had positive attitude (51.5%) and good practice (46.4%) in controlling aflatoxin contamination in their foods. Interestingly, the likelihood of having detected urinary AFM_1 was higher among those with positive attitude and good practice as compared with those with negative attitude and poor practice.

Binomial logistic regression model

A binomial logistic regression was performed to ascertain the effect of independent factors on the likelihood of having detectable urinary AFM_1 among respondents (Table 4). Based on the results, ethnicity and monthly household income were the independent variables contributing to aflatoxin occurrence in

Table 3. Associations between knowledge, attitude, and practice (KAP) towards aflatoxin and the occurrence of urinary AFM_1 biomarker among respondents (n=444)

Variables	*AFM_1, n (%)*		*χ^2*	*Phi*	*p-value*
	Positive	*Negative*			
Knowledge			3.32	-0.09	0.07
Low	94 (40.7)	137 (59.3)			
High	105 (49.3)	108 (50.7)			
Attitude			8.61	-0.14	<0.01**
Negative	81 (37.7)	134 (62.3)			
Positive	118 (51.5)	111 (48.5)			
Practice			4.99	0.05	0.03*
Poor	95 (39.9)	143 (60.1)			
Good	104 (50.5)	102 (49.5)			

*p<0.05; **p<0.01 from Chi-square test for association

urine. Indeed, ethnicity had the highest Wald's value, indicating it as the main predictor of aflatoxin occurrence among the respondents. Those of Chinese ethnicity were 3.20 times more likely to exhibit aflatoxin occurrence in urine as compared with non-Chinese. Higher monthly household income was also associated with an increased likelihood of exhibiting aflatoxin occurrence.

DISCUSSION

Malaysia is a multiracial and multi-religious Southeast Asian country with different cultures among the ethnic groups. Therefore, populations living in the country may have different food preferences and lifestyles, leading to different aflatoxin exposure. This study found that people of Chinese ethnicity were more likely to be exposed to aflatoxin as compared to non-Chinese, including Malay, Indian, and other smaller ethnic groups. This finding is consistent with a previous local study conducted by Leong *et al.* (2012), which showed a 3.05-fold higher risk of aflatoxin exposure among the Chinese as compared with other ethnicities. The observation is plausible as Chinese tend to have higher intakes of dairy products, nuts, and cereal-based foods, and these food commodities are at high risk of being contaminated with aflatoxin (Nurul Fadhilah, Teo & Foo, 2016). In fact, Leong *et al.* (2012) claimed that aflatoxin metabolism may be influenced by genetic characteristics that vary across ethnic groups. Future study should explore this hypothesis.

Table 4. Binomial logistic regression predicting independent factors with the occurrence of urinary AFM_1 biomarker among respondents (n=444)

Variables	*Exp B (95% CI)*	*Wald (df)*	*p-value*
Sociodemographic factors			
Ethnicity	3.20 (2.04-5.03)	25.57 (1)	0.01**
Monthly household income	0.32 (0.19-0.57)	15.39 (1)	0.01**
Knowledge	0.86 (0.54-1.37)	0.41 (1)	0.52
Attitude	0.68 (0.42-1.10)	2.42 (1)	0.12
Practice	0.73 (0.45-1.19)	1.59 (1)	0.21

*p<0.05; **p<0.01

It is of interest to note that people with a monthly household income of RM1,500 or less were more protected from aflatoxin exposure than those with >RM1,500. According to the Economic Planning Unit (2013), the average monthly income of the urban households was almost twice higher than that of rural families. Majority of the study areas covered in this study were urban areas. The lifestyle of the urban population is usually more hectic than in rural areas. As such, urban dwellers tend to practise eating-out (Noraziah & Mohd Azlan, 2017), which makes the exposure of aflatoxin harder to be controlled since foods are managed and prepared by external food handlers. Therefore, it is reasonable to postulate environmental and lifestyle factors as possible inter-related factors to aflatoxin occurrence.

The evidence of aflatoxin occurrence trending across different age groups remains controversial. The current results reported to have younger people aged 18 to 24 years experiencing aflatoxin occurrence more than older people aged 25 to 60 years. This is in line with findings from Mohd Redzwan, Rosita and Mohd Sokhini Abdul (2012), whereby respondents aged 35 years and below had slightly higher AFM_1 level than those aged 36 years and above. However, Leong *et al.* (2012) indicated a reverse trend as higher risk of aflatoxin exposure was observed among older age group of 31 to 50 years as compared with younger age group of 18 to 30 years. On the other hand, earlier research done by Sun *et al.* (1999) showed high aflatoxin occurrence among males aged 30 to 45 years. Aflatoxin metabolism is correlated with liver and kidney functions (Mohd Redzwan *et al.*, 2014). A deterioration in liver and kidney function due to ageing may affect the production of aflatoxin metabolites in human. It would be interesting to explore further on this observation.

There is no specific antidote discovered yet to overcome aflatoxicosis, thus it is important to create awareness about aflatoxin among the people in order to control its exposure to our body. However, the awareness of people is still below satisfactory level as the outbreak of aflatoxicosis is still reported around the world (Kamala *et al.*, 2018). Indeed, the present study demonstrated that majority of the respondents did not know about aflatoxin and had negative attitude and poor practice in controlling aflatoxin contamination of foods. To the best of our knowledge, the association between KAP towards aflatoxin and urinary AFM_1 occurrence has not been reported in the literature. Interestingly, the current results found that those with positive attitude and good practice towards aflatoxin were more likely to have detected urinary AFM_1 as compared to those with negative attitude and poor practice. However, it should be noted that the attitude- and practice-related questions were focused on preventing the procurement of aflatoxin-contaminated foods rather than food storage and handling at home. There is a likelihood that respondents had negative attitude and poor practice in food storage and handling at home that exposed them to mould and aflatoxin, leading to the presence of AFM_1 biomarker in their urine samples.

There are several limitations to this study. First, the measurement of AFM_1 biomarker in the urine only reflected aflatoxin exposure for the past 1-2 days (Kensler *et al.*, 2010). The biomarker level may vary from day to day depending on the dietary intake of individuals, thus it is not suitable for assessing long term exposure. Therefore, it is advisable to assess other aflatoxin biomarkers, such as serum aflatoxin B_1-lysine adduct, that

represents long term exposure (Kensler *et al.*, 2010). Besides, this study only covered the Hulu Langat district, which is only one part of the Selangor state in Malaysia. Therefore, the results cannot be generalised to the whole population.

CONCLUSION

Ethnicity and monthly household income were the major contributing factors to aflatoxin exposure in the present study. People of Chinese ethnicity were 3.20 times more likely to have aflatoxin exposure as compared to non-Chinese. An increase in household income was associated with the likelihood of exhibiting AFM_1 occurrence in urine. The findings are believed to be useful in explaining the variations in aflatoxin exposure among the population of this country.

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Authors' contributions

SHS, conducted the study, data analysis and interpretation; CWL, reviewed the study and prepared the draft of the manuscript; RJ, principal investigator, conceptualised the study and reviewed the manuscript; MRS, co-supervised the study.

Conflict of interest

The authors declare that there is no conflict of interest.

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Content identification for the development of a nutrition resource kit for malnourished and at-risk elderly: A review

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ABSTRACT

Introduction: Elderly population is more likely to suffer from malnutrition, thereby requiring appropriate nutrition education as part of nutrition intervention to overcome this issue. This review aims to identify content suitable for developing a nutrition resource kit that provides nutritional guidance to combat malnutrition among malnourished and at-risk elderly in health clinics setting, particularly in Malaysia. **Methods:** A literature search was conducted up to 15th December 2019 in four databases: PubMed, Scopus, COCHRANE, and ProQuest Health & Medical Collection. Potential literature on nutrition education, suitable dietary guidelines and existing educational materials for elderly in the community, in English and Malay languages, were searched to identify suitable content for the nutrition resource kit. All relevant documents were included based on inclusion and exclusion criteria. Data were extracted and analysed according to the PRISMA-ScR guidelines. **Results:** A total of 27 documents consisting of articles, printed materials and guidelines were included for analysis. Suitable content included information related to malnutrition such as definition, signs and symptoms, cause-consequences, and nutrition management, which included food plate, serving size, menu suggestion, examples of recipes, tips to increase energy and protein intakes through food or drink, texture modification, a guide to using oral nutritional supplements, tips for maintaining nutrient content in food and drink, tips to encourage to eat, and oral health. **Conclusion:** A nutrition resource kit tailored for malnourished and at-risk elderly would be a beneficial nutrition intervention. There is a need to incorporate these information in the development of a nutrition resource kit to improve their dietary intake.

Keywords: malnutrition, elderly, community, nutrition education, scoping review

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INTRODUCTION

The number of elderly worldwide continues to grow. According to United Nations estimates, the elderly population aged 60 years and above is expected to reach nearly 1.4 billion in 2030, 2.1 billion in 2050, and 3.1 billion in 2100 (United Nations, 2017). In Malaysia, recent data show that the percentage of Malaysian elderly increased from 6.5% in the year 2018 to 6.7% in the year 2019 (Department of Statistics Malaysia, 2019).

The elderly population is susceptible to suffering from malnutrition due to numerous factors, such as eating difficulties (Mann, Heuberger & Wong, 2013), depressive symptoms, poor functional status and lifestyle factors (Van Bokhorst-de van der Schueren *et al.*, 2013), as well as socioeconomic changes (Damiao *et al.*, 2017). The prevalence of malnutrition among the elderly differs according to the setting. A systematic review and meta-analysis of 240 studies by Cereda *et al.* (2016) reported a range of 3 to 29% for the prevalence of malnutrition among elderly in different types of settings. In the community, the pooled prevalence of high malnutrition risk across European countries was reported to be 8.5% using various malnutrition screening tools (Leij-Halfwerk *et al.*, 2019). Similarly, 1.3% to 36.3% and 25.3% to 48.5% of Malaysian elderly living in the community were found to be malnourished and at-risk, respectively, as reported in a systematic review by Zainudin *et al.* (2016). Meanwhile, 48% to 55% of hospitalised elderly were reportedly malnourished in Malaysia (Nur Fazimah, Sakinah & Rosminah, 2013).

In order to overcome this multifactorial issue, nutrition education is an important part of nutrition intervention to improve dietary intake. Nutrition experts are recommended to provide information and education to malnourished and at-risk elderly in order to enhance their nutritional awareness and knowledge (Volkert *et al.*, 2019). Thus, providing a nutrition resource kit tailored for them would be a useful form of nutrition education (Hamirudin *et al.*, 2014), which could directly improve the nutrition knowledge of the elderly population. Higgins and Barkley (2004) also mentioned that the use of printed and other educational materials is effective in increasing the awareness and knowledge of elderly. Additionally, studies globally and locally have demonstrated the use of nutrition resource in delivering nutritional guidance for the elderly (Schoberer *et al.*, 2018; Shahar *et al.*, 2012; Yahya *et al.*, 2020). However, these materials were not specifically made for the at-risk and malnourished elderly. They were developed for the general elderly population to prevent and overcome common nutritional problems among the elderly, including malnutrition. Hence, developing and providing a nutrition resource kit tailored specifically for the at-risk and malnourished elderly group is warranted to improve their nutritional status.

In view of this, the content or outline of the kit should be identified before proceeding to the proper development of a nutrition resource kit. To the best of our knowledge, there is still a lack of comprehensive content and discussion about suitable content that could be incorporated into a nutrition resource kit for malnourished and at-risk elderly. A comprehensive content is needed to ensure all the necessary and important information are included to improve the elderly's nutritional knowledge, dietary intake, and nutritional status. Hence, this scoping review aims to identify suitable content for future development of a nutrition resource kit

for malnourished and at-risk elderly who receive primary care services in the Malaysian health clinics setting. Appropriate and suitable information that could contribute to malnutrition prevention and management among the elderly are essential to improve their nutritional status and health outcomes.

MATERIALS AND METHODS

Data source

This scoping review employed the Preferred Reporting Items for Systematic and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR), which was performed up to 15th December 2019. Four online databases (PubMed, Scopus, COCHRANE, and ProQuest Health & Medical Collection) were searched with no restrictions on publication date to identify potential literature related to nutrition education for the elderly in community settings. In addition, a manual search was performed for suitable guidelines and educational materials to supplement the database search. A manual search can be described as an additional approach to database searches in order to identify additional documents for review (Vassar, Atakpo & Kash, 2016). The search terms used for this review are shown in Box 1.

Selection of studies

The study's inclusion and exclusion criteria were determined before the search. Studies included were the ones with (1) elderly aged 60 years old and above; (2) community setting; (3) documents written in English and Malay languages; and (4) full text only. Exclusion criteria included studies that involved (1) hospital setting; (2) medical conditions that required specific nutrition intervention; and (3) animal, nutrients or biomarkers studies. Articles that were not relevant to the specified criteria were excluded.

Data extraction, quality assessment, data synthesis and analysis

The author(s), title, year of publication, setting, study design, study objective, details of nutrition education, and findings were extracted from the reviewed studies. Selected relevant articles were further assessed for their level of evidence and study quality. The level of evidence was identified according to the rating scheme for Level of Research Evidence by Ackley *et al.* (2008), in which Level I is considered as the highest level of evidence consisting of systematic reviews and meta-analysis, while Level VII is the lowest level of evidence consisting of expert opinion or report. Providing information on the level of evidence would be beneficial for readers to prioritise these information.

Meanwhile, the study quality was determined by using the available study quality assessment tool and was

Box 1. Search terms used in the review

(malnutrition OR undernutrition OR undernourished OR malnourished) AND (elder* OR geriatric OR senior* OR "older adult*" OR "old* people" OR aging OR ageing) NOT (children OR youth OR infant* OR pediatric OR paediatric OR adolescent*) AND community OR "health clinic*" OR clinic* OR outpatient OR "primary care" OR "general practice") NOT (ward* OR inpatient OR hospital*) AND ("diet* education" OR "nutrition* education" OR education* OR "health education" OR "food guide" OR "health promotion" OR "education* module*" OR "health information" OR "education* model*" OR "nutrition* module*" OR "nutrition* resource*" OR "nutrition* education* package*")

rated as good, fair or poor based on the judgement of two researchers. Two researchers independently assessed the study quality, and any inconsistency was resolved through discussion and agreement with other researchers. For cross-sectional and controlled intervention studies, the National Heart,

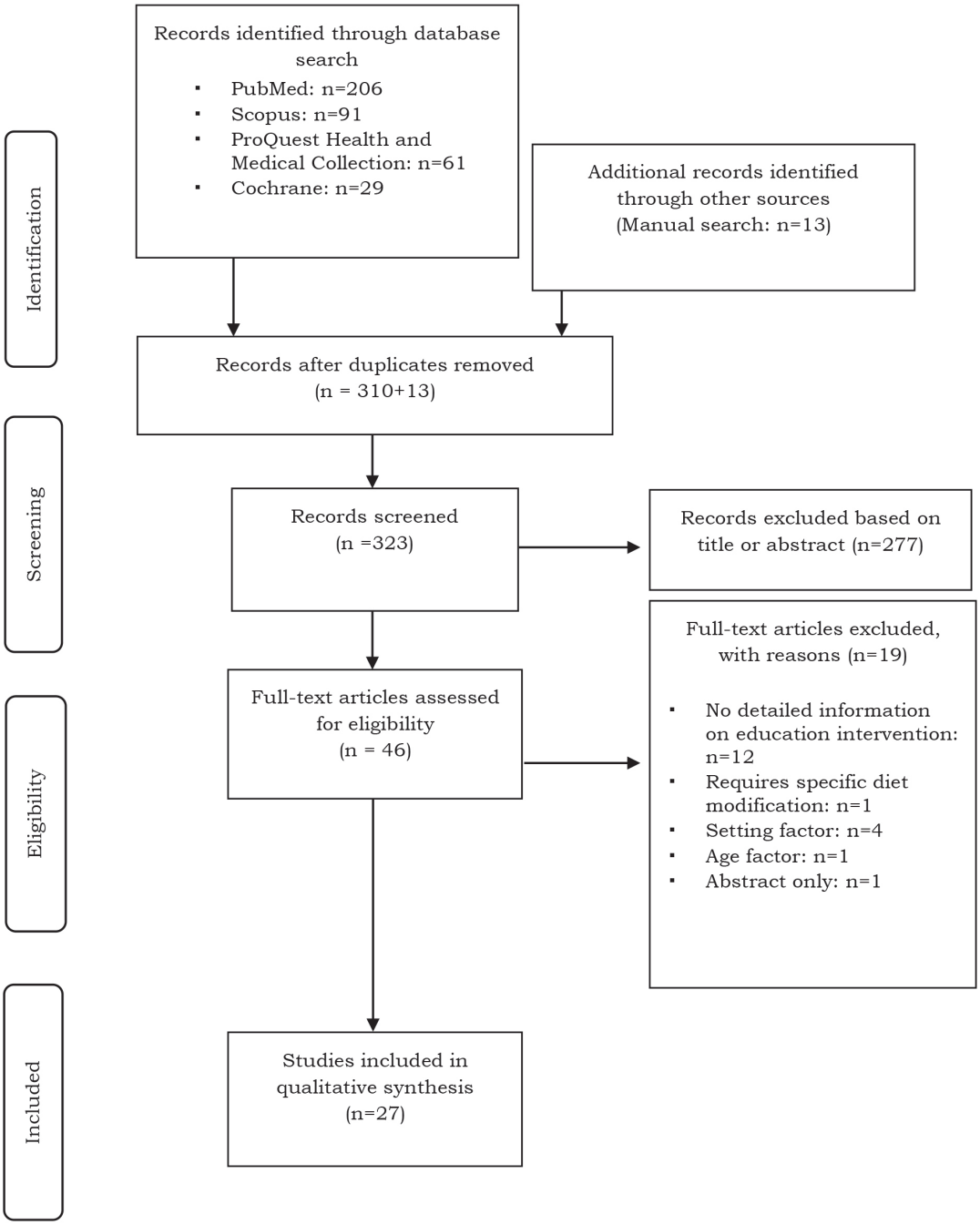

Figure 1. Study selection process for scoping review

Lung and Blood Institute (NLHBI) study quality assessment tool was used to rate the study quality. Qualitative and mixed-method studies were rated using the Critical Appraisal Skills Programme (CASP) checklist. For discussion paper and case report, they were not applicable to be rated for study quality. Currently, only the Joanna Briggs Institute (JBI) provides a critical appraisal checklist for these types of papers. So, it was used as a checklist for the papers to be included in the review.

Any information in the selected documents that could serve as topics in a nutrition resource kit were extracted. The information were listed as potential topics and discussed among the research team members before finalising the content of the nutrition resource kit.

RESULTS

Overview of studies identified

The process of identifying relevant studies is summarised in Figure 1. Electronic searches via online databases retrieved 487 articles and 13 documents from a manual search were found to be potentially relevant to the present scoping review. After duplicates were removed, a total of 323 records were screened thoroughly for relevant abstracts. This resulted in 47 records that were reviewed against the inclusion and exclusion criteria. Finally, 14 papers which consisted of seven controlled intervention studies, three cross-sectional studies, two mixed-method studies, once case report, and one discussion paper were selected. Overall, 27 records consisting of articles, printed materials and guidelines that met the criteria were included for this review. The level of evidence among these studies ranged from level II to level VII, which were of fair and good quality.

The results were summarised and tabulated in tables. Tables 1 and 2 indicate the summary of the outline or topics that can be included in a nutrition resource kit. Tables 3 and 4 mainly display the nutritional requirements for elderly, particularly for malnourished and at-risk populations, and act as references for content development. Meanwhile, Table 5 displays the summary of topics suitable to be included in the nutrition resource kit. In general, the suitable content was categorised into three components; 1) understanding malnutrition; 2) managing malnutrition; and 3) implementing malnutrition management, which will be explained below.

Content in nutrition resource kit

Understanding malnutrition

This review identified that general information related to malnutrition were given to the elderly and caregivers to ensure their understanding of the issue. The information provided to the target population included definition, signs and symptoms, as well as causes and consequences (Fernández-Barrés *et al.*, 2017; van Doorn-van Atten *et al.*, 2018). These kind of information would provide new insights for the elderly, which may directly increase their awareness of malnutrition issues.

Managing malnutrition

Management of malnutrition including information on macronutrient and fluid requirements, and serving size or exchange should also be considered as content in a nutrition resource kit. Generally, most studies provided tailored and non-tailored information on the needs for adequate intake of macro- and micronutrients among elderly participants in order to prevent and overcome malnutrition (Ahmadzadeh Tori *et al.*, 2019; Brooke & Ojo, 2015; Endevelt *et al.*, 2011; Fernández-Barrés *et al.*, 2017; Luger *et al.*, 2016;

Table 1. Studies included for qualitative synthesis to develop a nutrition resource kit

No	*Title, author, year*	*Setting*	*Study design*	*Study objective*	*Details in nutrition education and key findings*	*Suggested topics to be included in nutrition resource kit*	*Level of evidence and risk of bias*
1	Needs and preference assessment for an in-home nutrition education programme using Social Marketing Theory (Francis *et al.*, 2004)	Community-residing elderly in Guilford County, NC	Mixed-method study	Study One: (1) To identify the nutritional needs of caregivers and their care recipients. Study Two: (1) Develop nutrition education materials (2) Test nutrition education materials with caregivers and their care recipients and professional staff who work with elders (3) Compare responses regarding the education materials between the caregivers and their care recipients and the professional staff	For the elderly and caregiver. (1) Using social marketing theory (2) Content of NEWS materials (for CG and CR): 1. Water – Are you drinking enough? 2. Healthy snacks 3. Money matters–how to shop on a budget 4. Add some spice to your life – A guide to low sodium eating 5. Nutrition guidelines for older adults 6. Nutrients – Are you getting enough? Food guide pyramid for older adults 7. What's in a name – A guide to what the front of the food label is saying 8. Eating well when you don't feel well 9. Serving up good nutrition – A guide on serving sizes 10. Herb and spice combination list for vegetables and meats 11. Chewing problems left you hungry? 12. Diet and drugs: they don't always mix – A guide on drug nutrient interactions *Participants chose nutrition topics that addressed: -Hydration -Serving sizes -Healthy cooking tips -Polypharmacy *Participants did not desire this information: -Shopping on budget	-Serving size -Hydration -Menu suggestion -Recipe of high energy and protein -Tips to maintain nutrients content in food and drink	Level VI Fair quality

Table 1. Studies included for qualitative synthesis to develop a nutrition resource kit (continued)

No	*Title, author, year*	*Setting*	*Study design*	*Study objective*	*Details in nutrition education and key findings*	*Suggested topics to be included in nutrition resource kit*	*Level of evidence and risk of bias*
2	Factors influencing dietary intake frequencies and nutritional risk among community-residing older adults (MacNab *et al.*, 2018)	Community-residing older adults (aged 60+)	Cross-sectional study	To identify factors influencing dietary intake frequencies and nutritional risk among community-residing older adults	(1) Study found elderly who enrolled in lifestyle interventions in these three states have "low" intakes of lean protein and dairy and are "at possible nutritional risk" or "at nutritional risk" (2) Sociodemographic characteristics (e.g., state of residence, gender, and age) of participants were shown to influence both nutritional risk and dietary intake (3) Educators should consider sociodemographic factors to promote dairy and protein- rich foods to elderly at nutrition risk	-Recipe of high protein food/drink/ snack -How to increase protein intake through food or drink. -Suggestion of protein-dense food/ drink/snack	Level VI Fair quality
3	Effects of a home-based and volunteer-administered physical training, nutritional, and social support programme on malnutrition and frailty in older persons: a randomised controlled trial (Luger *et al.*, 2016)	Community-dwelling older persons at home in Vienna, Austria	RCT study	The aim of this study was to examine the effects of a home-based and volunteer-administered physical training and nutritional intervention programme compared with social support intervention on nutritional and frailty status in prefrail and frail community-dwelling older persons	(1) The aim of the nutritional intervention-ensure adequate fluid, protein, and energy intake, preferably by regular foods and beverages, without the use of nutritional supplements (2) Provision of booklet: included 3 main nutritional aspects**:** fluid intake, animal and plant protein intake, and energy intake (3) Provision of ideas of how to enrich food with protein, and they were provided with recipes of dishes that are protein and energy rich (4) Equipped with the "Healthy-for-Life Plate" guide	-Adequate intake of fluid, protein, and energy intake, preferably by regular foods and beverages -Hydration -Menu suggestion -Recipe of high energy food/drink/ snack -How to increase calorie and protein intake through food or drink	Level II Good quality

Table 1. Studies included for qualitative synthesis to develop a nutrition resource kit (continued)

No	*Title, author, year*	*Setting*	*Study design*	*Study objective*	*Details in nutrition education and key findings*	*Suggested topics to be included in nutrition resource kit*	*Level of evidence and risk of bias*
4	Development and analysis of acceptance of a nutrition education package among a rural elderly population: an action research study (Shahar *et al.*, 2012)	Health clinics in a rural area of Malaysia	Action research (Data collected at one point. Therefore, we classified this paper as cross-sectional study)	To develop a nutrition education package about healthy ageing and reducing the risk of chronic diseases for implementation at health clinics in a rural area of Malaysia	For the elderly and healthcare staffs. Key: Nutrition guide and increase physical activity (1) Booklet Message 1: Take a variety of food Message 2: Be physically active for muscle strength Message 3: Take at least 3 main meals in a day Message 4: Increase the consumption of fruits and vegetables Message 5: Meet your calcium requirement Message 6: Reduced intake of foods high in fat and cholesterol Message 7: Reduced salt in cooking and foods high in sodium content Message 8: Reduced sugar and foods high in sugar Message 9: Drink plenty of water Message 10: Safe food handling (2) Flipchart Guide 1: Weight management Guide 2: To reduce fat & cholesterol Guide 3: To control blood pressure Guide 4: To control blood sugar Guide 5: To increase fibre in diet Guide 6: Exercise for older people (3) Placemat -'Food Plate: Daily Food Portions for Older People' -Food plate indicated serving sizes of foods from the main food groups *Results also found that elderly subjects were easy to understand using food plate	-Serving size -Menu suggestion -Hydration -Tips to maintain nutrients content in food and drink	Level VI Fair quality

Table 1. Studies included for qualitative synthesis to develop a nutrition resource kit (continued)

No	*Title, author, year*	*Setting*	*Study design*	*Study objective*	*Details in nutrition education and key findings*	*Suggested topics to be included in nutrition resource kit*	*Level of evidence and risk of bias*
5	Effects of a multi-component nutritional telemonitoring intervention on nutritional status, diet quality, physical functioning and quality of life of community-dwelling older adults van Doorn-van Atten *et al.* (2018)	Dutch community-dwelling elderly aged > 65 years	RCT study	To evaluate the effects of an intervention including nutritional telemonitoring, nutrition education, and follow-up by a nurse on nutritional status, diet quality, appetite, physical functioning and quality of life of Dutch community-dwelling elderly	Nutrition education: -Tailored information: advice given, according to the score for that specific nutrient or food group -Non-tailored information: targeted determinants of dietary and physical activity behaviour such as awareness, knowledge and attitude	-Sign and symptoms of malnutrition -Cause and consequences of malnutrition -The needs of high energy and high protein to overcome and treat malnutrition -Menu suggestion -Recipe of high energy food/drink/ snack -How to increase calorie and protein intake through food or drink -Suggestion of energy and protein-dense food/drink/ snack	Level II Fair quality
6	The efficacy of a nutrition education intervention to prevent risk of malnutrition for dependent elderly patients receiving Home Care: a randomised controlled trial (Fernández-Barrés *et al.*, 2017)	10 Primary Care Centres, Spain (aged 65+)	RCT study	To assess the effect of a nutrition education intervention included in the Home Care Programme for caregivers to prevent the increasing risk of malnutrition of dependent patients at risk of malnutrition	(1) Nurse explained causes and consequences of malnutrition to the caregiver and the patient (2) The nurses gave general information about: -Foods, macronutrients and some micronutrients. They showed foods rich in nutritional content. -How to design a healthy diet, focusing in macronutrient distribution and food choices -Advice on dietary adaptation to address the most common nutritional problems in this group, such as energy, protein, vitamin, mineral and water deficiency and adaptation of textures. -Recommendations on basic cooking techniques	-Cause and consequences of malnutrition -Menu suggestion -Hydration -Recipe of high energy food/drink/ snack -How to increase calorie and protein intake through food or drink -Suggestion of energy and protein-dense food/drink/ snack -Tips to maintain nutrients content in food and drink	Level II Good quality

Table 1. Studies included for qualitative synthesis to develop a nutrition resource kit (continued)

No	*Title, author, year*	*Setting*	*Study design*	*Study objective*	*Details in nutrition education and key findings*	*Suggested topics to be included in nutrition resource kit*	*Level of evidence and risk of bias*
7	Effect of BASNEF-based nutrition education on nutritional behaviours among the elderly people and Mini Nutritional Assessment on nutritional status in elderly with diabetes with type 2 diabetes (A clinical trial intervention) (Ahmadzadeh Tori *et al.*, 2019)	Community includes all elderly people with diabetes in health centres of Babol city, Iran (aged 60+ years)	RCT study	To investigate the nutritional status of elderly people with diabetes and the effect of educational intervention based on the BASNEF model on promoting nutritional behaviours in the elderly with type 2 diabetes	Educational intervention was based on the BASNEF model Nutrition education intervention was done aiming: -To increase the number of meals -To decrease eating simple carbohydrates and fats -To increase eating fruits and vegetables for the elderly people with diabetes of intervention group	-Menu suggestion -Promoting intake of fruits and vegetables -How to increase calorie and protein intake through food or drink. -Suggestion of energy and protein-dense food/drink/ snack.	Level II Fair quality
8	The eating experience: Adaptive and maladaptive strategies of older adults with tooth loss. (Zelig *et al.*, 2019)	Older adults attending the clinics of an urban northeast US school of dental medicine	Mixed-method study	The aim of this study was to explore the impact of tooth loss on the eating experience and ERQOL of older adults attending the clinics of an urban northeast US school of dental medicine	Adaptive and maladaptive behavioural responses to tooth loss: (1) Adaptive strategies included: -Modification in food preparation and cooking methods -Food texture selection -Meal timing -Approaches to chewing (2) Maladaptive behaviours included: -Food avoidance -Limiting eating and smiling in front of others	-Tips to modify texture of the food during food preparation and cooking	Level IV Good quality

Table 1. Studies included for qualitative synthesis to develop a nutrition resource kit (continued)

No	*Title, author, year*	*Setting*	*Study design*	*Study objective*	*Details in nutrition education and key findings*	*Suggested topics to be included in nutrition resource kit*	*Level of evidence and risk of bias*
9	Older consumers' readiness to accept alternative, more sustainable protein sources in the European Union. (Grasso *et al.*, 2019)	Community-dwelling older adults aged 65 years or above in five EU countries (United Kingdom, the Netherlands, Poland, Spain, and Finland)	Cross-sectional study	(1) To assess the level of acceptance to consume the following alternative, potentially more sustainable protein sources: plant-based protein, insects, single-cell protein and in vitro meat. (2) To investigate how different food-related attitudes and behaviour and sociodemographic influence the acceptance to consume such protein sources	-Dairy-based protein was generally the most accepted protein source in food products (75% of the respondents found its consumption acceptable or very acceptable) -Plant-based protein was the most accepted alternative, more sustainable protein source (58%) -Single-cell protein (20%) -Insect-based protein (9%) -In vitro meat-based protein (6%)	-Source of protein (include protein menu from dairy, plant-based and meat -Protein exchange	Level IV Fair quality

Table 1. Studies included for qualitative synthesis to develop a nutrition resource kit (continued)

No	*Title, author, year*	*Setting*	*Study design*	*Study objective*	*Details in nutrition education and key findings*	*Suggested topics to be included in nutrition resource kit*	*Level of evidence and risk of bias*
10	Oral and enteral nutrition in dementia: an overview (Brooke & Ojo, 2015)	NA	Discussion paper	Discussion of interventions to improve oral nutrition	Recommendation: (1) Environment: -Use of tablecloths, placemats and laying of cutlery -Coloured crockery, such as dark blue or red -Good-quality lighting -Music -Smell of freshly baked bread -Tables to seat four people (2) Support with feeding difficulties -Grazing, staggered mealtimes, menus providing enhanced energy-dense foods, texture-modified diet, mid-morning supplements -Provision of finger food, offering small portions of food regularly, offering one course or item of food at a time, additional snacks (3) Nutritional supplements -Macronutrient supplementation, such as high- protein, high-calorie supplements (4) Education and training -To support family caregivers -Dietary changes in dementia, tools to monitor nutritional intake, how to provide a protein-rich diet, strategies to address eating difficulties	-Tips to encourage eating/ enhance mood for eating -Tips to modify texture of the food during food preparation and cooking. -How to increase calorie and protein intake through food or drink. -Suggestion of energy and protein-dense food/drink/ snack. -Suggestion on the use of ONS.	Level V NA

Table 1. Studies included for qualitative synthesis to develop a nutrition resource kit (continued)

No	*Title, author, year*	*Setting*	*Study design*	*Study objective*	*Details in nutrition education and key findings*	*Suggested topics to be included in nutrition resource kit*	*Level of evidence and risk of bias*
11	Intensive dietary intervention by a dietitian as a case manager among community-dwelling older adults: the edit study (Endevelt *et al.*, 2011) an intensive nutritional intervention led by a dietitian, or a Medical Treatment (MT	Community-dwelling patients aged 75 or over at nutritional risk were identified from two districts, the north (haifa) and Sharon (petach-tikva) districts of maccabi healthcare Services	RCT study	To determine the impact of an intensive nutritional intervention programme led by a dietitian on the health and nutritional status of malnourished community-dwelling older adults	(1) Dietetic intervention treatment (DIT): -Nutritional assessment -Nutritional tailored treatment -Food supplements, if needed -Information regarding centres for subsidised prepared food, if needed -Evaluation of dietary intake -Recommendation for improving consumption with the goal of increasing quantity and quality of dietary intake -Evaluation of dietary intake -Adjust recommendations according to the patient's nutritional status and personal (2) Medical treatment (MT): -Booklet; information regarding the nutritional needs of older adults	-The needs of high energy and high protein to overcome and treat malnutrition -How to increase calorie and protein intake through food or drink. -Suggestion of energy and protein-dense food/drink/ snack. -Suggestion on the use of ONS if needed	Level II Fair quality
12	Effects of individual dietary counselling as part of a comprehensive geriatric assessment (CGA) on nutritional status: a population-based intervention study (Nykänen *et al.*, 2014)	Community-dwelling people aged 75 years or older. *Subpopulation of participants in the population-based Geriatric Multidisciplinary Strategy for the Good Care of the Elderly (GeMS)	RCT study	To evaluate the effects of individual dietary counselling as part of a Comprehensive Geriatric Assessment on nutritional status among:	(1) Nutrition intervention (based on the recommendations of the National Nutrition Council) -Aim: Increasing the frequency of meals and/or adding energy (if necessary) and proteins to the meals without nutritional supplements -Tailored meal plan with enough energy and proteins. -Special leaflets were given; for example: snacking (2) Nutritional interventions need to reflect different energy needs and include the provision of nutrient-dense food	-Menu suggestion -How to increase calorie and protein intake through food or drink -Suggestion of energy and protein-dense food/drink/ snack	Level II Fair quality

Table 1. Studies included for qualitative synthesis to develop a nutrition resource kit (continued)

No	*Title, author, year*	*Setting*	*Study design*	*Study objective*	*Details in nutrition education and key findings*	*Suggested topics to be included in nutrition resource kit*	*Level of evidence and risk of bias*
13	Dietary management of older people with diabetes (McClinchy, 2018)	Elderly living in the community or in a care home	Case report	Focus on older people living in the community or in a care home who have or are at risk of malnutrition	Interventions to manage or prevent malnutrition include an increase in foods high in energy and protein, regular meals and snacks and fortification of foods with high protein, high-energy foods such as milk powder, cheese, cream or butter	-How to increase calorie and protein intake through food or drink -Suggestion of energy and protein-dense food/drink/ snack.	Level VII NA
14	Guidance improves nutrient intake and quality of life, and may prevent falls in aged persons with Alzheimer disease living with a spouse (NuAD Trial) (Suominen *et al.*, 2015)	People with Alzheimer disease (≥ 65 years) living with their spouses in the Helsinki metropolitan area.	RCT study	To examine the effect of tailored nutritional guidance on nutrition, health-related quality of life (HRQoL) and falls in persons with Alzheimer disease (AD)	The nutritional care plan and personal guidance covered the following themes: -Adequate energy intake, sufficient protein intake -The benefits of fresh fruit and vegetables -The possible need for dietary supplements Received booklet about: -The assessment of adequate protein and calcium intake, as well as the use of 20 µg/day vitamin D supplements, and a guide about balanced nutrition for older adults	-Menu suggestion -How to increase calorie and protein intake through food or drink -Suggestion of energy and protein-dense food/drink/ snack. -Promoting intake of fruits and vegetables	Level II Fair quality

RCT: Randomised Controlled Trial

Table 2. Additional sources included from manual search for qualitative synthesis to develop a nutrition resource kit

No	*Title*	*Source*	*Target group*	*Details in nutrition education materials*	*Suggested topics to be included in nutrition resource kit*
1	Pamphlet – Nutrition for the elderly (*Risalah – Pemakanan Warga Tua*) (Kementerian Kesihatan Malaysia, no date-a)	Malaysian Ministry of Health	-Elderly with NCD -Elderly with eating difficulty, underweight	1. Introduction (‘*Pengenalan*’) 2. Tips on healthy practices (‘*Tips amalan secara sihat*’) 3. Issues on food intake and how to overcome it (‘*Masalah pengambilan makanan dan cara penyelesaian*’) 4. Menu suggestion (1 day menu) (‘*Cadangan menu (1 hari)*’) 5. Food measurement (‘*Sukatan makanan*’)	-Cause and consequences of malnutrition -Adequate energy, protein and fluid intake -Menu suggestion -Serving size -Recipe of high energy food/drink/ snack -How to increase calorie and protein intake through food or drink.
2	Pamphlet – Nutrition Guide for the elderly (*Risalah - Panduan Pemakanan Untuk Warga Tua*) (Kementerian Kesihatan Malaysia, no date-b)	Malaysian Ministry of Health	-General elderly population -Healthy eating for the elderly	1. Healthy foods for health (‘*Makanan yang baik untuk kesihatan*’) 2. Unhealthy foods for health (‘*Makanan yang tidak baik untuk kesihatan*’) 3. Menu suggestion (1 day) (‘*Cadangan menu (1 hari)*’) 4. Tips to promote happiness during eating (‘*Tips – Jadikan masa makan menggembirakan*’)	-Suggestion of energy and protein-dense food/drink/snack. -Tips to maintain oral health
3	Booklet – Guide for Caregivers of the elderly (*Buku kecil - Panduan untuk Penjaga Warga Emas*) (Kementerian Kesihatan Malaysia, 2008)	Malaysian Ministry of Health	-For caregiver	A section related to healthy eating: *Makanan sihat* (*1 bahagian*): 1. Food pyramid (‘*Piramid makanan*’) 2. Menu suggestion (‘*Cadangan menu*’) 3. Feeding assistance for the elderly (‘*Cara bantu warga emas makan*’)	
4	Booklet – Nutrition Guide for the elderly (*Buku kecil - Panduan Pemakanan Warga Tua*) (Kementerian Kesihatan Malaysia, 2000)	Malaysian Ministry of Health	-General elderly population	1. Factors associated with food intake (‘*Perkara yang mempengaruhi pengambilan pemakanan*’) 2. Food for good health (complete meal) (‘*Makanan yang baik untuk kesihatan (makanan lengkap)*’) 3. Information on vitamin and minerals needed for the elderly (‘*Ketahui vitamin*	

Table 2. Additional sources included from manual search for qualitative synthesis to develop a nutrition resource kit (continued)

No	*Title*	*Source*	*Target group*	*Details in nutrition education materials*	*Suggested topics to be included in nutrition resource kit*
				dan mineral yang penting untuk warga emas') 4. Food pyramid (*'Piramid makanan'*) 5. Menu suggestion (1 day) (*'Contoh menu (1 hari)'*) 6. Tips to prepare soft foods (*'Petua menyediakan makanan lembut'*) 7. Soft Food Recipe (*'Resepi makanan lembut'*) 8. Tips to maintain nutrients content in food (*'Cara mengekalkan zat dalam makanan'*) 9. Requirement on additional vitamin and minerals (*'Keperluan vitamin dan mineral tambahan'*) 10. Tips to maintain oral health (*'Jagalah kesihatan mulut anda'*)	-Cause and consequences of malnutrition -The needs of high energy and high protein to overcome and treat malnutrition -Menu suggestion -Serving size -Recipe of high energy food/drink/ snack -How to increase calorie and protein intake through food or drink. -Suggestion of energy and protein-dense food/drink/snack.
5	Booklet – Nutrition Guide for the elderly in Institution (*Buku kecil - Panduan Pemakanan Warga Tua di Institusi*) (Kementerian Kesihatan Malaysia, 2001)	Malaysian Ministry of Health	-General elderly population -Elderly with anaemia, underweight, NCDs, constipation, vegetarian	1. Problem and tips to overcome (*'Masalah dan cara penyelesaian'*) 2. Food hygiene (*'Kebersihan makanan'*) 3. Oral hygiene (*'Kebersihan mulut'*) 4. Menu suggestion (7 days) (*'Cadangan menu (7 hari)'*) 5. Menu suggestion for Chinese, Indian and Westerner (1 day) (*'Cadangan menu (1 hari) untuk warga Cina, India dan Barat'*)	
6	Booklet – Guidelines for Menu Planning in Institution (*Buku kecil - Garis Panduan Perancangan Menu di Pusat Jagaan* (Kementerian Kesihatan Malaysia, no date-c)	Malaysian Ministry of Health	-Institution	1. Menu suggestion for main meals and snacks (7 days) – 1800kcal (*'Contoh menu untuk hidangan utama dan sampingan (7 hari) – 1800kcal'*)	

NCD: non-communicable disease

Table 3. Energy and macronutrients requirement for the elderly

No	*Guideline*	*Gender*	*Energy (kcal/ day)*	*Carbohydrates (% of energy intake @ g/ day)*	*Fat (% of energy intake)*	*Fluid*
1	Recommended Nutrient Intake (RNI), 2017	Male	2030	50-65%	25-30	
		Female	1770		25-30	
2	Malaysian Dietary Guideline, 2010	All	1500			6-8 glasses of plain water daily
3	ESPEN guideline on clinical nutrition and hydration in geriatrics, 2019	All	30kcal/kg BW	50-55%		2.0 litres per day for women and 2.5 litres per day for men (from a combination of drinking water, beverages and food)
4	Haute Autorité de santé, Nutritional support strategy for protein-energy malnutrition in the elderly, 2007	All	30-40kcal/kg BW			1.0 to 1.5 litres of water per day (or other drinks: herbal tea, fruit juice, etc.) and drinking before feeling thirsty
5	Dietary Guidelines for Americans (8th edition), 2015-2020	Male	2000-2200 (Sedentary)	130g/day (45-65%)	20-35	
		Female	1600 (Sedentary)	130g/day (45-65%)	20-35	

BW: body weight

Table 4. Protein requirement for malnourished elderly

No	*Source*	*Protein Requirement*
1	ESPEN guideline on clinical nutrition and hydration in geriatrics, 2019	1.2-1.5g/kg BW and up to 2.0g/kg BW
2	Haute Autorité de santé, Nutritional support strategy for protein-energy malnutrition in the elderly, 2007	1.2-1.5g/kg BW

BW: body weight

Table 5. Summary of suitable topics to be included as content in nutrition resource kit

No	*Component*	*Suitable topics to be included in nutrition resource kit*
1	Understanding on malnutrition	• Definition • Signs and symptoms • Cause-consequences
2	Malnutrition management	• Food plate • Serving size
3	Implementation of malnutrition management	• Menu suggestion • Examples of recipes • Tips to increase energy and protein intakes through food or drink • Texture modification • Guide to use oral nutritional supplements • Tips to maintain nutrients content in food and drink • Tips to encourage to eat • Oral health

Nykänen *et al.*, 2014; Shahar *et al.*, 2012; Suominen *et al.*, 2015; van Doorn-van Atten *et al.*, 2018). Serving size was also mentioned (Francis *et al.*, 2004; Shahar *et al.*, 2012). In addition, several studies targeted on hydration status (Fernández-Barrés *et al.*, 2017; Luger *et al.*, 2016) or educational materials (Francis *et al.*, 2004; Shahar *et al.*, 2012). Most available educational materials and guidelines also provided information related to fluid requirement. The use of a plate to portray and deliver information was also mentioned in two studies (Luger *et al.*, 2016; Shahar *et al.*, 2012).

Implementing malnutrition management

A few studies highlighted the possible methods to prevent and overcome malnutrition, such as texture adaptation and modification in food preparation and methods of cooking (Brooke & Ojo, 2015; Fernández-Barrés *et al.*, 2017; Zelig *et al.*, 2019), recommended cooking methods (Fernández-Barrés *et al.*, 2017), healthy cooking tips (Francis *et al.*, 2004), menu suggestion (Brooke & Ojo, 2015; Nykänen *et al.*, 2014), and recipes for high energy and high protein menu (Luger *et al.*, 2016). Other studies mentioned promoting energy and protein-rich foods (Brooke & Ojo, 2015; Fernández-Barrés *et al.*, 2017; MacNab *et al.*, 2018; McClinchy, 2018; Nykänen *et al.*, 2014) including food fortification and nutritional supplementation (Brooke & Ojo, 2015; Endevelt *et al.*, 2011; McClinchy, 2018; Suominen *et al.*, 2015). Ways to control certain nutrients in foods

and oral health were also mentioned in several studies and available educational materials. Information related to the implementation of malnutrition management are suggested to be included in the nutrition resource kit as this may guide the target population specifically on how to improve their nutritional status in their daily lives.

DISCUSSION

Malnutrition is linked to various adverse clinical outcomes, including prolonged hospitalisation due to longer time needed to recover, increased risk of complications, effect on the patient's recovery, and increased risk of morbidity and mortality (Correia & Waitzberg, 2003). The health status of elderly is highly dependent on their nutritional risk. Wallace, Lo and Devine (2016) advocated the view that tailored nutrition education in elderly can lead to sustained dietary behaviour changes. Therefore, it is recommended to provide a nutrition resource kit to this target group in order to combat this issue. Previous systematic reviews concluded that nutrition education interventions might help improve malnutrition-related outcomes in elderly populations. However, more studies are required to support this evidence (Rea, Walters & Avgerinou, 2019).

This review is mainly to identify relevant topics for the content development of a nutrition resource kit for malnourished and at-risk elderly, with the purpose of providing nutritional knowledge and information for them to improve their dietary intake in order to overcome and prevent malnutrition. Suitable content identified through this review included information related to malnutrition such as definition, signs and symptoms, cause-consequences, and nutrition management, which included food plate, serving size, menu suggestion, examples of recipes, tips to increase energy and protein intakes through food or drink, texture modification, guide to using oral nutritional supplements, tips for maintaining nutrient content in food and drink, and oral health. The level of evidence among these research papers ranged from levels II to VII. All papers included in this review were of fair and good quality. All papers provided credibility to the body of knowledge.

Available printed versions of educational materials from the Ministry of Health, Malaysia, were also included in the manual search. However, it is worth noting that none of them were designed specifically for malnourished and at-risk elderly. Nevertheless, the details in these nutrition education materials were extracted to identify suitable content for the nutrition resource kit.

This nutrition resource kit will act as a guide to which malnourished and at-risk elderly would be able to refer to whenever needed. Even though the kit is mainly targeted for the elderly, participation of family members and caregivers would be beneficial as this would facilitate the use of this kit in the target group (Marshall & Hale, 2017).

Understanding malnutrition

Information related to malnutrition is suitable for the kit (Fernández-Barrés *et al.*, 2017; van Doorn-van Atten *et al.*, 2018). This includes a brief explanation on the definition, signs and symptoms, and causes and consequences. The purpose of this information is to provide an overview of malnutrition to the elderly. Therefore, they will acquire general information and awareness about this issue. Besides, this general information primarily aims to enhance belief selection and consciousness, as well as to provide information on the consequences of behaviour (van Doorn-van Atten *et al.*, 2018).

Managing malnutrition

The nutritional requirement of the elderly could differ considerably from other age groups due to the normal ageing process, medical condition or lifestyle. Generally, nutritional requirements, specifically energy and protein, are higher for the elderly at risk of malnutrition or are already malnourished. Therefore, a specific nutritional recommendation for this target group is needed to be incorporated in the nutrition resource kit according to any available and suitable dietary guidelines. Several studies highlighted the need for adequate fluid intake among the elderly (Fernández-Barrés *et al.*, 2017; Francis *et al.*, 2004; Luger *et al.*, 2016; Shahar *et al.*, 2012), as inadequate fluid intake could contribute further to dehydration and affect the elderly's quality of life (Begum & Johnson, 2010). Hence, information on fluid requirement needs to be considered as a content in the nutrition resource kit.

Implementing malnutrition management

In addition, information related to strategies to increase their daily energy and protein intakes should be incorporated into the kit. Most of the studies emphasised the need to include menu suggestion, examples of recipes, tips to increase energy and protein intakes through food or drink, texture modification, a guide to using oral nutritional supplements, and tips to maintain nutrients content in food and drink. Offering texture-modified, enriched foods for the elderly who are malnourished or at risk of malnutrition is a good practice to ensure adequate dietary intake among them (Volkert *et al.*, 2019).

Several studies emphasised the use of food or nutritional supplements for malnourished and at-risk elderly (Brooke & Ojo, 2015; Endevelt *et al.*, 2011; McClinchy, 2018; Suominen *et al.*, 2015). Oral nutritional supplement (ONS) can be described as an energy and nutrient-dense product aimed at increasing one's dietary intake when diet alone is unable to meet the daily energy requirements of the elderly (Volkert *et al.*, 2019). ONS can be categorised as standard ONS and disease-specific ONS. ONS are frequently recommended for those malnourished and at risk of malnutrition (Uí Dhuibhir, Collura & Walsh, 2019). According to Parsons *et al.* (2017), the use of ONS is quite effective as one of the options to increase a person's oral dietary intake. Hence, a brief guide on the use of ONS that are commonly found in the Malaysian setting should be included in the kit. Additionally, instructions for elderly to get advice from a dietitian and nutritionist on the use of ONS should also be mentioned for accurate prescription on ONS intake upon referral by physician.

Information about oral health should be included as well in the nutrition resource kit (Zelig *et al.*, 2019). Oral health is one of the contributing factors to malnutrition among the elderly. Oral health issues could reduce the ability of elderly to chew and eat, which directly leads to practical issues in the provision of adequate nutrition (Krishnamoorthy *et al.*, 2018). A study conducted by Rosli *et al.* (2019) in Kuala Pilah, Malaysia, demonstrated that oral health-related quality of life was significantly associated with nutritional condition among the elderly participants. Therefore, it is important for the elderly to maintain their oral health in order to prevent and overcome malnutrition.

Furthermore, studies have aimed to develop nutrition education materials that suit not only the elderly population but also their caregivers (Francis *et al.*, 2004) or healthcare professionals

(Shahar *et al.*, 2012). This has been demonstrated in *'Panduan untuk Penjaga Warga Emas'*, an educational material provided by the Ministry of Health, Malaysia, that is aimed to provide information for caregivers. Francis *et al.* (2004) also included caregivers as their target audience as they were required to be actively involved in healthcare delivery. Shahar *et al.* (2012) also developed a nutrition education package that healthcare professionals can use as a teaching tool. Nevertheless, this review is important as it identified suitable topics to be included in a nutrition resource kit. Thus, any suitable and relevant information to caregivers or healthcare staffs were extracted and included.

The strengths of this review were that it followed the PRISMA-ScR guidelines, and the data were checked and discussed among the researchers. This research nevertheless had its limitations. Since articles were limited to English and Malay languages only, other articles that might have provided relevant information to develop content for the nutrition resource kit were not included.

CONCLUSION

To conclude, this scoping review offered new insights into the content that can be included in the future development of a nutrition resource kit aimed at tackling malnutrition among the elderly in community settings. The content identified included information related to malnutrition such as definition, signs and symptoms, cause-consequences, and nutrition management, which included food plate, serving size, menu suggestion, examples of recipes, tips to increase energy and protein intakes through food or drink, texture modification, a guide to using oral nutritional supplements, tips to maintain nutrients content in food and drink, and tips to encourage to eat, and oral health. The topics identified can be incorporated into the kit in order to facilitate the elderly in improving their dietary intake. Therefore, a nutrition resource kit that provides nutritional guidance for malnourished and at-risk elderly can be useful for healthcare professionals as a nutrition intervention strategy. Further review could be performed in the future to measure its outcomes, particularly in providing nutrition education materials for the elderly to overcome malnutrition.

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Authors' contributions

INNA, conducted the study, data analysis and interpretation, prepared the draft of the manuscript and reviewed the manuscript; AHH, principal investigator, conceptualised and designed the study, contributed expertise, data analysis and interpretation, and reviewed the manuscript; SH, contributed expertise and reviewed the manuscript; MAMA, contributed expertise and reviewed the manuscript; KHAA, contributed expertise and reviewed the manuscript; SNASH, contributed to data analysis and interpretation; NSAR, contributed expertise and reviewed the manuscript.

Conflict of Interest

The authors declare no conflict of interest.

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Survey on salt content in selected food products of fast food restaurants and determination of salt intake awareness among fast food consumers in Klang Valley

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ABSTRACT

Introduction: Malaysians are exposed to a high salt diet, which is one of the contributors to the prevalence of hypertension among them. This study aimed to identify the salt content in selected food products of fast food restaurants and to determine the salt intake awareness among fast food consumers. **Methods:** Salt content data were collected through online survey from the official websites of selected restaurants (Kentucky Fried Chicken, McDonald's, Subway® and Texas Chicken). The food products were classified into eight food categories (chicken-based, potato-based, rice-based, sandwich, salad, bread, dessert, and sauce). The cross-sectional study on salt intake awareness was conducted among 108 Malaysian adults from these restaurants. A knowledge, attitude and practice (KAP) questionnaire was disseminated online. The salt content and the consumers' salt intake awareness were analysed using Statistical Products and Service Solution (SPSS) software version 25.0. **Results:** A total of 105 food products were surveyed in this study. Sauce products contained the highest salt content (1.9±0.8 g/100g), followed by bread (1.2±0.3 g/100g), potato-based (1.2±0.4 g/100g), chicken-based (1.2±0.3 g/100g), sandwich (1.1±0.6 g/100g), rice-based (0.7±0.3 g/100g), salad (0.4±0.2 g/100g), and dessert (0.3±0.4 g/100g). For the KAP study, a total of 108 consumers had participated and mostly (48.2%) had a fair level of salt intake awareness. **Conclusion:** Most food products of fast food restaurants contained high salt content and majority of fast food consumers had a fair level of salt intake awareness. More strategic interventions are needed to control the salt intake among adults in Malaysia.

Keywords: salt, sodium chloride, fast foods, awareness

INTRODUCTION

The fifth National Health and Morbidity Survey (NHMS) by the Institute for Public Health (IPH, 2015) reported that the prevalence of hypertension in Malaysia is currently at 30.3% for adults aged 18 years and above. In addition, Malaysia's latest Burden of Disease Study (IPH,

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2017) revealed that hypertension is estimated to cause 42.2% of deaths and 21.6% of disease burden (DALY) among both men and women. High or excess salt intake are stated to be one of the factors for hypertension (Mozaffarian *et al.,* 2014). In the 2020 Malaysian Dietary Guidelines (MDG), hypertension is said to be one of the main risk factors for developing cardiovascular diseases and premature death (NCCFN, 2021).

According to the tenth key message of MDG (NCCFN, 2021), that is "choose and prepare food with less salt, sauces and flavour enhancers", a way to limit salt intake to 5 g/day is to reduce the consumption of fast foods. In the nutrition area, fast food is defined as "processed food that needs a minimum and quick preparation before consumption" or "food that is prepared quickly in fast food restaurants" (Dewan Bahasa dan Pustaka, 2010). MySalt 2015 study (IPH, 2016) also stated that fast food is a high salt food. Moreover, the Malaysian Adult Nutrition Survey (MANS) 2014 (IPH, 2014) had also added fast foods consisting of burgers, pizzas, potatoes, sausages, nuggets, coleslaw, fried chicken, and mashed potatoes as a new category compared to MANS 2003. Since fast food restaurants can be found nearly everywhere nowadays and is convenient since the food takes less time to prepare, phase one of this study aimed to survey the salt and sodium content in selected food products of fast food restaurants available in Klang Valley. The salt and sodium content of these food products were also compared between categories and to the respective sodium criteria stated in the International Product Criteria (IPC) (Choices International Foundation, 2016).

A study by Ambak *et al.* (2014) using 24-hour urine analysis reported that the average intake of salt even among normotensive health staffs of the Ministry of Health (MOH) Malaysia was 8.7 g/day, which exceeded the 5 g of salt per day as recommended by the World Health Organization (WHO, 2012). This is especially concerning, since salt intake among a population working in the health sector was expected to be below average. Therefore, the second phase of this study was to determine the knowledge (K), attitude (A) and practice (P), as well as the overall awareness (KAP) on salt intake among the Malaysian population, which was expected to be better than the population studied by Ambak *et al.* (2014).

This study is important as the findings may assist Malaysia's MOH in their aim to reduce salt intake by 30% and the prevalence of hypertension by 25% among adults in Malaysia by the year 2025 (MOH, 2016). Additionally, salt intake reduction is the easiest and most cost-effective way to reduce the prevalence of hypertension (MOH, 2016).

MATERIALS AND METHODS

Study design

The current study comprised of two phases. The first phase of the study consisted of an online survey on fast foods and their nutrition information available in purposively selected fast food restaurants. The second phase was a cross-sectional study to determine the awareness of salt intake among the Malaysian population.

Food samples

The restaurants involved in the study were Kentucky Fried Chicken (KFC), McDonald's, Subway®, and Texas Chicken, which were purposively selected for this study. For KFC and McDonald's, an online surveying of the menus available in the restaurants was conducted through the restaurants' Malaysia official websites; whereas for Subway® and Texas Chicken, data consisting of the menus available with

the respective nutrition information were obtained by personally emailing the respective department of the restaurants, as data given were solely intended for this research study and not available to the public. The list of food products available on the restaurants' menus were then grouped into these respective categories: chicken-based (chicken nuggets, fried chicken, chicken tenders); potato-based (french fries, mashed potatoes, hash browns, potato wedges); rice-based (rice congee, *nasi lemak*, cooked rice); sandwich (wraps, burgers); salad, bread, dessert (cakes, ice creams, pies, biscuits, sweet corn), and sauce products. These categories were identified following reports from O'Donnell *et al.* (2018) and Dunford *et al.* (2012). The data collected consisted of:

(a) Product name
(b) Serving size (g)
(c) Salt content (g) in every serving and every 100 g serving
(d) Sodium content (mg) in every serving and every 100 g serving

If only the salt content was available, sodium content of the product was obtained by multiplying the salt content with 400 since 5 g of salt contains 2000 mg of sodium (WHO, 2012). Following the identification of the salt and sodium content, the sodium content for each product was compared to the sodium content in the IPC by Choices International Foundation (2016), and the percentage of products that exceeded the criteria was determined. The average salt and sodium content for every category was then calculated and compared between categories and to their own criteria.

Subjects

This cross-sectional study was conducted online among Malaysian adults who gave their informed consent to participate. Malaysian adults who were eligible for this study were those who had experienced eating food products from KFC, McDonald's, Subway®, and Texas Chicken in the Klang Valley area. The potential subjects were selected using convenience sampling, in which they were approached through WhatsApp, Instagram or Twitter. Those who were not Malaysians, below 18 years old or did not have any experiences eating food products from the selected restaurants were excluded. Subjects were provided with a KAP questionnaire on salt intake that consisted of an informed consent, information sheet of the study, and the questionnaire itself if they abided by the accepted criteria.

The sample size was calculated according to Cochran (1977), $n=[(z_{a/2})^2 p(1-p)]/\Delta^2$, in which n indicates the desired sample, $z_{a/2}$ indicates the critical value at significant value of 0.10%, p indicates the population of subject that practices salt intake control according to the MySalt 2015 study (IPH, 2016), and Δ indicates the level of accuracy. Assuming 90% confidence level, $z_{a/2}$ of 1.645, p of 0.613, and Δ of 0.10, the sample size was calculated as $n=[(1.645)^2 0.613(1-0.613)]/ 0.10^2$. According to this formula and after assuming that the drop-out rate of subjects was 20%, the needed sample size was 77. However, a total of 108 subjects had participated in this study.

Prior to the start of the study, ethical approval was provided by the Research Ethics Committee of Universiti Kebangsaan Malaysia with reference number UKM.FSK.800-1/1/5 (NN-2019-133).

KAP questionnaire

KAP towards salt intake was assessed using a validated questionnaire that was administered through Google Forms. The KAP questionnaire on salt intake was retrieved from the MySalt 2015 study

(IPH, 2016), which had adapted the questionnaire from WHO and validated it. In the current study, the MySalt 2015 study (IPH, 2016) questionnaire was modified and validated again. The questionnaire consisted of an informed consent, information sheet, and the questionnaire itself. The subjects needed to fulfil every acceptable criteria of participation, and every question must be answered before proceeding to the next question. Another four questions regarding knowledge, five questions regarding attitude, and one question regarding practice towards salt intake were added in this study. Validation was performed by pre-testing the modified set of questionnaires on 65 Malaysian adults who had experience eating food products from the selected restaurants in Klang Valley. The reliability was then analysed using Cronbach's alpha analysis. Cronbach's alpha for KAP was 0.70 indicating that the reliability for the KAP scores were good (Cronbach's alpha ≥0.07) (Pallant, 2005).

The knowledge, attitude and practice domains comprised of six questions each with multiple choice answers. Different marks were given for each answer, and the scores for every domain and KAP were presented as mean±standard deviation (*SD*) in percentages. For the knowledge domain, subjects who scored <60% were categorised as having poor level, 60-70% as fair, and >70% as good. For the attitude domain, subjects who scored <60% were categorised as negative, 60-70% as neutral, and >70% as positive. Meanwhile, for practice domain, subjects who scored <60% were categorised as inadequate, 60-70% as adequate, and >70% as good (Bakarman, Kurashi & Hanif, 1996).

Statistical analysis

Statistical analysis was performed using the Statistical Products and Service Solution (SPSS) version 25.0 (Inc., Chicago, IL, USA). Descriptive statistics were used to identify the average salt and sodium content as mean±*SD* for each food category, the percentage of products that exceeded the criteria in IPC, and the scores for every domain and KAP as mean±*SD* in percentages. One-way analysis of variance (ANOVA) test was used to compare the average sodium content between categories. Meanwhile, one-sample *t*-test was used to compare the average sodium content for each category to their own criteria. The average salt and sodium contents for each group was reported as mean±*SD*. The significance level for all analysis was set at $p<0.05$. In ensuring that assumptions of sample homogeneity were met, Levene's test was conducted prior to ANOVA and *t*-test, whereby $p>0.05$ indicated that the assumptions had not been violated.

RESULTS

Salt and sodium content of fast food product categories

A total of 105 food products consisting of 41 sandwich products, 11 chicken-based products, eight potato-based products, 15 dessert products, 13 salad products, six bread products, six sauce products, and five rice-based products were involved in the study of salt content in food products of fast food restaurants. Table 1 shows the average salt and sodium content per 100 g in the fast food product categories. Findings showed that sauce was the category that contained the highest salt content (1.9±0.8 g/100 g), followed by bread (1.2±0.2 g/100 g), potato-based (1.2±0.4 g/100 g), chicken-based (1.2±0.3 g/100 g), sandwich (1.1±0.6 g/100 g), rice-based (0.7±0.3 g/100 g), salad (0.4±0.2 g/100 g), and dessert (0.3±0.4 g/100 g). Using one-way ANOVA test, the salt and sodium contents for sauce product category were significantly ($p<0.05$) higher compared

to sandwich, dessert, salad, and rice-based product categories. Meanwhile, the salt and sodium contents for salad and dessert product categories were significantly (p<0.05) lower compared to other categories.

Percentage of fast food products that exceeded the sodium content in the International Product Criteria

Of the 105 products involved, all potato-based products contained sodium content that exceeded the value stated by IPC. This was followed by bread products (66.7%), rice-based products (60.0%), sauce products (50.0%), sandwich products (36.6%), salad products (30.8%), and dessert products (6.7%); whereas none of the chicken-based products contained sodium content that exceeded the one stated in the IPC.

Table 2 shows the comparison of sodium content per 100 g for each category between the values stated in IPC and the findings from this study. Using one-sample t-test, results showed that the potato-based product category contained sodium content (458.1±154.1 mg/100 g) that significantly (p<0.001) exceeded the value stated in IPC, which is ≤100 mg/100 g. Meanwhile, chicken-based and dessert product categories contained sodium content (456.4±130.6 mg/100 g and 101.3±148.0 mg/100 g) that were significantly (p<0.001) lower than the values stated in IPC (2016), which are ≤820 mg/100 g and ≤400 mg/100 g. Moreover, the sodium content in bread and rice-based product categories also exceeded the values stated in IPC, although not significantly (p=0.721 and p=0.616). On the other hand, the sodium content in sauce, sandwich, and salad product categories were lower than the values in IPC, although not significantly (p=0.954, p=0.539 and p=0.321).

General characteristics of study population

A total of 108 fast food consumers (76 females, 32 males) had participated in the salt intake awareness study. Most subjects (75.0%) were aged between

Table 1. Salt and sodium content per 100 g in the fast food product categories (mean±*SD*)

Fast food product categories	*Salt content (g/100 g)*	*Sodium content (mg/100 g)*
Sauce (n=6)	1.9±0.8[a]	742.1±317.4[a]
Bread (n=6)	1.2±0.3[b]	467.4±112.5[b]
Potato-based (n=8)	1.2±0.4[c]	458.1±154.2[c]
Chicken-based (n=11)	1.2±0.3[d]	456.4±130.6[d]
Sandwich (n=41)	1.1±0.6[e]	425.7±251.3[e]
Rice-based (n=5)	0.7±0.3[f]	265.7±105.8[f]
Salad (n=13)	0.4±0.2[g]	149.3±72.2[g]
Dessert (n=15)	0.3±0.4[h]	101.3±148.0[h]

Different letters (a-b-c) indicate significant difference in salt and sodium content between categories determined by one-way ANOVA test

a – Sauce compared to sandwich, salad, dessert, rice-based

b – Bread compared to salad, dessert

c – Potato-based compared to salad, dessert

d – Chicken-based compared to salad, dessert

e – Sandwich compared to sauce, dessert

f – Rice-based compared to sauce

g – Salad compared to sauce, bread, potato-based, chicken-based, sandwich

h – Dessert compared to sauce, bread, potato-based, chicken-based, sandwich

Table 2. Sodium content per 100 g for each fast food product categories between the values stated in IPC (2016) and the findings from this study (mean±*SD*)

Fast food product categories	*Sodium content (mg/ 100 g)*		*p*
	IPC	*Amount*	
Sauce (*n*=6)	≤750	742.1±317.4	0.954
Bread (*n*=6)	≤450	467.4±112.5	0.721
Potato-based (*n*=8)	≤100	458.1±154.2*	<0.001
Chicken-based (*n*=11)	≤820	456.4±130.6*	<0.001
Sandwich (*n*=41)	≤450	425.7±251.3	0.539
Rice-based (*n*=5)	≤240	265.7±105.8	0.616
Salad (*n*=13)	≤170	149.3±72.2	0.321
Dessert (*n*=15)	≤400	101.3±148.0*	<0.001

Statistically significant at *p<0.05 determined by one-sample *t*-test

18-29 years, followed by 30-39 years (1.9%), 40-49 years (3.7%), and 50-59 years (19.4%). Almost all subjects were Malay (88.9%), followed by Chinese (7.4%), Indian (1.9%), and others (1.9%). Majority of the subjects (78.7%) were not married and 21.3% were married. Education level for most of the subjects (60.2%) was degree, followed by Foundation or Matriculation or Diploma or Certificate or *Sijil Tinggi Pelajaran Malaysia* (STPM) (24.1%), 7.4% with *Sijil Pelajaran Malaysia* (SPM), others (5.6%), and Masters (2.8%). Most of the subjects (73.2%) did not have any monthly income or they earned less than RM1,000 a month; while 19.4% subjects earned at least RM3,000 a month, whereas 7.4%

Table 3. Average score and distribution of subjects for every category level for knowledge (K), attitude (A), practice (P), and awareness (KAP) towards salt intake

Category level	*Average score (%) (Mean±SD)*	*Total (n=108)*	
		n	*%*
Knowledge (K)			
Poor (<60%)	52.8±8.1	44	40.7
Fair (60%-70%)	64.6±2.1	37	34.3
Good (>70%)	74.0±5.6	27	25.0
Attitude (A)			
Negative (<60%)	51.3±7.7	11	10.2
Neutral (60%-70%)	64.9±2.5	20	18.5
Positive (>70%)	80.5±8.7	77	71.3
Practice (P)			
Inadequate (<60%)	48.1±5.9	77	71.3
Adequate (60%-70%)	65.2±3.6	27	25.0
Good (>70%)	82.6±7.9	4	3.7
Awareness (KAP)			
Poor (<60%)	54.6±4.5	29	26.9
Fair (60%-70%)	63.6±3.4	52	48.2
Good (>70%)	74.2±3.1	27	25.0

subjects earned between RM1,000-RM2,999 a month.

Consumers' level of knowledge, attitude, practice, and overall awareness (KAP) towards salt intake

Table 3 shows the average score and number of subjects for every category level for knowledge, attitude, practice, and overall awareness towards salt intake. Most of the subjects (40.7%) who participated had poor level of knowledge with an average score of 52.8±8.1%. In contrast, 71.3% of the subjects had positive level of attitude with an average score of 80.5±8.7%. However, most of the subjects (71.3%) also had an inadequate level of practice with an average score of 48.1±5.9%. For overall awareness (KAP), nearly half of the subjects (48.2%) were at a fair level with an average score of 63.6±3.4%. Meanwhile, 26.9% were at a poor level and only 25.0% were at a good level.

Table 4 shows the overall average score for knowledge, attitude and practice levels towards salt intake. Based on this table, fast food consumers involved in this study had a fair knowledge level of salt intake with an average score of 62.2±10.5%, positive attitude level of salt intake (74.6±12.6%), but an inadequate practice level of salt intake (53.6±10.8%).

Table 4. Overall average score for knowledge (K), attitude (A) and practice (P) levels towards salt intake (*n*=108)

Category	*Overall average score (%) (Mean±SD)*
Salt intake knowledge	62.2±10.5
Salt intake attitude	74.6±12.6
Salt intake practice	53.6±10.8

Table 5 shows the distribution of subjects according to answers for questions regarding KAP towards salt intake. A total of 32.4% subjects knew that the recommended amount of salt in a day is 5 g. However, majority (43.5%) of them did not know the recommended amount of salt in a day and 74.1% subjects thought they can consume a right amount of salt. More than half of the subjects (60.2%) chose processed foods such as soy sauce, fast foods and snacks as the main sources of salt in the Malaysian diet. Only 37.0% subjects answered correctly on the relationship between salt and sodium. Almost all subjects (94.4%) knew that a high salt diet could cause a serious health problem. Majority (63.0%) responded that a high salt diet causes high blood pressure, but 25.9% thought it could cause more than one health problem.

For attitude towards salt intake, only 53.7% subjects believed that identifying foods that have high amount of salt is very important and most of them (59.3%) agreed that they try to minimise the amount of salt they consume. In addition to that, 51.9% of them thought that lowering the salt intake in their diet is important. However, only 45.4% of the subjects strongly agreed that their health would improve if they reduce their salt intake. Majority (51.9%) of them also believed that adding salt to food would make the food tastier and 53.7% subjects thought that it is important for them to check for salt content on food labels.

Most of the subjects (69.4%) sometimes added sauce or soy sauce to their food. However, 72.2% of them claimed that they added the right amount of salt during preparation of food at home. In addition to that, most of them (71.3%) also did not ask for less salt in the foods ordered when eating out. A total of 54.6% claimed that they consumed the right amount of salt and most of them (52.8%) did not do anything on regular basis to control their salt intake, in which only 23.2% controlled the consumption of processed foods,

Table 5. Distribution of subjects according to answers for questions regarding knowledge (K), attitude (A) and practice (P) towards salt intake

Questions	*Answers*	*Total (n=108)*	
		n	*%*
Knowledge (K)			
Health professionals recommend that we should eat not more than a certain amount of salt each day. How much salt do you think that is?	5 g (about 1 teaspoon)†	35	32.4
	8 g (about 1 and a 1/2 teaspoons)	15	13.9
	10 g (about 2 teaspoons)	11	10.2
	Don't know	47	43.5
Which of the following do you think is the main source of salt in the Malaysian diet?	Salt added during cooking‡	31	28.7
	Salt from processed foods such as soy sauce, fast foods and snacks	65	60.2
	Salt from natural food sources such as shellfish and milk	6	5.6
	Don't know	6	5.6
How much salt do you think you can consume?	Very little‡	13	12.0
	Right amount	80	74.1
	Too much	7	6.5
	Don't know	8	7.4
Information on the amount of salt within a food product in Malaysia is usually displayed on the food label. What is the relationship between salt and sodium?	Salt contains sodium†	40	37.0
	Salt and sodium are the same	32	29.6
	Sodium contains salt	5	4.6
	Don't know	31	28.7
Do you think that a high salt diet could cause a serious health problem?	Yes†	102	94.4
	No	4	3.7
	Don't know	2	1.9
If you answer Yes in question 5 above, what are the health problems? (Subjects can choose more than one answer)	High blood pressure†	68	63.0
	Osteoporosis†	0	0.0
	Stomach cancer†	0	0.0
	Kidney stones†	1	0.9
	None of the above	8	7.4
	Don't know	3	2.8
	More than one health problem†	28	25.9

Table 5. Distribution of subjects according to answers for questions regarding knowledge (K), attitude (A) and practice (P) towards salt intake (continued)

Questions	*Answers*	*Total (n=108)*	
		n	*%*
Attitude (A)			
How important is it for you to identify food that has high amount of salt?	Very important‡	38	35.2
	Important	58	53.7
	Less important	9	8.3
	Not important	3	2.8
I try to minimise the amount of salt that I consume.	Strongly agree‡	26	24.1
	Agree	64	59.3
	Slightly agree	16	14.8
	Disagree	2	1.9
How important for you in lowering the salt intake in your diet?	Very important‡	42	38.9
	Important	56	51.9
	Less important	8	7.4
	Not important	2	1.9
My health would improve if I reduce the salt intake in my diet.	Strongly agree‡	49	45.4
	Agree	49	45.4
	Slightly agree	9	8.3
	Disagree	1	0.9
I believe that by adding salt to food would make the food tastier.	Strongly agree	19	17.6
	Agree	56	51.9
	Slightly agree	25	23.2
	Disagree‡	8	7.4
How important is it for you to check for salt content on food labels?	Very important‡	24	22.2
	Important	58	53.7
	Less important	23	21.3
	Not important	3	2.8

Table 5. Distribution of subjects according to answers for questions regarding knowledge (K), attitude (A) and practice (P) towards salt intake (continued)

Questions	*Answers*	*Total (n=108)*	
		n	*%*
Practice (P)			
During each meal time, do you add sauce or soy sauce to the food?	Never‡	15	13.9
	Sometimes	75	69.4
	Often	14	13.0
	Always	4	3.7
How much salt is added during preparation of food at home?	None‡	1	0.9
	Very little	28	25.9
	Right amount	78	72.2
	Too much	1	0.9
Do you ask for less salt in the food that you ordered when eating out?	Never	77	71.3
	Sometimes	30	27.8
	Often	1	0.9
	Always‡	0	0.0
How much salt do you think you consume?	Very little‡	13	12.0
	Right amount	59	54.6
	Too much	24	22.2
	Don‘t know	12	11.1
Do you do anything on regular basis to control your salt intake?	Yes‡	45	41.7
	No	57	52.8
	Don‘t know	6	5.6
If you answer Yes in question 11, what do you do? (Subjects can choose more than one answer)	Avoid/minimise the consumption of processed foods†	25	23.2
	Read the salt content on the food labels†	0	0.0
	Buy alternative foods with low salt†	7	6.5
	Not adding salt when cooking†	1	0.9
	More than one routine action†	10	9.3
	All of the above†	2	1.9
	None	63	58.3

†Correct answer
‡Best answer

6.5% bought alternative foods with low salt, and 0.9% did not add salt when cooking. Only 9.3% of them did more than one of these actions routinely. On the other hand, majority of them (58.3%) did none of these actions.

DISCUSSION

In the first phase of this study, salt content in food products of fast food restaurants were identified and assessed. The results showed that in general, sauce was the category that contained the highest salt content (1.9 g/100 g) compared to the other categories and were significantly (p<0.05) higher compared to sandwich, dessert, salad, and rice-based product categories. This result is consistent with a previous study by Heredia-Blonval *et al.* (2014), which reported that the highest salt content was found in the sauce category (2.2 g/100 g) compared to other food categories of fast food restaurants. According to MDG (NCCFN, 2021), sauces are one of the high salt sources. Additionally, this study also found that salad category was one of the categories that contained the lowest amount of salt compared to other categories besides dessert. Heredia-Blonval *et al.* (2014) in their study also reported that salad category contained the lowest amount of salt compared to other categories.

In comparison with the sodium content stated in the IPC, 50.0% of the products under the sauce product category exceeded the criteria value suggested by IPC. Although the average sodium content in the sauce product category (742.1 mg/100 g) was not significantly (p=0.954) higher than the criteria in IPC, it is still worrying considering that sauces are not often eaten just as they are. Instead, sauces are often eaten with other foods such as fast food (Codex Alimentarius, 1995), which is also a high salt source (NCCFN, 2021). This study also found that all potato-based products contained sodium content (458.1 mg/100 g) that significantly (p<0.001) exceeded the value stated by IPC.

In the second phase of this study, KAP towards salt intake among fast food consumers was assessed. Overall, majority of the consumers who participated in this study were reported to have a fair level of salt intake awareness (63.6%).

The results showed that in general, consumers had a fair knowledge level (62.2%). However, two in five consumers had poor level of knowledge. Additionally, three quarters of subjects claimed that they can consume a right amount of salt despite only a third of them who actually knew the correct recommended amount of salt in a day, which is 5 g (WHO, 2012). Moreover, 43.5% of them were not knowledgeable about this recommended level. This finding is in line with a study by Grimes *et al.* (2017), in which most of their subjects did not know the recommended amount of salt in a day. More than half of the subjects in this current study (60.2%) were knowledgeable about the sources of salt in the Malaysian diet, which are processed foods such as soy sauce, fast foods and snacks (NCCFN, 2021). This study also found that only 37.0% subjects were informed on the relationship between salt and sodium, in which salt contains sodium. This differed from a study by Nasreddine *et al.* (2014) where a majority of their subjects knew about the correct relationship between salt and sodium. Other than that, almost all subjects (94.4%) knew that a high salt diet could cause a serious health problem, with majority of them (63.0%) thinking that a high salt diet could cause hypertension alone. However, only 25.9% of them knew that it could pose more than one health problems including hypertension, osteoporosis, stomach

cancer, and kidney stones. This finding is in line with studies by IPH (2016) and Aparna *et al.* (2019), in which most of the subjects in these studies were not aware of the relationship between a high salt diet and other diseases, aside from hypertension.

For attitude towards salt intake, the consumers were generally at a positive level (74.6%). This is expected as majority of them (71.3%) had a positive level with an average score of 80.5%. Most of them (53.7%) knew that identifying foods that have high amount of salt is important and 59.3% of them claimed that they try to minimise their consumption of salt. Additionally, 51.9% of them knew that lowering the salt intake in their diet is important. This finding is similar to a study by Aparna *et al.* (2019) that was conducted in North India. The current study also found that 45.4% of subjects agreed and strongly agreed that their health would improve if they reduce their salt intake in their diet, which is also in line with a study by Grimes *et al.* (2017) that was conducted among Australians. Besides that, 51.9% of the subjects claimed that adding salt to food would make the food tastier and 53.7% claimed that it is important to check for salt content on food labels.

In contrast to the fair level of knowledge and positive level of attitude towards salt intake, the consumers in general had an inadequate level (53.6%) of practice towards salt intake, as majority of them (71.3%) were scored at an inadequate level (48.1%). According to Mat Daud *et al.* (2018), being equipped with the knowledge of nutrition often probes a person to practise healthy eating habits. In accordance to that, Spronk *et al.* (2014) also reported that having higher knowledge of nutrition was associated with better or healthier food consumption. In this study, 72.2% of the consumers claimed to practise adding salt in a right amount during the preparation of foods at home and 54.6% claimed that they practise consuming salt in a right amount. However, majority of the consumers did not know the recommended amount of salt in a day. This showed that even if the consumers had good knowledge of food and nutrition, it does not ensure good practices of salt intake. According to Banwat *et al.* (2012), the good practices of healthy eating cannot be ensured solely based on nutrition knowledge alone.

According to Shaziman *et al.* (2017), the attitude towards healthy eating influences a person's dietary habits. However, most of the findings in this study showed otherwise. Firstly, this study reported that 69.4% of consumers sometimes added sauce or soy sauce to their food. According to Shahar *et al.* (2019), Malaysians still consume high amount of salt through sauces even if they do not add salt to their food. As mentioned previously, sauces contain the highest amount of salt compared to other fast food categories (Heredia-Blonval *et al.,* 2014) and are often eaten with other meals (Codex Alimentarius, 1995). This practice has contradicted majority of the consumers' attitude in this study, which reported that identifying foods that have high amount of salt is important. In addition to that, 71.3% of the consumers never asked for less salt in the foods ordered when eating out despite majority of them claiming that they try to minimise their salt consumption and that lowering their salt consumption is important. In light of this, it is worth mentioning that while fast food restaurants serve ready-to-eat dishes compared to other forms of food, request on lowering salt in fast foods at the point of re/heating the food can be made. For example, consumers could ask for less salt to be sprinkled on their French fries during order. Only 41.7% of the consumers controlled their salt intake on a regular basis, and 58.3%

consumers claimed to do none of the salt intake practices such as controlling their consumption of processed foods, buying alternative foods with low salt or not adding salt when cooking. Aside from that, 58.3% of them also did not read the salt content on food labels although most of the consumers claimed that checking for salt content on food labels is important.

Phase two of this study showed that although the knowledge and attitude of the consumers towards salt intake were good, their practice proved otherwise. Similar findings were also reported on a study of KAP towards healthy eating among university students in Selangor (Hassan *et al.,* 2015). The limitations in this current study were that the types of food products involved were limited and did not cover other categories of fast foods such as pizza. Additionally, the number of restaurants chosen were also limited. Hence, the findings cannot be generalised to represent all fast food products from all fast food restaurants. In regards to the study on KAP, the questionnaires were distributed online instead of physically approaching the samples. This method of administering the questionnaire might have posed bias in this age group of samples, whereby the questionnaire might have reached more of the younger age groups who are internet savvy compared to the older age groups. For future study, more food products covering all fast food categories from more restaurants should be considered. In addition, future KAP study should also involve approximately equal number of subjects from every age group to minimise bias.

CONCLUSION

Among the fast food categories, sauce product category had the highest amount of salt. Additionally, potato-based product category contained sodium content that significantly (p<0.05) exceeded the criteria in IPC. As for the KAP study, fast food consumers generally had fair level of overall awareness, fair level of knowledge and positive attitude towards salt intake. Still, they did not practise it in their daily lives. Therefore, more strategic interventions that will enable the control of salt intake among adults in Malaysia are needed.

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Authors' contributions

ZNZA, led the data collection, data analysis and interpretation, and prepared the manuscript; NZMS, assisted in the statistical analysis; HH, principal investigator, conceptualised and designed the study and reviewed the manuscript.

Conflict of interest

There was no conflict of interest involved.

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Relationship between maternal characteristics and stunting in children aged 0 to 23 months in the Philippines

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ABSTRACT

Introduction: Stunting is the most prevalent form of child malnutrition worldwide, and is the best overall indicator of growth. This study aimed to determine the relationship between maternal characteristics and nutritional status of children aged 0-23 months based on their length/height-for-age. **Method:** The study used data from the 2015 Updating Survey conducted by the Philippines' Food and Nutrition Research Institute – Department of Science and Technology. It employed a stratified multi-stage sampling technique covering all regions in the Philippines. Mothers (n=5,254) of sampled children 0-23 months were the respondents of the Maternal Health and Nutrition survey. The length-for-age z-scores (LAZ) of children and maternal characteristics were analysed. Rao-Scott Chi-square test was used for association analysis. Logistic regression was performed for model fitting. **Results:** A quarter (25.2%) of children aged 0-23 months in the Philippines at the time of the survey were stunted, with the highest prevalence (36.2%) observed among 12-23 months. Children being stunted or normal in height was associated with prenatal services, maternal nutritional status, education, and duration of lactation. Maternal education (OR: 0.39; p=0.012), age-appropriate breastfeeding (OR: 0.63; p=0.042), and prenatal services like tetanus toxoid vaccination (OR: 0.67; p=0.011) and ultrasound (OR: 0.71; p=0.025) lowered the likelihood of a child being stunted. **Conclusion:** It is recommended to strengthen and intensify service delivery among pregnant and lactating women because of the implication of maternal factors to the length-for-age status of children 0-23 months.

Keywords: stunting, maternal factors, length-for-age, education, young children

INTRODUCTION

Stunting is a form of chronic undernutrition and is used to describe populations of children who are short for their age (UNICEF, 2019). According to de Onis and Branca (2016), childhood stunting is the best overall indicator of well-being in children. Irreversible consequences of stunting under the age of 24 months include compromised motor skills and cognitive function, which may insinuate poor academic performance in the future (UNICEF, 2007). Stunting is the most prevalent form of child malnutrition worldwide, where one out of three children aged under 5 years or 149 million children aged under 5 years are affected (UNICEF,

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2019). In the Philippines, about 33% or 3.6 million children aged 0-60 months were stunted in 2015, making the country ranked 9th in terms of countries with the highest burden of stunting (DOST-FNRI, 2015). Among all the age groups, the highest rate of stunting was recorded among children between the ages of 12-23 months with a prevalence of 36%. Moreover, there has been little improvement in the percentage of stunted children since 2003 when the prevalence of stunting decreased to 34% from the previously recorded 45% in 1989. The observed innate relationship between mother and child made past researches like Babatunde *et al.* (2011), and Kandpal and McNamara (2009), use maternal characteristics as possible factors in predicting child nutrition, since young children are more dependent on their caretakers, which oftentimes are their mothers.

Improvement in child nutrition has long been associated with human capital investment. Healthier children are bound to have lesser chances of suffering from premature death compared to malnourished children. In addition, stunting among young children, in particular, is known to affect the mental capacity of children, as well as their cognitive skills (UNICEF, 2007). The psychological function was also found to be negatively affected amongst adolescents that have a history of stunting before they were two years old (Walker *et al.*, 2007). Anxiety, depression, and low self-esteem were more prevalent amongst those that suffered from stunting before the age of two compared to those with no history of stunting (Walker *et al.,* 2007). The study by Boah *et al.* (2019) in Ghana showed that food intake, birth weight, history of diseases, and sex are some of the main factors that are related to malnutrition among young children. The study also mentioned that maternal nutrition can affect foetal growth because there are some intrauterine growth limitations commonly observed among underweight mothers. Socioeconomic factors have also been observed to be related to young child malnutrition. Based on the factors mentioned, there is high maternal influence observed in the nutrition of infants and young children— especially since children aged 0-23 months are highly dependent on their mothers. Thus, this study aimed to determine the relationship between maternal characteristics and nutritional status of children aged 0-23 months based on their height-for-age anthropometric indicator. Besides that, the likelihood of stunting among children aged 0-23 months using maternal characteristics as predictors was identified using an estimated model.

The results of this study can be a basis for policy makers in the Philippines in its design of national interventions to address stunting, specifically focusing on maternal factors that relate to stunting within the first two years of life. Stunting in children is known to have grave irreversible effects on the child's growth and development, therefore nutrition interventions and policies on stunting must recognise the importance of addressing maternal factors that might have an impact on improving the malnutrition situation. Future studies on stunting or malnutrition among infants and young children may use the results of this study as a reference to achieve a deeper understanding of child nutrition.

This study used the survey data on children under two years of age in the Philippines. Any conclusions that could be made from this study will only reflect children of that age group in the country. Since the data used were from the 2015 Updating of the Nutritional Status of Filipino Children and Other Population Groups survey conducted by the Department of Science and Technology-Food and Nutrition Research Institute (DOST-FNRI), more recent data could reveal different results from

this study. Any factors related to infant nutrition other than that of maternal characteristics were not included nor reflected in the study.

MATERIALS AND METHODS

Data source

The study used the Maternal Health and Nutrition and Infant and Young Child Feeding (MHN-IYCF) Surveys, Socio-Economic Survey, and Anthropometric Survey data from the 2015 Updating Survey conducted by the Food and Nutrition Research Institute – Department of Science and Technology (FNRI-DOST). The survey used the Master Sample (MS) developed by the Philippine Statistics Authority (PSA) where the country's 17 administrative regions served as the domains. Stratified multi-stage sampling was employed to cover all regions and provinces in the country. The first stage was the selection of the primary sampling units (PSUs), which were barangays with at least 500 households. Following that was the selection of enumeration areas (EAs) or barangays with 150-200 households, and then the selection of households from EAs, which served as sampling units (SUs). Respondents for the MHN survey were mothers with their youngest biological child aged between 0-36 months, while the IYCF survey considered households with children aged between 0-23 months (FNRI-DOST, 2016). This study considered children under 2 years of age with no missing information on their measurements and their mother's characteristics, yielding a total of 5,254 sampled children aged 0-23 months.

Variables of interest

The dependent variable considered in the study was the nutritional status of children aged 0 – 23 months based on their length-for-age *z*-scores (LAZ), classified as stunted, normal, and tall. LAZs were computed using the World Health Organization (WHO) Anthro Survey Analyser. Children with *z*-scores of <-2 standard deviation (*SD)* were classified as stunted, those with -2*SD* to +2*SD* were considered as normal in height, and those with *z*-scores of >+2*SD* were identified as tall. Moreover, the magnitude and severity of malnutrition in the country in terms of stunting was assessed as low, medium, high, and very high with the prevalence of stunting as <20%, 20-29%, 30-39%, and ≥40%, respectively (WHO/UNICEF, 2019). The maternal characteristics used in the study were clustered into four groups. The first group comprised of socio-demographic information about the mothers such as ethnicity, educational attainment, employment status, and occupation. The second group was about the fertility and health of the mothers, which included nutritional status, vitamin intake, and all the physiological status of mothers. The third group composed of those variables that determined pregnancy practices such as prenatal care/lack of prenatal care, taking/failure to take pregnancy supplements, and counselling/ lack of counselling during pregnancy. The last group comprised of maternal knowledge and practices like breastfeeding and complementary feeding.

Data collection

The length of children younger than two years old and the height of those two years and older were measured using a medical plastic infantometer and stadiometer, respectively. The length/ height measurements were recorded to the nearest 0.1 cm, adhering to standard procedures. Calibration of the instruments was done using standard procedures. Meanwhile, data on maternal characteristics were generated through personal interviews among mothers or primary caregivers of the 0-23 month-old children in sampled households using an electronic data

collection system (e-DCS) (FNRI-DOST, 2016).

Ethical review

The 2015 Updating Survey received approval from the FNRI Institutional Ethics and Review Committee. Written consent was obtained from the subjects through the mother or guardian for the conduct of the survey and measurements. Moreover, all the questionnaires used in the survey were pretested and approved by the PSA (FNRI-DOST, 2016).

Data analyses

The subjects in this study were described by constructing weighted percentage distributions. Likewise, the nutritional status of children 0-23 months based on the length-for-age indicator was presented by constructing a weighted percentage distribution. To test whether the stunting condition of children was associated with maternal characteristics, the Rao-Scott Chi-square test was used. To measure the degree of association between anthropometric variables and maternal characteristics, the Cramer's *V* coefficient was computed, which ranged from 0 to 1 only. A value between 0 and 0.1 indicated a weak association between the variables, while a value between 0.1 and 0.3 referred to a moderate association, and a coefficient of >0.3 denoted a strong association between the variables (Akoglu, 2018). Factors found with significant association to the stunting condition of a child were further subjected to model fitting using the binary logistic regression analysis. The nutritional status based on LAZ, which served as the dependent variable, was set to 0 for the normal category and 1 for stunting. The assumption that each child belonged to one of the two mutually exclusive categories (0 or 1) was held. The normal category (Y=0) served as the reference category. The tallness of a child using LAZ is usually not a problem unless there is the presence of uncommon endocrine disorders that cause excess growth hormones (WHO, 2008). There was no information about endocrine disorders in the 2015 Updating Survey, therefore, a separate category for tallness was not considered in this study.

Before model fitting, the data were divided into two parts: one part to serve as a training dataset and the other as a test dataset. The training dataset, which was 70% of the original dataset, was used to fit the models for each anthropometric indicator. The remaining 30% of the original data – the test data, was used to assess the predictive ability of the models. The 70-30 ratio of the training and test dataset is one of the most common ways of partitioning datasets from empirical studies and is sometimes considered the rule of thumb (Ng, 2017). Division of the original dataset was necessary to avoid overfitting, which can occur when the generated model becomes too specific for a dataset that it becomes unusable for other datasets (Gindro, 2020). The generated models were assessed based on the corresponding values on the diagnostic tests: sensitivity, specificity, and overall classification rate (Altman & Bland, 1994). Sensitivity (true positive rate) provides the proportion of correctly classified stunted children aged 0-23 months. The higher the value of sensitivity, the more likely the model could be able to predict stunted children. Alternatively, specificity (true negative) provides the proportion of correctly classified children with normal nutritional status. Higher specificity values imply fewer chances of having false positives, meaning the model is able to detect normal children efficiently. Meanwhile, the overall classification rate or accuracy provides the proportion of correctly classified observations (true positives and true negatives). Likewise, the Receiver Operating Characteristic (ROC) curve graphically shows the trade-off between sensitivity and specificity (Zweig & Campbell, 1993). The area under the ROC curve (AUC) shows how

well the estimated model is. In addition, model tests such as the Hosmer-Lemeshow test were applied to show more evidence that the latest or current model has a better fit compared to models with less predictors or the intercept-only model (Fagerland & Hosmer, 2012). The null hypothesis tested by the model was that the current model is more adequate compared to previous models, therefore, a high p-value from the test would give support to the current model.

RESULTS

About a quarter (25.2%) of children aged 0-23 months at the time of the survey were stunted. The stunted male children outnumbered stunted females with an estimated rate of 28.7% and 21.6%, respectively. The largest portion of stunted children was registered by those aged between 12 and 23 months, accounting for 36.2% of the children population – implying that stunting was highly prevalent in this age group, particularly for males with a higher prevalence rate of 40.7% as compared to females with 31.7%. On the other hand, children aged 0-5 months and 6-11 months both registered low magnitude and severity of stunting with a prevalence rate of 12.1% and 16.4%, respectively (Table 1).

Among the several maternal characteristics considered in the survey, Table 2 presents those found to be significantly associated with the stunting status of children aged 0-23 months at the 5% level of significance. In particular, being stunted or normal in height was weakly associated with the practice of post-natal check-up, taking an ultrasound, tetanus toxoid vaccine prenatal services, taking folic acid, and single vitamin and multivitamins during pregnancy, diabetic complications during pregnancy, nutritional status of the mother, and highest educational attainment. Meanwhile, the duration of lactation of a mother was moderately associated with the stunting of children aged 0-23 months. Furthermore, based on the model fitting, highest educational attainment, months of lactation, age-appropriate breastfeeding, having tetanus toxoid vaccination and ultrasound during pregnancy, and trimester of pregnancy were found to be significant influencing factors for a child aged 0 to 23 months being stunted at the 5% level of significance (Table 3). The odds of a child being stunted was 61% lower if the mother had attained at least a college level of education than if the mother had no formal schooling. Also, whether a mother was lactating or not at the time of the survey was found to be a significant influencing factor for a child being stunted. It was estimated that the odds of a child being stunted was 42% lower if a mother had been lactating between 1 to 6 months compared to a mother that was not lactating. However, the likelihood to be stunted was 2.64 times higher if the mother was lactating for more than a year compared to a mother that was not lactating. In relation to lactation, it was found in this study that age-appropriate breastfeeding also lowered the odds of a child being stunted

Table 1. Weighted percentage distribution of children aged 0-23 months based on LAZ indicator, by age group and sex in the Philippines

Age group (month)	*Male*			*Female*			*Both sexes*		
	Stunted %	*Normal %*	*Tall %*	*Stunted %*	*Normal %*	*Tall %*	*Stunted %*	*Normal %*	*Tall %*
00-05	14.3	81.7	4.0	11.0	82.5	6.5	12.7	82.0	5.3
06-11	21.1	75.7	3.2	13.2	83.5	3.3	17.3	79.4	3.3
12-23	40.7	56.3	3.0	31.7	65.6	2.7	36.2	61.0	2.8

by 37%. Meanwhile, a child whose mother was in her third trimester of pregnancy at the time of the survey was more likely to be stunted by almost three times (2.95) compared to a child whose mother was not pregnant. Pregnancy practices of mothers also contributed to child nutrition. A decrease of 33% in the chance of a child being stunted was observed if the mother had availed tetanus toxoid vaccination during her pregnancy. Lastly, the mother having an ultrasound during pregnancy also decreased the chance of a child being stunted by 29%. Hosmer and Lemeshow's goodness-of-fit test signified that the estimated model fitted the data well (p=0.143). The generated ROC with an

Table 2. Association between maternal characteristics and stunting status of Filipino children aged 0-23 months

Maternal Characteristics	*Chi-square test statistic*	*Cramer's V coefficient*	*p-value**
Months of lactation	61.19	0.107	<0.001
Practice of post-natal check-up	46.17	0.094	<0.001
Highest educational attainment	39.9	0.088	<0.001
Trimester of pregnancy	39.37	0.086	<0.001
Prenatal service: ultrasound	28.64	0.075	<0.001
Currently taking vitamins	24.73	0.073	<0.001
Pregnancy supplement: single vitamin/mineral	17.21	0.061	<0.001
Nutritional status	15.33	0.054	0.003
Prenatal service: tetanus toxoid vaccine	12.58	0.050	0.001
Pregnancy supplement: folic acid	8.30	0.042	0.010
Complications in pregnancy due to diabetes	3.24	0.040	0.005
Knowledge of child vaccine	5.27	0.032	0.023

*significant at $p \leq 0.05$

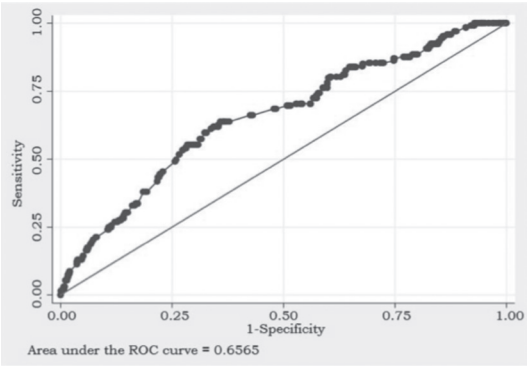
Table 3. Estimated logistic regression model for stunting among Filipino children aged 0-23 months

Maternal characteristics	*Coefficient*	*Standard error*	*Odds ratio*	*p-value**
Education[†]				
At least college level	-0.941	0.394	0.39	0.012
Current months of lactation[‡]				
1-6 months	-0.545	0.276	0.58	0.049
Over 1 year	0.969	0.264	2.64	<0.001
Age appropriate breastfeeding[§]				
Yes	-0.464	0.228	0.63	0.042
Trimester of pregnancy[¶]				
Third	1.083	0.385	2.95	0.005
Prenatal service: tetanus toxoid vaccine[††]				
Availed	-0.405	0.160	0.67	0.011
Prenatal service: ultrasound[††]				
Availed	-0.342	0.152	0.71	0.025
Constant	-1.220	0.393	0.30	0.002

*significant at $p \leq 0.05$
Base category:
[†]No formal schooling, [‡]Not lactating, [§]No, [¶]Not pregnant, [††]Did not avail

AUC of 0.66 revealed that the generated model has low discriminatory power over stunted and normal children. However, the overall accuracy rate of the model was 70.10% - fair enough for a model (Figure 1). Moreover, specificity and sensitivity tests showed that 55.24% of the stunted children were correctly classified, while 71.53% of the normal children were properly classified. The accuracy tests revealed that the model can discriminate stunted with normal children.

Figure 1. ROC curve generated using the model for LAZ indicator



DISCUSSION

The stunting condition of children aged 0-23 months in the Philippines can be classified in the medium magnitude and severity, and the prevalence of stunting increased by 1.8% in two years. This showed that no improvement has been recorded in the stunting condition of this age group population from 2013 to 2015 – implying a failure to meet the target reduction in the prevalence of stunting by 2015 as outlined in the Millennium Development Goals. It can be observed that as a child grows older, the degree of magnitude and severity of stunting gets higher. In particular, those aged 12-23 months exhibited higher magnitude and severity of stunting, with more serious condition noted among male children. This finding is similar to the study of Khaldi and Bouguerra (2000), where they found that children grew well until the ages of 5 to 6 months, then growth often faltered with the introduction of inadequate complementary foods and continued to decline until 24 months.

The lower magnitude of stunting within ages 0-11 months and higher magnitude in children 12-23 months could be attributed to infant feeding and complementary feeding practices. As recognised by Shrimpton *et al.* (2001), the age of 6-24 months in young children is one of the most critical periods of linear growth. This is also the time when the prevalence of stunting is at its peak in developing countries because this period is characterised by high demand for nutrients coupled with limited quality and quantity of complementary foods (Dewy & Adu-Afarwuah, 2008). These findings are vital for consideration since the first 1000 days of life is the most effective time to prevent stunting. Children suffering from stunting may still be able to reverse that condition to avoid future health and mental problems (Black *et al.,* 2013).

A child being stunted or normal in height was found to be associated with the practice of post-natal check-up, taking an ultrasound, tetanus toxoid vaccine prenatal services, taking folic acid, and single vitamin and multivitamins during pregnancy, diabetic complications during pregnancy, nutritional status of the mother, highest educational attainment, and the duration of lactation of a mother, with the latter having a higher degree of association as compared to the other maternal characteristics. These results can be supported by several previous studies. In a study conducted by Aturupane *et al.* (2008), it was concluded that maternal education, nutrition knowledge, and post-pregnancy processes contributed to a child's nutritional status. In addition, prenatal services were also found to decrease the odds of birth complications that could affect future child nutrition

(Turner *et al.,* 1996). Ultrasound is one of the most accessible prenatal services since it allows parents and doctors to detect any abnormalities while the child is still in the womb (Gudex *et al.,* 2006). Tetanus toxoid vaccine is also highly recommended for expecting mothers since the vaccine is known to reduce neonatal mortality (Blencowe *et al.,* 2010). The intake of vitamins during pregnancy is important especially for underweight mothers since micronutrient deficiency can lead to pregnancy complications that can affect the ability to lactate and the growth of the foetus (Yakoob *et al.,* 2010). Furthermore, Piper and Parks (1996) revealed that social status, smoking history of mothers, and parity can all affect the duration of lactation.

In this study, maternal education lowered the likelihood of a child being stunted. Maternal education had been cited by Aturupane *et al.* (2008) and Babatunde *et al.* (2011) to be a significant factor in child nutrition in their studies. From the study of Babatunde *et al.* (2011), a higher level of maternal education would decrease the chances of a child suffering from undernourishment. Children with mothers that have at least a college level of education had a lower chance of being stunted compared to children with mothers that had no formal education. Higher maternal education is often associated with better health practices and nutrition knowledge, which explains the observed decrease in the likelihood of being stunted in all the fitted models. A mother that is either working or still a student also decreases the likelihood of their children being stunted. Boah *et al.* (2019) suggested that household income has a significant effect on child nutrition, which is related to the employment status of others. Higher educational attainment also suggests better chances of being employed, which may explain why the two maternal characteristics have a positive effect on improving child nutrition.

Several studies have found that mothers being pregnant in the third trimester at the time of survey was an influencing factor to a child's stunting. Blencowe *et al.* (2010) stated that neonatal and maternal death are greatly reduced by tetanus toxoid vaccination on expecting mothers, which is why it is a staple recommended vaccination during pregnancy. It was also found that mothers having an ultrasound during pregnancy could lower the chance of a child being stunted. Gudex *et al.* (2006) stated that mothers who only learned of their pregnancy in the second trimester specifically viewed ultrasound as a way to be certain on whether the child was growing normally and void of any abnormalities. They also noted that mothers who had previous abortions or miscarriages hunted for reassurance during ultrasounds.

CONCLUSION AND RECOMMENDATION

Malnutrition is one of the recurring problems in the Philippines. Stunting, as the most common type of undernutrition among children in the Philippines has been the focus of this study. The results of this study gave further support to the assertion that human capital is necessary to improve child nutrition. A healthy and educated mother would tend to understand the possible long-term effects of malnutrition and why young children need to be well taken care of, thus mothers with enough nutrition knowledge would prevent their child from becoming stunted. According to Martorell and Zongrone (2012), stunting is a cyclical process because a mother who is stunted in childhood tends to have stunted babies. Thus, addressing the problem of stunting early in life is important to break the intergenerational cycle of poverty and reduced human capital that are also associated with stunting. This modelling suggested the strong

association between formal education of mothers with the height-for-age status of children 0-23 months. Improving the degree of education among women of reproductive age could be a good entry point to reduce the prevalence of stunting in children 0-23 months of age. Also, the Philippines already has numerous health and nutrition programmes. The government should strengthen service delivery among pregnant and lactating women, as well as children ages 0-23 months, to cover the first 1000 days of life. Ensuring a higher coverage rate and accessibility to programmes like micronutrient supplementation, local delivery of maternal and newborn service package, and nutrition education among the target groups may help reduce the magnitude of stunting in the country. Lastly, initiatives towards the promotion of exclusive breastfeeding for the first six months of life, timely introduction of complementary feeding, and continued breastfeeding with a longer lactation period, should be intensified because of their association in lowering the odds of having a 0-23 months child with low height-for-age.

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Authors' contributions

APVH, conceptualised, designed and prepared the manuscript, conducted data analysis and reviewed related articles; NAT, conceptualised, designed and prepared the manuscript; DGCD, conducted review of related literatures. All authors interpreted the results of analysis, read and approved the manuscript.

Conflict of interest

The authors declared no conflict of interest.

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Improving maternal nutrition in public health facilities by strengthening the dietary component of Janani Shishu Suraksha Karyakram – A government of India programme

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ABSTRACT

Introduction: The Janani Shishu Suraksha Karyakram (JSSK) is a government of India initiative for all pregnant women visiting public health facilities, with many free entitlements – free diet being one. After an in-depth study of existing dietary provisions in all community health centres, an elaborate cyclic-weekly nutritious menu was designed taking into consideration the latest recommendations (2019) by the Ministry of Family and Child Welfare, India to improve maternal health nutrition. **Methods:** The health functionaries from all ten community health centres of rural Vadodara were chosen for an in-depth estimation of the different meals served in the facilities. Standard measuring cups and spoons were used to measure the exact serving sizes for each person. Each meal served was supervised, checked and quantified in triplicate, while macro- and micronutrients were calculated using the Indian Food Composition Tables 2017 (Longvah *et al.* 2017). To bridge the gap in service delivery, two new models of cyclic-weekly menu were developed, keeping in mind the amount per mother per day as one hundred Indian rupees. **Results:** On average the foods served in the community health centres provided 69% of recommended energy intake, while mean recommended dietary allowance met for protein was 51%, calcium 18%, iron 50%, and fat 267%. **Conclusion:** The recommendations specified in this paper would improve the nutritional status of all pregnant and lactating women availing the services in rural health facilities, which would go a long way in ensuring safe and healthy motherhood.

Keywords: institutional delivery, nutrition, pregnant women, lactating women, public health facility, weekly cycle menu

INTRODUCTION

The Janani Shishu Suraksha Karyakram (JSSK) is a government of India programme initiated in 2011 with free entitlements to benefit pregnant women who access government health facilities for their delivery and also to motivate those who still choose to deliver at their homes to opt for institutional delivery across all states of India. The free

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entitlements include free and cashless delivery, free Caesarean section, free drugs and consumables, free diagnostics, free diet during the stay in the health institutions, free provision of blood in case of blood transfusion, exemption from user charges, free transport from home to health institutions, free transport between facilities in case of a referral, and free drop back from institutions to home after 48 hours stay (National Health Portal, 2015). The Indian Institute of Health Management and Research (IIHMR, 2012) conducted a study in Rajasthan and reported that 60% of mothers received free diet, whereas free diagnostic services were availed by 75% of them. The government of Gujarat extended the benefits of this scheme from neonates up to infants one year of age and up to 42 days post-partum for pregnant women.

Free diet is one of the main entitlements, but one which is not well taken care of with regards to quality and nutrients. Most of the women who register in these centres are from economically distressed background with moderate or severe malnutrition. All these conditions ultimately lead to maternal health problems and health issues in the newborns. If the beneficiaries are given proper nutritious diet during this crucial period, it would lead to safe delivery and good postnatal health. Numerous studies have been conducted on the awareness, utilisation, and out-of-pocket expenditure incurred in this programme, but no data is available on the nutrient content of the diets served, whether the recommended dietary allowances were met or fell short. A sedentary pregnant woman should consume 2500 kilocalories (kcal) per day, with 74 grams (g) protein, 30 g fat, 1200 milligrams (mg) calcium, and 21 mg iron (National Health Mission, 2018). This should be distributed in three main meals [two-thirds of the Recommended Dietary Allowance (RDA) distributed in three meals] and two snacks [one-third the RDA distributed in snacks]. The present study was aimed at evaluating the free diets served in different public health facilities and recommending two models of cyclic-weekly menu which could bridge the gap between the recommended dietary allowances prescribed by The Indian Council of Medical Research (Gopalan *et al.*, 2011) guidelines for pregnant and lactating women and the actual diets served in the public health facilities.

MATERIALS AND METHODS

The study was a community cum facility based cross-sectional study, conducted in all the Community Health Centres (CHCs) of rural Vadodara district, in the state of Gujarat, India during the years 2019-2020. This study was approved by the Institutional Ethics Committee for human research under approval number: IECHR/2019/10, Department of Foods and Nutrition, The Maharaja Sayajirao University of Baroda, Vadodara, Gujarat, India. Rural Vadodara has eight blocks, in which there are ten CHCs. Written permission was sought from the Regional Deputy Director, Health and Medical services and from the Chief District Health Officer's (CDHO) office, Vadodara for conducting the study. At the beginning of data collection, before interviews were conducted, written consents were taken from all superintendents, head nurses, diet-aides-in-charge of the ten CHCs, and also from mothers who had then delivered and were using the health facilities. Weekly menu of the diet provided by the facilities was obtained using a descriptive, detailed questionnaire, which was made after an in-depth study of the service delivery of

the programme in all health facilities. This tool (questionnaire) was pre-tested and modified several times until full details like the time of admission, time of delivery, date of discharge for normal and caesarean deliveries were incorporated, in order to study the extent of days the mothers were in the institution and availing diet provision.

The Maternal Health Division under the Ministry of Health and Family Welfare had published an operational guideline manual for diet provision under JSSK programme for all public health facilities in India (National Health Mission, 2018). The RDA for pregnant and lactating women (0-6 months) was used as the basis for developing the daily diet plans to provide food for mothers during their stay in the public health facilities, before and after delivery (National Health Mission, 2018). The portion sizes for one individual was weighed for each meal and the ingredients in each item were identified and quantified referring to the Indian Food Composition Tables (Longvah *et al.*, 2017). Energy, protein, calcium, iron, and fat were calculated manually. Ten CHCs were serving two meals a day and since the menu was the same every day, random samples in triplicate were used to calculate the nutrients intake manually. Standard measuring cups and spoons were used to measure the exact serving sizes for each mother.

The collected primary data were analysed with the help of Microsoft Excel by using appropriate statistical tests. Diet consumption (energy and nutrients) per day and the cost of the daily menu were estimated (Tables 2 and 4, respectively). Mean and standard deviation (*SD*) was calculated for all the nutrients in the diet (Table 2) and for the cost estimation for daily diet (Table 4).

RESULTS

For convenience of expression, the result section is divided into two sub-sections:

a) Assessment of diet menu

Out of the ten CHCs, seven had no kitchen facilities either due to lack of staff or infrastructure or less number of deliveries, so the meals were outsourced. Three of them were serving foods from their respective kitchens. Under the JSSK government programme, Indian rupees one hundred per person per day is allotted for the whole day's diet, which should include three main meals and two high energy snacks.

The mothers who availed the facilities in government health institutions were those near or below the poverty line and who were mostly malnourished. Illiteracy also accounted for not consuming nutritious diets and hence the onus lies on these institutions to make available nutritious diets and counsel the mothers to follow the same after discharge. In this study, it was observed that the diets prepared in the CHCs (three centres) using kitchen facilities and the institutions who had outsourced (seven centres) to caterers or restaurant owners, were not meeting the nutritional requirements as per the prescribed RDA. In one of the public health facilities, only one meal (lunch) was served, hence the lower intake of calories by mothers. In four of the health facilities, only two (lunch and dinner) meals were given. Only 50% health facilities were serving three or more than three meals per day. The meals provided were neither balanced nor uniformed. All nutrients, except fat, were much lower than the recommended values. On average, only 53% of RDA for protein, 20% RDA for calcium, and 52% RDA for iron were met. The RDA for a pregnant

Table 1. Recommended dietary allowance (RDA) for a sedentary pregnant mother for the entire day

	Energy (Kcal)	*Protein (g)*	*Fat (g)*	*Calcium (mg)*	*Iron (mg)*
Recommended dietary allowance (RDA)	2500	74	30	1200	21
Meals – breakfast, lunch, dinner					
3 main meals (2/3 of the RDA)	1667	49	20	800	14
Snacks-mid-morning, evening					
2 times snack (1/3 of the RDA)	833	25	10	400	7
Total	2500	74	30	1200	21

Source: Gopalan, Rama Sastri & Balasubramanian (2011)

and lactating (0-6 month) sedentary mother in terms of energy is 2500 kcal per day and the distribution is shown in Table 1. Ideally, three main meals in totality should give approximately 1667 kcal, with 49 g protein, 20 g fat, 800 mg calcium, and 14 mg iron, while two snacks daily should give approximately 833 kcal with 25 g protein, 10 g fat, 400 mg calcium, and 7 mg iron.

b) Development of the improved weekly cycle menu

Comparing with the recommendation of three main meals (breakfast, lunch, dinner) which satisfies two-third of the RDA and two snacks (mid-morning & evening tea) providing one-third the RDA, descriptive statistics of the existing daily RDA met per person in each public health facility in the rural blocks of Vadodara district were tabulated and presented in Table 2. Only five CHCs which were serving three meals or more a day were nearly meeting the energy requirements. Calcium and iron in the diets were dismal and these are some of the most important minerals needed during pregnancy, delivery and lactation phases, equally important to both mother and child.

Looking into the deficits of the nutrients in the diets, great efforts were made to develop a weekly cycle menu incorporating locally available vegetables and cereals, taking care of the requirements for macro- and micronutrients, yet keeping the cost at INR 100 per day per woman.

The majority of the people in Gujarat are vegetarians and hence recommendation for a weekly vegetarian menu for vaginal delivery is described in Table 3. Since it was not feasible to serve freshly cooked breakfast in the CHCs as per the existing conditions, hence, a practical weekly menu was also developed substituting freshly cooked breakfast with ready-to-eat high energy snacks that met the daily RDA (Table 4).

DISCUSSION

The JSSK programme has increased institutional deliveries since its launch. But in this study, it was seen that though free diet was given to all beneficiaries, the quality and nutrient content were dismal. The diets served to all mothers in the public health facilities in rural Vadodara was the general diet served to all patients who were admitted in the facility. This diet did not meet the dietary requirements for mothers whose nutritional needs were more. There was a shortage of kitchen facilities, proper infrastructure, diet counsellors and dietitians to prescribe and monitor the menu regularly. The caterers and restaurant owners who were entrusted with food delivery were either ignorant of the RDA or were not instructed

Table 2. Comparative data of nutrients in the foods served in the rural public health facilities with reference to JSSK Government programme

Name of the CHC	*Average delivery per months*	*Number of meals served*	*Energy (Kcal)*	*% RDA† met*	*Protein (g)*	*% RDA† met*	*Calcium (mg)*	*% RDA† met*	*Iron (mg)*	*% RDA† met*	*Fat (g)*	*% RDA† met*
CHC-1	19	2	1399	56	36.8	50	162	13.5	10.0	48	48.5	162
CHC-2	40	2	1256	50	34.7	47	218	18.1	8.4	40	62.6	209
CHC-3	68	2	1479	59	37.5	51	233	19.0	10.8	51	68.9	230
CHC-4	38	3	2087	83	40.0	54	290	24.0	9.8	47	84.7	282
CHC-5	45	2	1332	53	35.0	47	187	15.5	9.4	45	61.6	202
CHC-6	170	3	1904	76	35.0	47	174	14.5	10.2	49	90.0	300
CHC-7	14	3	2274	91	44.0	59	207	17.0	11.6	55	144.0	480
CHC-8	42	4	2613	104	48.0	65	337	28.0	16.3	78	123.0	410
CHC-9	205	3	2218	89	44.0	59	329	27.0	11.6	55	94.6	315
CHC-10	28	1	737	29	21.0	28	67	5.6	5.7	27	22.5	75
% RDA met (mean±*SD*)				69±23		51±10		18±7		50±13		267±118
Mean±*SD*			1730±579		38±7		220±82		10±3		80±36	

†RDA as per JSSK Diet norms: energy = 2500 kcal, protein = 74 g, calcium = 1200 mg, iron = 21 mg, fat = 30 g

Table 3. Proposed weekly cycle vegetarian menu

Menu	*Day 1*	*Day 2*	*Day 3*	*Day 4*	*Day 5*	*Day 6*	*Day 7*
Early morning	Tea (1/2 cup) & 4 biscuits	Tea (1/2 cup) & 4 biscuits	Tea (1/2 cup) & 4 biscuits	Tea (1/2 cup) & 4 biscuits	Tea (1/2 cup) & 4 biscuits	Tea (1/2 cup) & 4 biscuits	Tea (1/2 cup) & 4 biscuits
Breakfast	1.Milk (200ml) with sugar	1. Milk (200ml) with sugar	1. Milk (200ml) with sugar	1. Milk (200ml) with sugar	1. Milk (200ml) with sugar	1. Milk (200ml) with sugar	1. Milk (200ml) with sugar
	2. Namkeendaliya (1/2 cup)	2. Vegetable upma (1/2 cup)	2. Parantha (2)	2. Bread (2 slices)	2. Idli (4 small)	2. Dal parantha (2)	2. Parantha (2)
	3. Boiled egg (1)	3.Dal sprouts (1/2 cup)	3. Besancheela (2 medium)	3. Vegetable omelette	3. Sambhar (1 bowl)	3. Any seasonal fruit (1) (100g)	3. Dal palak or channa with ghia
	4. Any seasonal fruit (1) (100g)	4.Any seasonal fruit (1) (100g)	4. Any seasonal fruit (1) (100g)	4. Any seasonal fruit (1) (100g)	4. Any seasonal fruit (1) (100g)		4. Any seasonal fruit (1) (100g)
Lunch	1.Roti (3)	1.Roti (3)	1.Roti (3)	1.Roti (3)	1.Roti (3)	1.Roti (3)	1. Roti (3)
	2. Dal (1/4 cup) & rice (3/4 cup)	2. Dal (1/4 cup) & rice (3/4 cup)	2. Dal (1/4 cup) & rice (3/4 cup)	2. Dal (1/4 cup) & rice (3/4 cup)	2. Dal (1/4 cup) & rice (3/4 cup)	2. Dal (1/4 cup) & rice (3/4 cup)	2. Dal (1/4 cup) & rice (3/4 cup)
	3. Curd (100g)	3. Curd (100g)	3. Curd (100g)	3. Curd (100g)	3. Curd (100g)	3. Curd (100g)	3. Curd (100g)
	4. Seasonal vegetable with green leafy vegetable (1/4 cup)	4. Seasonal vegetable with green leafy vegetable (1/4 cup)	4. Seasonal vegetable with green leafy vegetable (1/4 cup)	4. Seasonal vegetable with green leafy vegetable (1/4 cup)	4. Seasonal vegetable with green leafy vegetable (1/4 cup)	4. Seasonal vegetable with green leafy vegetable (1/4 cup)	4. Seasonal vegetable with green leafy vegetable (1/4 cup)
	5. Salad (small tomato/onion/ half radish/half carrot	5. Salad (small tomato/onion/ half radish/half carrot	5. Salad (small tomato/onion/ half radish/half carrot	5. Salad (small tomato/onion/ half radish/half carrot	5. Salad (small tomato/onion/ half radish/half carrot	5. Salad (small tomato/onion/ half radish/half carrot	5. Salad (small tomato/onion/ half radish/half carrot

Table 3. Proposed weekly cycle vegetarian menu (continued)

Menu	*Day 1*	*Day 2*	*Day 3*	*Day 4*	*Day 5*	*Day 6*	*Day 7*
Evening snack	1. Milk (200ml) with sugar	1. Milk (200ml) with sugar	1. Milk (200ml) with sugar	1. Milk (200ml) with sugar	1. Milk (200ml) with sugar	1. Milk (200ml) with sugar	1. Milk (200ml) with sugar
	2. Vegetable poha (1/4 cup)	2. Vegetable cutlet (1)	2. Ladoo (besan, peanut, rajgira, jaggery, gaund) (2)	2. Ladoo (besan, peanut, rajgira, jaggery, gaund) (2)	2. Vegetable poha (1/4 cup)	2.Vegetable cutlet	2. Vegetable poha (1/4 cup)
	3. Boiled kabulichannachaat (50g)	3. Dhokla (4 pieces) (50g)	3. Boiled kalachannachaat (50g)	3. Khandvi (4 pieces) (40g)	3. Boiled kalachannachaat (50g) -1	3. Dhokla (4 pieces) (50g)	3. Boiled kalachannachaat (50g)
Dinner	1. Roti (3)	1. Roti (3)	1. Roti (3)	1. Roti (3)	1. Roti (3)	1. Roti (3)	1. Roti (3)
	2. Dal (1/4 cup) & rice (3/4 cup)	2. Dal (1/4 cup) & rice (3/4 cup)	2. Dal (1/4 cup) & rice (3/4 cup)	2. Dal (1/4 cup) & rice (3/4 cup)	2. Dal (1/4 cup) & rice (3/4 cup)	2. Dal (1/4 cup) & rice (3/4 cup)	2. Dal (1/4 cup) & rice (3/4 cup)
	3. Seasonal vegetable with green leafy vegetable (1/4 cup)	3. Seasonal vegetable with green leafy vegetable (1/4 cup)	3. Seasonal vegetable with green leafy vegetable (1/4 cup)	3. Seasonal vegetable with green leafy vegetable (1/4 cup)	3. Seasonal vegetable with green leafy vegetable (1/4 cup)	3. Seasonal vegetable with green leafy vegetable (1/4 cup)	3. Seasonal vegetable with green leafy vegetable (1/4 cup)
	4. Banana (1 medium size; 100g) or any seasonal fruit	4. Banana (1 medium size; 100g) or any seasonal fruit	4. Banana (1 medium size; 100g) or any seasonal fruit	4. Banana (1 medium size; 100g) or any seasonal fruit	4. Banana (1 medium size; 100g) or any seasonal fruit	4. Banana (1 medium size; 100g) or any seasonal fruit	4. Banana (1 medium size; 100g) or any seasonal fruit
Total amount of nutrients provided	Energy: 2539 kcal	Energy: 2699 kcal	Energy: 2998 kcal	Energy: 2914 kcal	Energy: 2624 kcal	Energy: 2707 kcal	Energy: 2648 kcal
	Protein: 64.7 g	Protein: 77.0 g	Protein: 81.5 g	Protein: 72.0 g	Protein: 70.1 g	Protein: 58.1 g	Protein: 67.1 g
	Calcium: 867 mg	Calcium: 766 mg	Calcium: 960 mg	Calcium: 855 mg	Calcium: 864 mg	Calcium: 858 mg	Calcium: 879 mg
	Iron: 14.0 mg	Iron: 15.4 mg	Iron: 20.5 mg	Iron: 16.9 mg	Iron: 13.9 mg	Iron: 14.8 mg	Iron: 15.3 mg

Table 4. Practical diets for mothers with vaginal delivery in rural public health facilities of Vadodara District

Menu	*Day 1*	*Day 2*	*Day 3*	*Day 4*	*Day 5*	*Day 6*	*Day 7*
Early morning†	Tea (150ml) & 2 khakhara INR 12	Tea (150ml) & 2 khakhara INR 12	Tea (150ml) & 2 khakhara INR 12	Tea (150ml) & 2 khakhara INR 12	Tea (150ml) & 2 khakhara INR 12	Tea (150ml) & 2 khakhara INR 12	Tea (150ml) & 2 khakhara INR 12
Breakfast	1. Milk (200ml) 2. Namkeendaliya (250g) 3. Any seasonal fruit (1) (100g) INR 25	1. Milk (200ml) 2. Vegetable upma (250g) 3. Any seasonal fruit (1) (100g) INR 24	1. Milk(200ml 2. Parantha (2) 3. Any seasonal fruit (1) (100g) INR 24	1. Milk (200ml) 2. Masala sewain (250g) 3. Any seasonal Fruit (1)(100g) INR 25	1. Milk (200ml) 2. Idli (4 small) Sambhar (150g) 3. Any seasonal fruit (1) (100g) INR 25	1. Milk(200ml) 2. Thepla (2) 3. Any seasonal fruit (1) (100g) INR 24	1. Milk (200ml) 2. Besancheela (2 medium) 3. Any seasonal fruit (1) (100g) INR 28
Lunch	1. Roti (3) 2. Tuver dal (250g) & rice (150g) 3. Seasonal vegetable (120g) INR 20	1. Roti (3) 2. Mung dal (250g) & rice (150g) 3. Seasonal vegetable (120g) INR 20	1. Roti (3) 2. Mix pulses dal (250g) & rice (150g) 3. Seasonal vegetable (120g) INR 20	1. Roti (3) 2. Channa dal (250g) & rice (150g) 3. Seasonal vegetable (120g) INR 20	1. Roti (3) 2. Channamung dal (250g) & rice (150g) 3. Seasonal vegetable (120g) INR 20	1. Roti (3) 2. Channatuver dal (250g) & rice (150g) 3. Seasonal vegetable (120g) INR 20	1. Roti (3) 2. Tuver mung dal (250g) & rice (150g) 3. Seasonal vegetable (120g) INR 20
Evening snack†	Dates & oats bar (2 piece) INR 15	Bajraladoo (4 pieces) INR 13	Peanut dates ladoo (4 pieces) INR 11	Sesame seeds ladoo (4 pieces) INR 10	Ragimodak (4 pieces) INR 18	Peanut oats bar (2 pieces) INR 14	Besanladoo (4 pieces) INR 15
Dinner	1. Roti (2) 2. Kadhi (250g) & Khichadi(150g) 3. Seasonal vegetable (120g) INR 20	1. Roti (2) 2. Kadhi (250g) & Masala khichadi (150g) 3. Seasonal vegetable (120g) INR 20	1. Roti (2) 2. Kadhi (250g) & Kodri(150g) 3. Seasonal vegetable (120g) INR 20	1. Roti (2) 2. Kadhi (250g) & Khichadi (150g) 3. Seasonal vegetable (120g) INR 20	1. Roti (2) 2. Kadhi (250g) & Masala khichadi (150g) 3. Seasonal vegetable (120g) INR 20	1. Roti (2) 2. Kadhi (250g) & Kodari(150g) 3. Seasonal vegetable (120g) INR 20	1. Roti (2) 2. Kadhi (250g) & Khichadi(150g) 3. Seasonal vegetable (120g) INR20
Total amount of nutrients provided	Energy: 2581 kcal Protein: 76.7 g Calcium: 764 mg Iron: 20.3 mg ‡Fat: 40 g	Energy: 2548 kcal Protein: 80.7 g Calcium: 704 mg Iron: 21.6 mg ‡Fat: 50 g	Energy: 2416 kcal Protein: 71.0 g Calcium: 987 mg Iron: 24.0 mg ‡Fat: 50 g	Energy: 2708 kcal Protein: 75.8 g Calcium: 1273 mg Iron: 23.0 mg ‡Fat: 40g	Energy: 2733 kcal Protein: 85.5 g Calcium: 686 mg Iron: 20.7 mg ‡Fat: 40 g	Energy: 2731 kcal Protein: 80.7 g Calcium: 809 mg Iron:18.3 mg ‡Fat: 40 g	Energy: 2792 kcal Protein: 81.0 g Calcium: 930 mg Iron: 21.0 mg ‡Fat: 50 g
Estimated Cost, INR (Mean±*SD)*	92±20	89±20	87±20	87±20	95±20	90±20	95±20

† Have long shelf life & can be stored for more than 15 days
‡ Visible fat

accordingly. The monetary allowance for a diet comprising of three fresh meals and two high energy snacks for a mother was only one hundred Indian rupees per day, which was insufficient, especially considering the inflation in food prices. The feasibility of serving fresh meals thrice a day was cumbersome and practically near to impossible. In a study by Sharma (2015), it was stated that INR 100 was not enough and he had also recommended to give nutritious freshly cooked meals and soups instead of raw eggs or bread when there is a lack of kitchen facility. Chaudhary *et al.* (2017) had reported that hot cooked meals were provided to all patients in general hospitals and tertiary care centres, but in periphery wards (Primary Health Centre/Community Health Centre) in rural Lakhan Majra, Haryana state, mothers were only given two dry packs of biscuits and a milk packet.

The fat intake exceeded the RDA, whereas calcium, iron, and protein requirements were difficult to meet because all the public health facilities followed a vegetarian diet, which did not have micronutrient-rich recipes, while a non-vegetarian diet was not feasible because the population were mainly vegetarians. Breastfeeding is associated with transfer of approximately 200 mg/day of calcium from mother to infant and studies have demonstrated that the increased calcium demand leads to mobilisation of this important mineral from the mother's skeleton, leading to transient reduction in bone mineral density (BMD) of the lumbar spine and femoral neck regions (4-7 %) during 3-6 months of lactation. The iron requirement during lactation is 25 mg/day. The baby is born with a relatively larger reserve of iron since milk is not a good source of iron. Iron requirement during lactation is the sum of the mother's requirement and the iron required to make up for iron lost in breast milk. Since there is amenorrhea during lactation, the basal requirement for women is at 14 microgram/kg (Srilakshmi, 2014). Unfortunately, foods rich in calcium (milk and milk products) and iron (green leafy vegetables) were unaffordable in the meagre amount of one hundred Indian rupees.

Only 51.6% of the women were aware about free diet provisions in JSSK in Marathawada, Maharashtra in a sample of one thousand women studied (Deshpande *et al.*, 2016). A community-based cross-sectional study conducted among 210 mothers in rural Bankura of West Bengal by Mondal *et al.* (2015) stated that the availability of free foods at the government health facilities was 59.5%. Utilisation of services under JSSK for institutional deliveries in seven public sector facilities in Sirmaur District, Himachal Pradesh was studied by Tyagi *et al.* (2016) on 156 mothers. The mothers had to pay an extra amount ranging from INR 12 to 700 for their foods. Rupani *et al.* (2019) carried out a cross-sectional descriptive study in Sir Takhtsinhji hospital of Bhavnagar in Gujarat and found that 99.7% of the mothers were aware of the JSSK free diets provided during the stay, out of which 96.0% of mothers reported that they were offered free foods, whereas 16.0% of the mothers opted for home-made foods during their stay. To date, there are no studies reporting on the nutrient content analysis of the foods served through the JSSK programme. Hence, this present study has bridged the gap in explaining in detail the quantification of the nutrients in the diets and recommends modifications required in the dietary intake for mothers who avail these services in the public health facilities.

Proper utilisation of the JSSK grant will be successful if the functionaries are diligently working towards applying, receiving and monitoring the funds,

inviting quotations for the best food delivery agents, well in advance at the beginning of each financial year, with the meticulous planning of diets especially for high risk mothers (diabetic and hypertensive). Diets for caesarean section delivery also calls for slight modifications of a semi-liquid diet for the initial two to three days post-operation. Every CHC should have a counsellor, preferably with a nutrition background, who would do continuous follow-up with mothers and would counsel them on different recipes for the required diet to be followed at home after discharge. More attention to maintaining diet registers and helping to reduce out-of-pocket expenses related to diet is also strongly suggested. The postnatal period is very critical for a mother and her newborn, and hospital stay is advised for three days for a normal vaginal delivery and seven days in case of a caesarean section. A mother who has just delivered her baby has increased nutrition demands and needs to be provided with a healthy balanced diet meeting the requirements to support her recuperation and for better milk production. A caesarean section delivery needs immediate nutritional care and attention. If dietary nutritional norms are clearly defined with operational guidelines, it would ensure quality postnatal care.

CONCLUSION

In this study, it was found that none of the CHCs had specific and separate diet provisions for the mothers. Functional kitchen was prevailing only in a few (three out of ten) public health facilities. Outsourcing of food preparation did not necessarily cater to the recommended daily allowances, unless food suppliers are trained or instructed according to the guidelines. The diets served in all the facilities were inadequate in macro- and micronutrients. There was no special diet provision for high risk pregnant mothers, such as those who were severely anaemic, hypertensive, or diabetic). It was found that only two fresh meals, namely lunch and dinner, were served in most of the public health facilities, which was the main reason for the deficit in nutrient intakes. Since serving freshly prepared foods more than twice was not feasible, ready-to-eat, calorie-dense snacks meeting the required RDA per serving, with reasonable shelf life and which could be served in the early morning and evening was developed in this study.

Awareness needs to be created among health functionaries for proposing and utilising the diet grant under JSSK. The convergence of health departments and nutrition-related academic institutions is essential to strengthen JSSK implementation in all public health facilities. The recommendations suggested in this study, if accepted and abided, would improve maternal nutritional status before and after delivery; and if properly counselled, could be adopted by mothers during their lactation period too. In the long run, this can reduce maternal and infant mortality which is common in this population due to varied factors of poverty, illiteracy, blind beliefs, superstition etc.

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Authors' contributions

AK, principal investigator, conceptualised and designed the study, conducted final data analysis and interpretation, prepared the manuscript; KP, handled the survey, data collection, compilation and writing of the final manuscript; NP, conducted tool preparation, data coding and compilation, final data analysis and interpretation.

Conflict of interest

The authors declared that there is no conflict of interest.

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Prevalence and factors associated with undernutrition among Dayak children in rural areas of Sarawak, Malaysia

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ABSTRACT

Background: Undernutrition among children has become a major public health issue due to the high risk of morbidity and mortality involving this vulnerable age group. This study focused on the rural population, especially among the Dayak children in Sarawak, Malaysia. **Methodology:** This community-based cross-sectional study was conducted in Sarawak's rural areas using a multistage stratified cluster sampling technique. Data were collected through face-to-face interviews using an interviewer-guided questionnaire. The nutritional status of the under-five children was measured according to the World Health Organization guidelines. The nutritional indicators were calculated as z-scores. Multivariate logistic regression analyses were performed using SPSS to identify the factors associated with nutritional status. **Results:** The prevalence of undernutrition among the under-five Dayak children in the rural areas of Sarawak was 39.6%. The analysis suggested that wasting was predominantly associated with parental education levels of primary and below, poor wealth index, environmental and sanitation issues, children with history of low birth weight, shorter duration of exclusive breastfeeding, and poor appetite. Stunting was high within the age group of <3 years old and was associated with parents' occupation and household wealth index. Low parental education, poor wealth index, environmental and sanitation issues, poor appetite, and the children's recent illness predicted underweight. **Conclusion:** These findings imply that a multi-sectoral and multi-dimensional approach is essential to address undernutrition in rural settings. Improvement on households' socioeconomy, environment and sanitation should be emphasised to reduce undernutrition among the children.

Keywords: undernutrition, wasting, stunting, underweight, under-five children, Dayak, Sarawak

INTRODUCTION

Undernutrition among children has always been a major public health issue. The World Health Organization (WHO) reported that globally 170 million children were underweight in 2020 (WHO, 2020a). At the other end of the spectrum, more than 40 million children under the age of five years were overweight, and almost half of the cause of mortality among under-five children was related to malnutrition (Mekonnen *et al.*, 2005). Several indicators have been developed to assess

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the nutritional status of children, such as the dietary diversity of individual and household level suggested by the Food and Nutrition Technical Assistance III Project (FANTA, 2006), household food security by Coates, Swindale & Bilinsky (2007), and level of vitamins and minerals adequacy, and anthropometric measurements (WHO, 2010). In this study, anthropometric measurements were the important indicators that had been used to determine the prevalence of undernutrition in a population of under-five children (Kassa *et al.*, 2017). The WHO defined wasting, stunting, and underweight as z-scores <-2 standard deviation (*SD*) for weight-for-height, height-for-age, and weight-for-age, respectively (WHO, 2020b). Worldwide, it was reported that wasting prevalence was 7.3%, stunting 21.3%, and underweight 13.4% (Dukhi, 2020).

In Malaysia, the prevalence of malnutrition in children has been decreasing over the past decade. The latest report by the National Health and Morbidity Survey (NHMS) 2019 stated that the prevalences of wasting, stunting, and underweight among Malaysian children under five years were 9.4%, 21.8%, 14.1%, respectively (IPH, 2019). In comparison with another local study, Cheah *et al.* (2012) reported an alarming prevalence of undernutrition among the under-five Orang Asli children in the rural areas of Kelantan with 69.0% stunting, 40.0% wasting, and 63.4% underweight. A few studies had been conducted among the Dayak community children in Sarawak. There was a reportedly high prevalence of stunting and underweight among the under two Penan children in Belaga, Kapit (Bong, Karim & Ismail, 2018). Eunice, Cheah & Lee (2014) reported 20.9% underweight, 10.2% wasting, and 11.9% stunting, respectively, among children below five years in a Bidayuh community in Sarawak, Malaysia.

Many factors had been identified as being associated with undernutrition. Parental literacy, family size, duration of breastfeeding, health status, and history of the children's recent illnesses were among the variables associated with undernutrition (Gebre *et al.*, 2019). Sociodemographic and socioeconomic variables also have important influences on childhood malnutrition. Environmental factors such as sources of drinking water, types of sanitation, household built-up materials, and wealth index of households were reported to influence nutritional status (Kassie & Workie, 2020).

Despite high prevalence of undernutrition, specific studies on the factors affecting the nutritional status of under-five rural Dayak children have not been extensively carried out. The Dayak indigenous communities are among the majority ethnic groups that reside in the rural areas of Sarawak. Because of the remoteness of the Dayak community, differences in sociodemographic and socioeconomic backgrounds could pose some patterns to the children's nutritional status. Thus, this study focused on the prevalence of undernutrition and its determining factors among under-five children in the rural areas of Sarawak, Malaysia.

MATERIALS AND METHODS

Study setting and population

This was a cross-sectional community-based study conducted in Sarawak, Malaysia. Five divisions were randomly selected from 12 administrative divisions in the state. From each selected division, two districts were randomly selected. Then, five villages of Dayak communities were selected from each district. A total of 50 villages were involved in this study. The households in each village were selected through systematic random sampling based on

the total number of households in the respective village, using the headman's house as the starting point. Sample size was calculated with a base population proportion of children with malnutrition of 43% (Eunice *et al.*, 2014), with 1.96 standard values for two-tailed tests and 4% absolute precision. The sample size was further inflated, multiplying by a design effect of 2 and 15% non-response rate. So, the final sample size was 860. The study respondents consisted of both parents, having at least one under-five child in their households. Respondents who were residents of the study area <6 months, seriously ill, had communication difficulties, and had children with special needs and physical deformities that hindered height measurements at the time of data collection, were excluded from the study. In cases where there was >1 under-five child in the household, only one child was randomly chosen for data collection.

Data collection instrument

The instrument had several components based on the objectives of the study. It was prepared in the form of a booklet for easy handling during the interview. The instrument consisted of respondent's sociodemographic characteristics, such as parental age, level of education, type of occupation, size of the family, and household expenditure. Household assets consisted of 22 items that were intended to measure the respondent's economic status. The household environment and sanitation questions had 32 items. These questions were adapted from Lin *et al.* (2013). Children's characteristics and health status were also included in the questionnaire with 11 items, including their age, gender, upbringing, and medical history. Lastly, the child's body weight (kg) and height (cm) were measured following standard guidelines (WHO, 2008). Children were measured for standing height without shoes using a SECA portable body meter (SECA 206, Germany) to the nearest 0.1 cm. For children 6–23 months of age, recumbent length was measured. Body weight of infants and young children was measured using a digital weighing scale (Tanita 1583, Japan) to the nearest 0.01 kg. Children who were able to stand upright were weighed using a digital lithium-battery weighing scale (Tanita 318, Japan) to the nearest 0.1 kg. The measurements were recorded in the WHO Anthro version 3.2.2 software, which was downloaded from the WHO website.

Measurement

Nutritional status

Height-for-age (HAZ), weight-for-age (WAZ), and weight-for-height (WHZ) *z*-scores of the children were calculated by WHO Anthro 3.2.2 software according to age and gender. Anthropometric classifications were based on global standards: ≤3 *SD*, ≤2 *SD*, and ≥2 *SD*. Children with WHZ, HAZ, and WAZ below -2 *SD* of the reference population's median were considered wasted, stunted, and underweight, respectively (WHO, 2020b).

Wealth quintile

Wealth index was calculated based on usable household assets by Principal Component Analysis (PCA). Initially, 22 assets were included in the wealth index calculation. The household item with a frequency of <5% or >95% and communality sources <0.3 were excluded from the model. Finally, 18 assets entered a model with Kaiser-Meyer-Olkin (KMO) and Bartlett's Test that yielded the household's percentage distribution based on quintiles of wealth index. The scores were labelled as poorest for the lowest quintile and the highest quintile as the richest.

Household characteristics
A proxy economic status of the household was calculated based on in-house facilities and construction materials. The in-house facilities included the source of water supply, lighting, and type of sanitation. The construction materials were pertaining to the material composition of the walls, floor, ceiling, and roofing of the house described by Yakubu, Akaateba & Akanbang (2014). Based on the majority frequency of usage, the items were further classified into items, i.e., 'yes' for having the proper items and 'no' for improper items in the house. It yielded a total of seven items. Therefore, out of seven items, the score of 4 or less was considered Poor, 5-Satisfactory, 6-Good, and 7 - Excellent (Morris *et al.*, 2000).

Data collection procedure
A pilot test was conducted among 30 respondents. The purpose of this test was to determine whether the wordings used were clear and whether there was a need to further refine the questionnaire. Domain-wise, Cronbach's alpha was calculated, and it varied from 0.688 to 0.890. The interviewers were trained for one week to ensure high quality data were collected. Prior to data collection, a briefing session was held by the researcher and his team. This session was made compulsory to clearly understand the study objectives, selection criteria of the respondents, sampling methods, and proper manner for conducting interview to ensure everyone was tailored to their roles in data collection. The questionnaires were checked to make sure that relevant questions had been responded to and coded accordingly. The questionnaire distribution and collection was done between April 2019 till February 2020. At the end of the study period, a total of 920 questionnaires were distributed according to the divisions, districts and villages, and 808 complete responses were received, yielding a response rate of 88.2%. Data were collected by face-to-face interviews at a comfortable time. Three attempts were made to get the sampled respondents.

Ethical issues
Participation in this study was entirely voluntary. Respondents were briefed about the confidentiality of the information given. Informed written consent was obtained from the participants. No financial or any other incentives were provided for their participation. The study received ethical approval from the Ethics Committee of the Faculty of Medicine and Health Science, Universiti Malaysia Sarawak (UNIMAS) [UNIMAS/NC-21.02/03-02 Jld.3 (80)] and the Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia [KKM/NIHSEC/P19-877 (6)].

Data analysis
Any missing information in the questionnaire was corrected on the same day or the next day. Data coding and verification of response was made on the same day immediately after the interview. Complete data were entered into Microsoft Office Excel 2010 with a validation check. From Microsoft Excel, the data were exported to IBM Statistical Package for Social Science (SPSS) version 22.0. They were then validated for any inconsistencies, missing values, and duplication. The analysis output was presented in the form of mean, median, minimum and maximum values, and standard deviation for continuous data, and percentages for categorical data. All continuous variables were then transformed into categorical data for further analysis. Binomial logistic regression analysis was used to predict

the factors that affected the nutritional status of under-five children. Before interpreting the results, Chi-square goodness of fit, Nagelkerke R^2, predictive accuracy and classification were checked for model fit adequacy. A *p*-value of ≤0.05 was considered statistically significant.

RESULTS

Sociodemographic and socioeconomic of the respondents

A total of 808 household data were analysed in this study. Almost half of the fathers (45.6%) were 25 to 34 years old, followed by the age group of 35 to 44 years (35.4%). The mean age for fathers was 35.37 (8.28) years old. The mean age for mothers was 32.42 (7.63) years old, with the majority (56.9%) from the age group of 25 to 34 years old. Nearly four-fifths (78.3%) of the fathers had secondary level and above of education, while 73.0% of the mothers attained secondary level and above of education. One-third (35.5%) of the fathers were unemployed, followed by self-employed (32.9%), and working in private sectors (21.2%). The unemployment rate among the mothers was 69.7%, with only 30.3% being employed either as self-employed or working in private or government sectors. The median family size was six persons, with a minimum of two persons and a maximum of 15 persons in the household. The percentage distribution of the wealth quintile of the households was almost equal among the five groups, with a little extra percentage among the richest quintile (22.3%) or 180 households. The good score for household characteristics was the highest among the four categories at 30.7% or 248 households, followed by the poor score at 27.3% (221 households), excellent score at 17.6% (142 households), and 24.4% or 197 households with a satisfactory score (Table 1).

Characteristics of children and their health status

Among the under-five children, slightly more than half were boys (51.1%). The children's mean age was 30.35 months, with a minimum age of six months and a maximum age of 59 months. About one-fifth (22.2%) of children were born low birth weight (<2.5 kg). More than half were in the second to fourth birth order among their siblings. Seven-tenths (71.0%) of the children were exclusively breastfed six months or less, while 29.0% were breastfed for >6 months. A high percentage of children had a good appetite in the past week (78.5%). Although majority of the children had no illness in the past 14 days, 12.5% or 101 children had a fever, 40 children (5.0%) had respiratory illness, and 27 (3.3%) children had experienced gastrointestinal illness (Table 2).

Nutritional status of the children

Weight-for-height indicated that 1.2% were severely wasted, while 5.7% were wasted. Normal weight-for-height was 87.8%, and 5.3% were having a risk of being overweight. As for the height-for-age indicator for stunting, 2.8% were severely stunted, 16.1% were stunted, while 81.1% were within the normal category. Weight-for-age nutritional status showed that 14.2% were underweight, 0.4% were severely underweight, while 85.4% had normal weight-for-age (Table 3).

Patterns of undernutrition problems

Table 4 illustrates the patterns of standalone and co-occurrence of nutritional problems in children. It was found that the highest percentage of children with standalone forms of malnutrition were stunted (9.4%), followed by 2.8% being wasted, and 2.4% underweight. However, the total percentage of co-occurrence of

Table 1. Characteristics of the respondents and households

Characteristics	*n*	*%*	*Statistics*
Father's age in years			
<25	53	6.6	
25-34	367	45.4	Mean±*SD* = 35.37±8.28
35-44	286	35.4	Min = 21, Max = 63
≥45	102	12.6	
Mother's age in years			
<25	85	10.6	
25-34	460	56.9	Mean±*SD* = 32.42±7.63
35-44	199	24.6	Min = 20, Max = 60
≥45	64	7.9	
Father's level of education			
Primary and below	175	21.7	
Secondary and above	633	78.3	
Mother's level of education			
Primary and below	217	26.9	
Secondary and above	591	73.1	
Occupation of father			
Unemployed	287	35.5	
Government jobs	84	10.4	
Private jobs	171	21.2	
Self-employed	266	32.9	
Occupation of mother			
Unemployed	563	69.7	
Government jobs	77	9.5	
Private jobs	71	8.8	
Self-employed	97	12.0	
Family size			
2-3	75	9.4	
4-5	284	35.1	Mean±*SD* = 6.1±2.1
6-7	263	32.5	Median = 6
8-9	107	13.2	Min, Max = 2, 15
≥10	79	9.8	
Wealth quintile			
Poorest	161	19.9	
Poor	151	18.6	
Middle	158	19.6	
Rich	158	19.6	
Richest	180	22.3	
Household characteristics			
Poor (≤ 4)	221	27.3	
Satisfactory (5)	197	24.4	
Good (6)	248	30.7	
Excellent (7)	142	17.6	

Table 2. Characteristics of the children

Characteristics	*n*	*%*	*Statistics*
Age (months)			
<11	107	13.2	
11 – 23	204	25.3	Mean±*SD* = 30.35±16.16
24 – 35	169	20.9	Median = 29
36 – 47	144	17.8	Min = 6; Max = 59
48 – 59	184	22.8	
Gender			
Male	413	51.1	
Female	395	48.9	
Birth weight (kg)			
≥2.5	629	77.8	
<2.5	179	22.2	
Birth order			
First	297	36.8	Mean±*SD* = 2.23±1.33
2nd to 4th	455	56.3	Median = 2, Min = 1; Max = 9
5th or higher	56	6.9	
Duration of exclusive breastfeeding (months)			
≤6 months	574	71.0	Mean±*SD* = 3.97±1.69
>6 months	234	29.0	Median = 4, Min = 1; Max = 8
Parents' perception on child's eating appetite			
Good	634	78.5	
Moderate	148	18.3	
Poor	26	3.2	
Types of illness in the past 14 days			
No illness	640	79.2	
Fever	101	12.5	
Respiratory	40	5.0	
Gastrointestinal	27	3.3	

undernutrition problems involving stunting was 18.1%, followed by underweight 14.2%, and wasting (6.6%).

Factors associated with undernutrition: Multivariate analysis

Parental age, family size, and children's gender were factors excluded in the multivariate analysis as these variables were not statistically significant in the Chi-square test of independence.

Wasting

The multivariate analysis showed that fathers with education level of primary and below (AOR=1.139, 95% CI: 0.448-2.405), mothers with education level of primary and below (AOR=7.489, 95% CI: 3.275-17.122), poorest wealth index (Quintile 1) (AOR=4.835, 95% CI: 1.251-18.681), poor environment and sanitation score (AOR=2.603, 95% CI: 0.973-5.361), birth weight of <2.5 kg (AOR=2.106, 95% CI: 1.084-4.090), and poor eating appetite in the past one week (AOR=2.376, 95% CI: 0.108-1.306) were independent positive predictors for wasting among the children, while the duration of exclusive breastfeeding of six months and above

(AOR=0.397, 95% CI: 0.202-0.780) was the only negative predictor for wasting among the children (Table 5). Children whose fathers had an education level of primary and below were 1.139 times more likely to be wasted, and mothers with similar education levels were 7.489 times more likely to be wasted than fathers and mothers with an education level of secondary and above. The poorest wealth index households increased the likelihood of children being wasted at 4.835 times compared to the richest wealth index households. Children with poor environment and sanitation were 2.603 times more likely to be wasted than those with excellent environment and sanitation, while children with a history of low birth weight were 2.106 times more likely to be wasted compared to those with a birth weight of >2.5kg. Children who experienced a duration of exclusive breastfeeding for >6 months had 0.397 times of prevalence in wasting than those breastfed six months and less. Children with poor eating appetite were 2.376 times likelier to be wasted compared to those with good eating appetite.

Stunting

The independent predictors for stunting among the children were the unemployment status of fathers (AOR=1.726, 95% CI: 1.014-2.938) and mothers (AOR=2.888, 95% CI: 1.301-6.412), and each of the household wealth indices, from the poorest (AOR=5.895, 95% CI: 2.377-14.623), poor (AOR=5.221, 95% CI: 2.199-12.400), middle (AOR=3.477, 95% CI: 1.506-8.029) to rich (AOR=3.243, 95% CI: 1.405-7.484) households. Children whose fathers and mothers were unemployed were 1.726 times and 2.888 times more likely to be stunted, respectively. Based on wealth index, children with poor household scores were more likely to be stunted compared to those with richer household scores. Apart from that, the age of the children had a significant association as well,

Table 3. Nutritional status of the children

Nutritional status	*n*	*%*
†Weight-for-height (wasted)		
Severely wasted	10	1.2
Wasted	46	5.7
Normal	709	87.8
Risk of overweight	43	5.3
‡Height-for-age (stunted)		
Severely stunted	23	2.8
Stunted	130	16.1
Normal	655	81.1
§Weight-for-age (underweight)		
Severely underweight	3	0.4
Underweight	115	14.2
Normal	690	85.4

†Weight-for-height: severely wasted (≤-3*SD*), wasted (≤-2*SD*), normal (>-2*SD* to <2*SD*), overweight (≥2*SD*) and obese (≥3*SD*)
‡Height-for-age: severely stunted (≤-3*SD*), stunted (≤-2*SD*) and normal (>-2*SD* to <2*SD*)
§Weight-for-age: severely underweight (≤-3*SD*), underweight (≤-2*SD*) and normal (>-2*SD* to <2*SD*)

notably the age groups of 36 months to 47 months (AOR=0.469, 95% CI: 0.263-1.336) and 48 months to 59 months (AOR=0.592, 95% CI: 0.324-1.079). Children in these two age groups were 0.469 times and 0.592 times more likely to be stunted, respectively, compared to children <11 months old (Table 5).

Underweight

The multivariate analysis showed that the independent variables that were associated with the prevalence of underweight were: fathers (AOR=1.453, 95% CI: 0.510-2.977) and mothers (AOR=3.192, 95% CI: 1.646-6.191) with education level of primary and below; wealth index of households, from the poorest (AOR=3.634, 95% CI: 1.362-9.694), poor (AOR=2.565, 95% CI: 1.001-6.574) to rich (AOR=1.405, 95% CI: 0.894-3.246), and having poor environment and sanitation within the household (AOR=1.429, 95% CI: 0.840-2.432). Poor eating appetite in the past one week (AOR=2.213, 95% CI: 1.787-4.334) and fever as an illness in the past 14 days (AOR=2.537, 95% CI: 1.158-5.368) were also important variables that influenced underweight status among the children (Table 5). In comparison, fathers and mothers with an education level of primary school and below were 1.453 times and 3.192 times more likely to have children who were underweight than parents with an education level of secondary school and above.

In general, children who lived in poor households were more likely to be underweight compared to rich households. Children with poor environmental and sanitation scores were 1.429 times more likely to be underweight than children from households with excellent scores. Besides that, children with poor eating appetite were 2.213 times more likely to be underweight than those with a good eating appetite. Children with a history of fever were 2.537 times more likely to be underweight too compared to children with no history of illness.

DISCUSSION

Child malnutrition continues to be a major public health problem in developing countries, including Malaysia. Children are the most vulnerable to be malnourished due to multiple factors (Rikimaru *et al.*, 1998). The socioeconomic status of a household is one of the contributing factors. Socioeconomic status is also associated with occupation, which is indirectly related to the level of education in the household. In this study, several factors were found to influence undernutrition

Table 4. Distribution patterns of undernutrition problems among children

	Underweight	*Wasted*	*Stunted*	*Wasted & stunted*	*Total*
Underweight	2.4(A)	3.1(D)	8.0(E)	0.7(G)	14.2(H)
Wasted	3.1(D)	2.8(B)	0.7(F)		6.6(I)
Stunted	8.0(E)	0.7(F)	9.4(C)		18.1(J)
Wasted and stunted	0.7(G)				0.7(G)
Total	14.2(H)	6.6(I)	18.1(J)	0.7(G)	39.6(K)

A = underweight only
B = wasted only
C = stunted only
D = underweight + wasted
E = underweight + stunted
F = wasted + stunted
G = underweight + wasted + stunted
H = total underweight
I = total wasted
J = total stunted
K = total undernutrition

Table 5. Factors associated with nutritional status of under-five children: Multivariate analysis

Characteristics	*Weight-for-height (Wasted) n= 56*			*Height-for-age (Stunted) n= 153*			*Weight-for-age (Underweight) n=118*		
	AOR	*95 CI*		*AOR*	*95 CI*		*AOR*	*95 CI*	
		LL	*UL*		*LL*	*UL*		*LL*	*UL*
Level of education (Fathers)									
Secondary and above (RC)	1.000			1.000			1.000		
Primary and below	1.139**	0.448	2.405	1.274	0.658	2.465	1.453*	0.510	2.977
Level of education (Mothers)									
Secondary and above (RC)	1.000			1.000			1.000		
Primary and below	7.489**	3.275	17.122	0.800	0.436	1.469	3.192*	1.646	6.191
Occupation (Fathers)									
Self-employed (RC)	1.000			1.000			1.000		
Unemployed	1.452	0.679	3.105	1.726*	1.014	2.938	1.251	0.694	2.258
Government jobs	1.144	0.246	5.329	0.391	0.105	1.455	0.577	0.185	1.802
Private jobs	1.017	0.351	2.941	1.348	0.710	2.558	1.039	0.507	2.127
Occupation (Mothers)									
Self-employed (RC)	1.000			1.000			1.000		
Unemployed	1.414	0.456	4.390	2.888*	1.301	6.412	1.824	0.725	4.590
Government jobs	0.855	0.123	5.963	1.028	0.231	4.571	1.672	0.411	6.808
Private jobs	0.511	0.079	3.309	1.099	1.077	4.916	1.654	0.485	5.638
Wealth Index									
Quintile 5 (RC)	1.000			1.000			1.000		
Quintile 4	2.313	0.663	8.072	3.243*	1.405	7.484	1.405*	0.894	3.246
Quintile 3	2.438	0.697	8.534	3.477*	1.506	8.029	1.779	0.704	4.496
Quintile 2	2.650	0.731	9.603	5.221**	2.199	12.400	2.565*	1.001	6.574
Quintile 1	4.835*	1.251	18.681	5.895**	2.377	14.623	3.634*	1.362	9.694
Environment and sanitation score									
Excellent (RC)	1.000			1.000			1.000		
Good	1.178	0.452	3.073	0.746	0.409	1.363	1.155	0.689	1.936
Satisfactory	1.406	0.506	3.905	0.783	0.409	1.497	1.330	0.766	2.309
Poor	2.603*	0.973	5.361	0.758	0.408	1.407	1.429*	0.840	2.432

Table 5. Factors associated with nutritional status of under-five children: Multivariate analysis (continued)

Characteristics	*Weight-for-height (Wasted) n= 56*			*Height-for-age (Stunted) n= 153*			*Weight-for-age Underweight) n=118*		
		95 CI			*95 CI*			*95 CI*	
	AOR	*LL*	*UL*	*AOR*	*LL*	*UL*	*AOR*	*LL*	*UL*
Age of children in months									
≤11 (RC)	1.000			1.000			1.000		
12-23	0.840	0.292	2.411	0.739	0.359	1.518	1.279	0.689	2.375
24 – 35	0.733	0.304	1.769	0.793	0.437	1.439	1.261	0.755	2.106
36 – 47	0.733	0.302	1.781	0.469*	0.263	1.336	1.527	0.923	2.526
48 – 59	0.592	0.226	1.549	0.592*	0.324	1.079	1.093	0.642	1.861
Birth weight									
≥2.5 kg (RC)	1.000			1.000			1.000		
<2.5 kg	2.106*	1.084	4.090	0.700	0.452	1.084	1.828	1.239	2.698
Duration of exclusive breastfeeding									
≤6 months (RC)	1.000			1.000			1.000		
>6 months	0.397*	0.202	0.780	1.234	0.751	2.028	1.184	0.686	2.042
Parents' perception on child's eating appetite									
Good (RC)	1.000			1.000			1.000		
Moderate	1.569	1.172	2.343	2.093	1.337	3.531	1.174	1.068	1.946
Poor	2.376*	1.108	4.106	2.126	1.804	4.121	2.213*	1.787	4.334
Type of illnesses in the past 14 days									
No illness (RC)	1.000			1.000			1.000		
Fever	2.298	0.362	4.335	2.060	0.791	4.167	2.537*	1.158	5.368
Respiratory	1.568	0.144	3.334	1.948	0.673	3.742	1.490	0.585	2.479
Gastrointestinal	1.545	0.581	3.250	2.154	0.615	4.330	1.386	0.324	2.168
Classification		94.8			84.6			74.8	
Hosmer-Lemeshow		0.189			0.385			0.381	
Pseudo R-square		0.132			0.096			0.113	
LR test Chi-Square	45.478; df(27), $p<0.05$*			46.459; df(27), $p<0.05$**			63.161; df(27), $p<0.001$***		

*$p<0.05$, **$p<0.01$, ***$p<0.001$
AOR - Adjusted Odds Ratio; CI – Confident Interval
LL - Lower Limit; UL – Upper Limit
RC – Reference category; LR - Likelihood ratio

among Dayak children in the rural areas of Sarawak, Malaysia. The prevalence of undernutrition, which comprised of wasting, stunting, and underweight, were assessed to determine the extent of this public health issue among the children in rural areas. The current study revealed that 5.7%, 16.1%, and 14.2% of the under-five children were wasted, stunted, and underweight, respectively. However, these observed prevalences were lower than the UNICEF/WHO/ The World Bank Group joint child malnutrition estimates in 2021 (WHO, 2021).

In comparison with the other upper middle-income countries such as Thailand, it was reported that the prevalences of wasting, stunting, and underweight among the under-five children in rural areas were 4.8%, 17.4%, and 11.0%, respectively (UNICEF, 2018). NHMS 2019 reported that the prevalences of wasting, stunting, and underweight among Malaysian children under five years in the rural areas were 8.5%, 22.2%, and 15.6%, respectively, with wasting and stunting noted to be significantly higher compared to the current study. However, this is taking into consideration the high prevalence of undernutrition contributed by the Orang Asli children in rural areas of Peninsular Malaysia, as reported by Cheah *et al.* (2012), and the rural districts of Sabah by How *et al.* (2020). On the other hand, the prevalence of underweight in the current study was slightly higher compared to the national prevalence of underweight. This could be the small margin of difference between children who lived in rural and urban settings, whereby urban children have more issues of overweight and obesity than underweight (Agbozo *et al.*, 2016).

The pattern of nutritional status with stunting predominating over wasting indicated long nutritional deficiency among the under-five children, with underweight that signified acute and chronic nutritional deficiency. Chronic malnutrition is common among rural children as compared to urban children. However, not many studies have pointed to the co-occurrence of malnutrition; thus, the current study revealed the seriousness of nutritional deficiency periods experienced by the rural children that needs urgent medical interventions to treat those that are affected.

Among the factors that influenced wasting were the parents' level of education, poor household wealth index, environmental and sanitation factor, birth weight of <2.5 kg, shorter breastfeeding period, and poor eating appetite among the children. The household's socioeconomic status that were related to children's growth included parents' education, wealth index, and environmental and sanitation factors. These findings are consistent with Amare, Ahmed & Mehari (2019), where poor socioeconomic background was strongly related to malnourished children. Perceived child size at birth significantly determined the nutritional status of a child. Low birth weight can lead to a high risk of undernutrition in children (Rahman *et al.*, 2016). The current study showed that prolonged breastfeeding of >6 months reduced the risk of wasting among the children. The parent's perception of their children's poor appetite also reflected wasting among the children, whereby children experienced weight loss due to acute malnutrition (Gebre *et al.*, 2019). Poor eating appetite was almost similar to the loss of eating appetite, where the parents perceived that their children were unable to finish their usual portion of foods per meal (Scaglioni *et al.*, 2018). Apart from the parent's status of being unemployed, the prevalence of undernutrition was also associated with household wealth index, as well as environmental and sanitation factors.

Several studies indicated that a poorer wealth index was associated with a higher risk of undernutrition in children due to the lower priority for intra-household investment and resource-constrained households (Wali, Agho & Renzaho, 2020). The wealth index factor also influenced the adequacy of nutrition and proper living conditions (Wali *et al.*, 2020).

The risk of stunting was reduced when the children were in the age group of three years to five years old, in comparison with children in the age group of <3 years old. It is quite common for stunting to start increasing before the age of three years. This is because stunting is a sign of chronic undernutrition, and therefore, takes time to manifest compared with other undernutrition indicators. However, this finding varies in different countries. The prevalence of stunting was the highest among the age group of <2 years old in India, but a lower prevalence was reported in Maldives (Wali *et al.*, 2020). Jiang *et al.* (2015) reported a similar finding among the children in mid-western rural areas of China. This is probably because children >3 years old would have already established their feeding pattern, whereas children <3 years old were still at their transition feeding period.

Subsequent analysis showed that parental education and occupation affected the prevalence of underweight in children. Low levels of parental education had increased the risk of children with underweight. These findings were consistent with Hossain and Khan in Bangladesh (Hossain & Khan, 2018), where the higher the parental education, the lesser the risk of malnutrition. Better education ensured job security and better occupation and thus, improved the socioeconomic of the household. The wealth index in this study also proved that it had affected the nutritional status of the children. Low wealth index was associated with a higher risk of being underweight, while moderate to the wealthiest had reduced malnutrition risk in the households (Kassie & Workie, 2020).

Environmental and sanitation were seen as important variables that influenced undernutrition among the children. Poor sanitation and household environment led to an increased risk of 1.5 times in underweight compared to excellent sanitation and environment. Better sanitation and environment leads to reduced risk of diarrhoea-associated infections, including intestinal worms that can result in insufficient nutrient intakes and undernutrition among the vulnerable groups, particularly the under-five children. Improvement of water supply and cooked foods in the households have also been reported to reduce the risk of food-borne disease among the children and thus, lower the risk of undernutrition (Muoki *et al.,* 2008; Mshida *et al.,* 2018).

In our study, parents' perception of poor appetite among their children also revealed an increased risk of underweight by 2.2 times compared to children with good eating appetite. Eating appetite is responsive to external stimuli associated with the presence of food, smell or taste (Freitas *et al.*, 2018). Good eating appetite was also influenced by eating behaviour, food availability prepared in the households, parental factors, and family environment support (Scaglioni *et al.*, 2018). A recent fever resulted in the increased risk of underweight by 2.5 times compared to children without such history. It was also noted that poor eating appetite reduced the nutrient adequacy of children during such illness. Similar findings had been reported previously (Kassie & Workie, 2020).

In this research, both husband and wife were the respondents in each household to improve the recall of

history. Other important factors that might be associated with nutritional status need to be included in the study, such as maternal characteristics like body mass index and history of any antenatal risk factors. Apart from that, parents might not have given accurate information about their children's birth history and health status compared to the mothers in the households. Therefore, it is recommended that researchers assess medical history records and antenatal documents to verify their findings in future research.

CONCLUSION

The prevalence of undernutrition among the under-five Dayak children in the rural areas of Sarawak was low compared to the national and WHO levels. Wasting was predominantly associated with low parental education levels, poor wealth index, environmental and sanitation issues, low birth weight, shorter duration of exclusive breastfeeding, and perception of poor eating appetite among the children. Apart from parental occupation, the prevalence of stunting was associated with household wealth index and within the age group of <3 years old. The prevalence of underweight was influenced by low parental education levels, poor environment and sanitation, perception of poor eating appetite, and recent illness in children. These findings would contribute to the effort of tackling childhood undernutrition as a high priority public health issue. Government and non-government organisations should focus on prevention and an integrated approach to assist the rural poor, especially by creating more job opportunities in the rural areas, which may subsequently improve household wealth, environment, and sanitation. Awareness through health education among mothers pertaining to the importance of exclusive breastfeeding and child nutrition needs to be emphasised by health educators with support from the surrounding community.

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Authors' contributions

RMM, principal investigator, conceptualised and designed the study, analysed the data, prepared the draft of the manuscript and reviewed the manuscript; KA, conceptualised and designed the study, and reviewed the manuscript; SNR, led the data collection, advised on data entry, analysis and interpretation, and reviewed the manuscript.

Conflict of interest

The authors declare no potential conflicts of interest concerning the research, authorship, and publication of this article.

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Translation and validation of Food Insecurity Experience Scale (FIES)

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ABSTRACT

Introduction: Food insecurity has a complex and multifaceted concept and definition, thus assessing it has been an ongoing challenge for researchers, health practitioners, and policy makers. Previous studies reported inconsistent findings on the prevalence and severity of food insecurity, depending on the measuring tools used. To overcome this limitation, this study aimed to translate and validate the Food Insecurity Experience Scale (FIES) for Malaysians, which has been used as a standard measurement by Food and Agriculture Organization (FAO). **Methods:** Two forward and backward translations involving experts in food insecurity studies and experts in language were done, as well as the pre-test and cognitive interview stipulated in World Health Organization (WHO) translation guidelines. Content and face validity were conducted as part of the validation process. Content Validity Index (CVI) was done to analyse content validity. **Results:** The harmonised Malay version of FIES was produced with 1.0 CVI, which was above the 0.8 criteria. Face validity showed good understandability and clarity of FIES. **Conclusion**: The translated Malay version of FIES had good acceptability, as well as good face validity when tested among the target audience. Thus, a full validation study of the Malay version FIES should be done before it is widely used to measure food insecurity in the population, specifically the Malaysian population.

Keywords: food insecurity, FIES, Malay language, translation

INTRODUCTION

Food is a fundamental human right, providing nutrient for human growth and development. Food security exists when all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences for an active and healthy life (FAO, 2008). One of the challenges the world is facing now is to ensure that populations are free from hunger and achieve food

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security, which has been stated in the Sustainable Development Goals (SDG), specifically in goal number two. However, the process of understanding food security and the ways to achieve it is still debatable and ongoing worldwide. It is a complex and multidimensional concept (Norhasmah, Zalilah & Asnarulkhadi, 2010). However, the issue remains important since hundreds of millions of people and households are still living in poverty and unable to eat enough food, not only in developing countries but in developed countries too (FAO, IFAD, UNICEF, WFP & WHO, 2020). Recently, there are 820 million people reportedly hungry and almost 2 billion people who experienced moderate and severe food insecurity (FAO, IFAD, UNICEF, WFP & WHO, 2019).

Low socio-economic status and poverty have always been associated with food insecurity. This situation not only causes undernutrition, but also overnutrition. The Current Population Survey in the United States demonstrated that 34.5% households with an annual income of below 130% were food insecure (Coleman *et al.*, 2018). Studies in developing countries showed that the prevalence of food insecurity was 31.7% in rural households in India (Nagappa *et al.*, 2020), while the prevalence of food insecurity among adult households in Malaysia was estimated to be within 47.2% to 100.0% (Norhasmah *et al.*, 2021). Studies among low-income households in rural Kelantan demonstrated that 83.9% experienced some kind of food insecurity (Ihab *et al.*, 2015). A survey conducted in Kuantan revealed that 77% of households were food insecure (Roselawati *et al.*, 2017). However, the tools to measure food insecurity may differ from one study to another.

There is a clear need to improve the tools, understanding the phenomena and frameworks used for various intervention targets, especially the vulnerable groups of population. In relation to this issue, various food insecurity measurement tools were developed such as the Radimer/Cornell Food Insecurity Scale, the Household Food Security Survey Module (HFSSM), and Household Food Insecurity Access Scale (HFIAS). The Radimer/Cornell Food Insecurity has been adapted, modified, and validated for use in many countries including Korea (Oh & Hong, 2003), United Kingdom (Studdert, Frongillo Jr & Valois, 2001), Malaysia (Zalilah & Merlin, 2001) and Iran (Mohammadi *et al.*, 2012). The Radimer/Cornell Food Insecurity Scale, HFSSM and HFIAS use the idea of perception among people who experience food insecurity, as well as the coping strategies adopted during food insecurity measurements (Radimer *et al.*, 1992; Bickel *et al.,* 2000). However, the listed tools are based on the perception of people having food insecurity rather than their direct experiences and behaviours.

Thus, to have a standard measurement for cross-country comparisons, the United Nations under the FAO through the Voices of Hungry Project (VoH) had developed an instrument named the Food Insecurity Experience Scale (FIES) (Cafiero, Viviani & Nord, 2018), which is a severity metric of food insecurity at the household or individual level, based on people's self-reported experience of YES or NO answers regarding access to adequate food (Cafiero *et al.*, 2018). FIES was developed based on three established tools, which were the Household Food Security Survey Module (HFSSM), Household Food Insecurity Access Scale (HFIAS), and Carribean Food Security Scale (ELSCA) (Smith, Kassa & Winters, 2017; Ballard, Kepple & Cafiero, 2013). FIES has been used by almost 153 countries through the Gallop World Poll (GWP) survey for national monitoring of Sustainable Development

Goals (SDG2) (Cafiero *et al.*, 2018 & Smith *et al.*, 2017). However, the FIES instrument has not yet been translated into the Malay language. Therefore, this study aimed to translate FIES into the Malay language and validate its content and face validities.

MATERIALS AND METHODS

Food Insecurity Experience Scale (FIES)

FIES is a self-administered questionnaire consisting of eight items to evaluate an individual's or a household's experience and behaviour towards food accessibility. Specifically, it captures difficulties in accessing food due to resource constraints based on the following domains: uncertainty/anxiety feeling, changes in food quality, and changes in food quantity. Participants were required to answer yes or no to all eight questions. A raw score of 0 was provided for negative response and 1 for affirmative response. The total FIES score was the sum of scores from all eight questions and it was then further classified into the following levels of severity: food secure (0), mild food insecurity (1-3), moderate food insecurity (4-6), and severe food insecurity (7-8) (Jones, 2017).

Phase 1: Translation procedure

Malay translation of FIES

Prior to this study, permission for translation had been obtained from the original authors of The Food and Agricultural Organization (FAO). The translation was conducted in accordance to the standard translation guidelines by the World Health Organization (WHO, 2019). Five different stages were followed: (i) the initial translation from English to Malay by two independent bilingual translators, which were both food insecurity experts and Malay native speakers; (ii) the synthesis of the first two translations to provide a single pre-harmonised version of FIES (BMH1); (iii) the backward translation by two independent bilingual translators who were blinded from the original English version and who were both experts in English Literature and Linguistic; (iv) an expert committee review to compare the backward translations with the original FIES and consent on a harmonised Malay version of FIES (BMH2) [Note: The expert committee included food security experts and a representative from FAO]; and (v) the pre-test and cognitive interviewing of the 'BMH2' version on 20 participants to ensure that the adapted version retained its equivalent in the adapted situation and concluded with the FIES-Malay version, the final version of Malay FIES. The flow of translation is outlined in Figure 1.

Phase 2: Validation procedure

Content and face validation of Malay version of FIES

The initial validation of the Malay version of FIES was completed in two steps. Content validation, which aimed to assess the relevance of all eight FIES items, was conducted on eight experts from the fields of food security, nutrition, and psychology. Experts were required to evaluate each item on two dimensions (i.e., representativeness and clarity) using a four-point Likert scale, whereby 1 indicated not representative/ not clear, 2 indicated major correction needed to be representative/clear, 3 meant minor revision needed to be representative/clear, and 4 which meant representative/clear. Extra space was provided for further comments.

Face validation testing, which aimed to assess the comprehensibility of the translated items, was conducted on 40 target participants. The determination of sample size for face validity relied on the examples from previous studies due to a lack of theory. The study site involved both urban and rural areas in

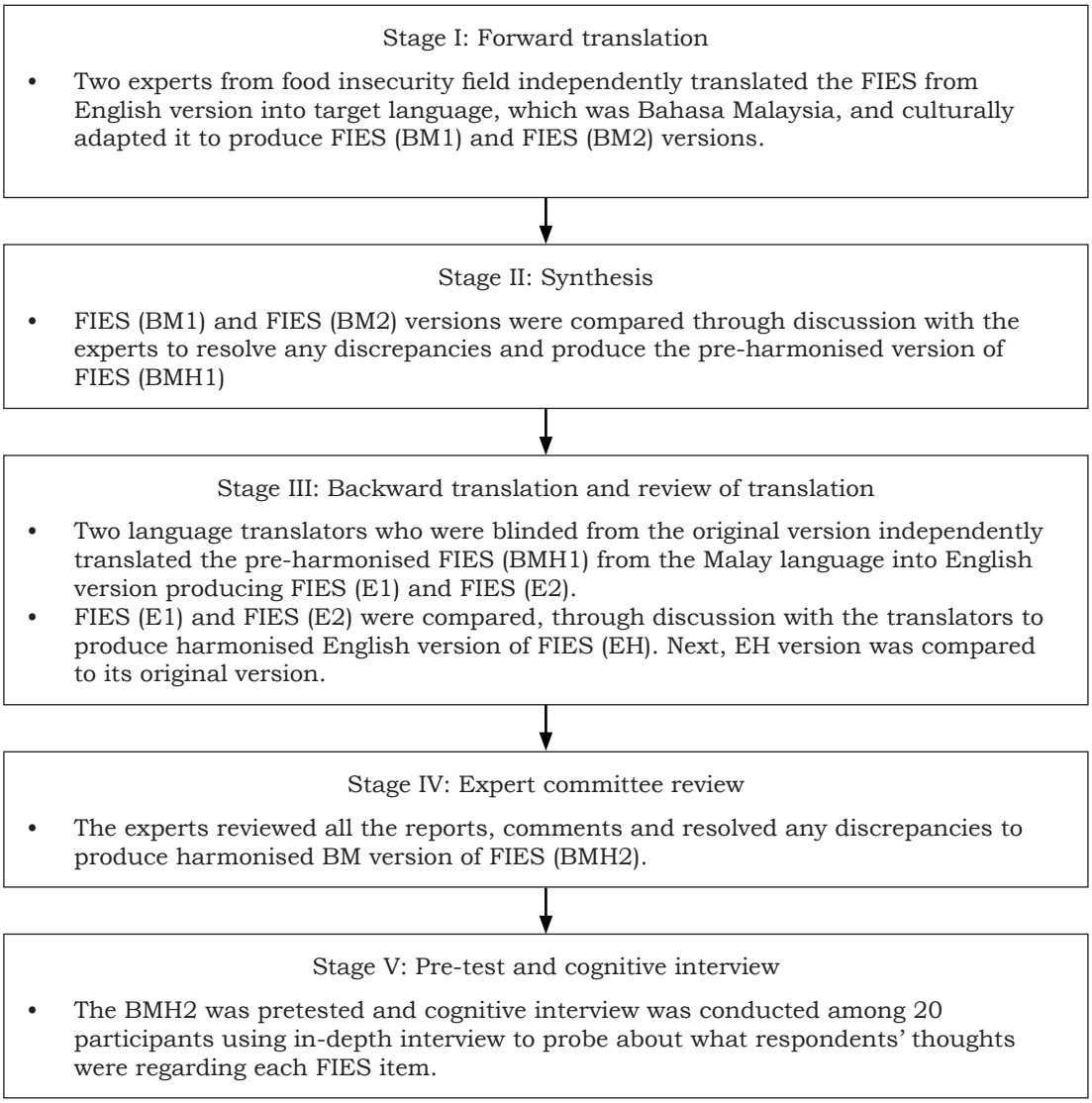

Figure 1. Flow chart of the translation and cross-cultural adaptation of FIES

Kuantan, Pahang. The list of urban and rural areas in Kuantan was obtained from *Majlis Perbandaran Kuantan (MPK*). The selection of the study sites, both rural and urban, was randomised but the selection of participants was based on purposive sampling. Inclusion criteria included married women of reproductive age between 19 and 49 years old. Although the age range of reproductive women in Malaysia is between 15-49 years old, those aged 15-17 years were excluded as they were still schooling. Women were chosen because they are responsible for food production, purchasing and preparation, and are often the key person for household food security (Kardooni *et al.*, 2014). Those who were lactating and pregnant were excluded. Participants were asked to

rate the Malay version of FIES on two dimensions (i.e., understandability and clarity) using a four-point Likert scale ranging from "item not understandable/ not clear" to "item understandable/very clear".

Ethical approval

Ethical approval was obtained from the International Islamic University Malaysia Research Committee (IREC) (Ref: IIUM/504/14/11/2/REC 2019-131). Consent from the participants was obtained prior to the participants answering the survey.

Data analysis

Data entry and statistical analysis were performed using IBM SPSS Statistics (Version 22, Armonk, NY, IBM Corp, Statistical Package for the Social Sciences, USA). To obtain scale level content validity index (S-CVI) of each item and content validity index (I-CVI), the scores of 3 and 4 were recategorised as 1 (representative / clear; relevant) and scores of 1 and 2 as 0 (not representative/ clear; not relevant). The I-CVI expresses the proportion of the agreement of the representativeness and relevancy of the item, which is between 0 and 1. To obtain I-CVI, the number of experts who rated the item as 3 and 4 were counted and divided by the number of experts. The S-CVI/Ave was calculated by taking the sum of the I-CVIs divided by the total number of items (Yusoff, 2019). For face validity index (FVI) analysis, the scores from 40 participants were recategorised as 1 for clear and understandable (scores 3 and 4), and 0 for not clear and not understandable (scores 1 and 2). The universal FVI was calculated by averaging the values for clarity and comprehension, and was computed by calculating the scale average of the universal value.

RESULTS

Phase 1: Translation

In the preliminary phase of the translated version, the panels suggested modification of the sentences to suit the Malaysian culture wherever possible, but at the same time, maintaining the meaning of the translated version as the original version. Commonly, literal translation does not work for all questions. For example, the phrase 'lack of money or other resources' was confusing in Angola and it was better understood as 'lack of means' (Ballard *et al.*, 2013). In the present study, 'other resources' was translated into "*sumber-sumber lain*". Most of the participants during cognitive interview session, especially urban participants, did not understand that it referred to other resources to acquire foods such as fishing, farming, transfer of food from family members or government etc. (Ballard *et al.*, 2013). Thus, the final version was "*sumber-sumber lain untuk mendapatkan makanan".*

Moreover, the word 'households' refers to the people living together. The FAO expert suggested "*orang-orang*" to represent households, which is a phrase commonly used in Indonesia, but brings a different meaning in Malaysia. The expert panel, as well as participants then agreed with the term "*ahli-ahli dalam isi rumah*". In question 5, the phrase was "ate less than you thought you should because of a lack of money or other resources?". This question enquired about eating less than what the participants considered they should, even if they did not skip a meal because they did not have money or other resources. The pre-final translation was "*makan kurang daripada apa yang anda fikir sepatutnya".* Some of the participants understood this question was asking about eating less than they normally ate.

But a few participants reported that the word "*fikir*" was confusing. They thought that the word "*fikir*" was referring to the changing of their mind from taking food they wanted to eat to another food which was cheaper. Thus, the final version was "*makan kurang daripada apa yang sepatutnya anda makan*".

Similarly, the sentence "went without eating" in question number 8 "Was there a time when you or others in your household went without eating for a whole day because of a lack of money or other resources?" cannot be literally translated into "*pergi tanpa makan*", which was not the intended meaning. The appropriate sentence should be "*tidak makan*". The linguistic challenges faced in adapting FIES into Malaysia's diverse culture are summarised in Table 1.

Phase 2: Validation

Content validation by experts

The content validation of FIES required no major corrections. The average CVI calculated was 1.00, which was clearly above the 0.80 criteria. The experts evaluated the comprehensiveness of the entire measure and there were no suggestion of addition or deletion of any items. However, one of the experts suggested to change the FIES into a statement form instead of a question form, and to switch the position between items 4 and 5 according to its level of severity. However, we maintained the format as in the original form and the position of the level of severity was only determined after construct validation using Rasch analysis.

Face validation by target audience

Among 40 participants, 33 participants (82.5%) rated 4 for understandability and 35 participants (87.5%) rated 4 for clarity, suggesting that the FIES item was easily understood and clear. However, FIES needed minor amendments in terms of clarity of certain terms as described in the linguistic adaptation phase.

DISCUSSION

Assessing food insecurity has evolved from capturing individual perceptions to individual lived experiences (Radimer *et al.*, 1992; Fronggillo *et al.*, 2013). One of the instruments to assess these experiences is through the FIES questionnaire, which is a standardised tool developed by FAO and has been used since 2014. The FIES questionnaire has been translated into 200 languages in order to be used in many countries (Frongillo *et al.*, 2017), so that comparison of food insecurity across countries can be made possible. Studies from other countries including the Sub Saharan Africa (Na *et al.*, 2019; Sadiddin *et al.*, 2019) Latin America and Caribbean (Smith *et al.*, 2017) United States, United Kingdom, Australia, New Zealand, East and South Asia (Jones, 2017) have found that the FIES is relevant for the assessment of food insecurity experiences). This study aimed to translate and validate the FIES into the Malay language and is the first to report the translation and validation of FIES questionnaire in Malaysia.

The translated FIES-Malay version was linguistically valid when it was applied. Based on the findings in this study, potential threat to validity related to language translation was reduced. In this study, the content equivalence and semantic equivalence were checked during backward and forward phases to ensure that the consistency of meaning in the translated version was similar to the original version. The translation and adaptation processes implemented in this study conformed to those used in a previous study related to FIES (Ballard *et al.*, 2013). According to Maneesriwongul & Dixon (2004), content, context, conceptual, semantic, and technical equivalence evaluations are needed for

Table 1. Linguistic issues addressed during the translation process

English original phrase	*Prefinal-translation*	*Suggested corrections*	*Reasons*
During the last 12 Months	*Dalam tempoh 12 bulan yang lepas*	*Sepanjang 12 bulan yang lepas*	In Malaysia, people thought that "*dalam*" is the depth of something. "*Sepanjang 12 bulan yang lepas*" is common to express the period of the last 12 months.
Other resources	*Sumber-sumber lain*	*Sumber-sumber lain untuk mendapatkan makanan*	In rural area, fishing, farming, transfer of food from family members or government was understood as " *sumber-sumber lain"* but for urban area, they did not understand the term "*sumber-sumber lain*". The term "*sumber-sumber lain untuk mendapatkan makanan*" was better understood.
Skip a meal	*Tinggalkan satu waktu makan*	*Meninggalkan waktu makan*	*"Tinggalkan"* was not suitable. The word "*tinggalkan*" was interpreted as to purposely skip a meal without force, but "*meninggalkan*" reflected the actual meaning of skipping or missing a meal (breakfast, lunch, dinner) due to lack of money or other resources.
Households	*Orang-orang dalam isi rumah or ahli keluarga*	*Ahli-ahli dalam isi rumah*	Household referred to people living together and sharing food and other resources. FAO expert suggested to use "*orang-orang rumah*", but it was not common for Malaysians. Some suggested to use "*ahli keluarga*", but participants in rural understood the term "*ahli keluarga*" as referring to their extended family including grandparents, aunties and uncle.
Worried	*Bimbang or khuatir*	*Risau*	FAO expert suggested to use "*bimbang*" or "*khuatir*" to express worry. However experts decided to use "*risau*" because *khuatir* is not widely used for Malaysians. The term *risau* was well understood both in rural and urban settings as a state of feeling worried or anxious that they might run out of food because there was not enough money or other resources.
Went without eating	*Pergi tanpa makan*	*Tidak makan*	Cannot be translated literally into "*pergi tanpa makan*". The appropriate sentence was "*tidak makan*", which was better understood by the public.
Few kinds of foods	*Hanya sedikit jenis makanan*	*beberapa jenis makanan sahaja*	After rephrasing the sentence, most participants understood that they had to eat a diet with a limited variety of foods because there was not enough money or other resources.
Ate less than you thought you should	*Makan kurang daripada apa yang anda fikir sepatutnya*	*Makan kurang daripada apa yang sepatutnya anda makan*	The word "*fikir*" was confusing. They thought that the word "*fikir*" referred to the changing of mind from taking food they wanted to eating another type of food which was cheaper. The panel experts also agreed to rephrase the sentence.

Table 2. Back-to-back translation of FIES

Item	*Original version*	*Translated version*	*Back translation*
	Now, I would like to ask you some question about food. During the last 12 MONTHS, was there a time when:	*Sekarang saya ingin bertanya kepada anda beberapa soalan tentang makanan. Sepanjang 12 BULAN yang lepas, adakah terdapat masa bila:*	Now I want to ask to you some questions about food. Throughout the last 12 MONTHS, was there is a time when:
Q1	You or others in your household worried about not having enough food to eat because of a lack of money or other resources?	*Anda atau ahli-ahli dalam isi rumah anda risau tidak mempunyai makanan yang cukup kerana kekurangan wang atau sumber-sumber lain?*	You or other family members in your house feel worried about insufficient food because of not having enough money or other sources?
Q2	Still thinking about the last 12 MONTHS, was there a time when you or others in your household were unable to eat healthy and nutritious food because of a lack of money or other resources?	*Masih memikirkan 12 BULAN yang lepas, adakah anda atau ahli-ahli dalam isi rumah anda tidak dapat makan makanan yang sihat dan berkhasiat kerana kekurangan wang atau sumber-sumber lain?*	Still thinking about the last 12 MONTHS, was there a time when you or other family members in your house not able to eat healthy and nutritious food because of not having enough money or other sources?
Q3	Was there a time when you or others in your household ate only a few kinds of foods because of a lack of money or other resources?	*Adakah anda atau ahli-ahli dalam isirumah anda makan hanya beberapa jenis makanan sahaja kerana kekurangan wang atau sumber-sumber lain?*	Was there a time when you or other family members in your house only eat some type of food because of not having enough money or other sources?
Q4	Was there a time when you or others in your household had to skip a meal because there was not enough money or other resources to get food?	*Adakah anda atau ahli-ahli dalam isi rumah anda terpaksa meninggalkan satu waktu makan kerana kekurangan wang atau sumber-sumber lain untuk mendapatkan makanan?*	Was there a time when you or other family members in your house have to skip one mealtime because of not having enough money or other resources to get food?

Table 2. Back-to-back translation of FIES (continued)

Item	*Original version*	*Translated version*	*Back translation*
Q5	Still thinking about the last 12 MONTHS, was there a time when you or others in your household ate less than you thought you should because of a lack of money or other resources?	*Masih memikirkan 12 BULAN yang lepas, adakah anda atau ahli-ahli dalam isirumah anda makan kurang daripada apa yang sepatutnya anda makan kerana kekurangan wang atau sumber-sumber lain?*	Still thinking about the last 12 MONTHS, was there a time when you or other family members in your house, eat less of what you think is supposed to be because of not having enough money or other sources?
Q6	Was there a time when your household ran out of food because of a lack of money or other resources?	*Adakah isi rumah anda kehabisan makanan kerana kekurangan wang atau sumber-sumber lain?*	Was there a time when family members in your house had run out of food due to not enough money or other sources
Q7	Was there a time when you or others in your household were hungry but did not eat because there was not enough money or other resources for food?	*Adakah anda atau ahli-ahli dalam isi rumah anda berasa lapar tetapi tidak makan kerana tidak mempunyai wang atau sumber-sumber lain yang cukup untuk makanan?*	Was there a time when you or other family members in your house feel hungry, but not eating anything because of not having enough money or other resources for food?
Q8	During the last 12 MONTHS, was there a time whenyou or others in your household went without eating for a whole day because of a lack of money or other resources?	*Adakah anda atau ahli-ahli dalam isirumah anda tidak makan sepanjang hari kerana kekurangan wang atau sumber-sumber lain?*	Was there a time when you or other family members in your house not eating anything throughout the day due to not having enough money or other sources?

a new instrument to be used in a new setting.

In this study, the CVI scale obtained a score of 1.0, which was considered as excellent, indicating that the content of the Malay version of FIES was well adapted into the local context. The FVI scores of 82.5% and 87.5% reported in this study indicated that the original FIES had been translated into understandable and clear sentences, easily readable to all 40 targeted participants.

Based on our study, commonly, literal translation does not work because the accuracy of the result of FIES is highly dependent on the words and terminologies used in the question. Each of the FIES questions had an intended meaning with the aim of detecting experiences and behaviours associated with increased severity. The meaning and terms used for the questions must be clearly understood by the respondents to give informative answers. For example, the phrase 'healthy and nutritious' was understood differently in urban and rural populations. The rural people interpreted *''makanan sihat dan berkhasiat''* as eating fruits and vegetables, while the urban people understood as food that gives energy. The phrase 'went without eating' or "*tidak makan sepanjang hari*" could be misunderstood as fasting. Fasting is a religious Muslim practice of abstaining from taking food from dawn until nightfall. This justified the importance of backward, forward, and cognitive interview phases to ensure semantic and technical equivalence. Previous studies conducted in Angola, Ethiopia, Malawi, and Niger documented some of the language barriers in adapting FIES (Ballard *et al.*, 2013), which were similar to the present study.

The limitation of this study was that due to different cultures, language barrier among participants occurred during the translation process, which led to the misinterpretation of terms. Although the selection of study sites for both rural and urban was randomised, but the selection of participants was based on purposive sampling, which was not the best method of sampling for the purpose of representativeness. However, this was the first study that had thoroughly translated and validated the content and face validities of FIES for the Malaysian population.

CONCLUSION

The Malay version of FIES had been translated properly, with positive expert review ratings, as well as good face validity by target audience. Thus, a full validation study of the Malay version of FIES, especially its construct validity, needs to be done before it is widely used to measure food insecurity in the Malaysian population.

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Author's contributions

RMY, conducted data collection, ran the analysis and wrote the manuscript; SS, JAB, NS, provided advice on data analysis, interpretation of the results, and reviewed the manuscript; NAY, HS; helped in data collection; NHJ; provided advice on data analysis, interpretation of the results, and reviewed the manuscript; WAMAB, principal investigator, conceptualised, designed the study, and reviewed the manuscript.

Conflict of interest

There is no conflict of interest to declare.

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The correlations between gut microbiota of Muslim Thai lactating women and their dietary intake and gut microbiota of breastfed infants

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ABSTRACT

Introduction: Foods and nutrients are essential not only for human health, but also for the balance of gut microbiota. This research aimed to correlate the gut microbiota of lactating women with their food/ nutrient intakes, as well as with their infants' gut microbiota. **Methods:** A cross-sectional study was conducted in 27 pairs of mothers and their exclusively breastfed infants. For lactating women, the dietary assessment was conducted by 24-hour recall, and food groups were assessed following the Food and Agriculture Organization's guidelines, while nutrient intake was analysed using INMUNCAL V3 programme. Gut microbiota of mothers and infants were measured in stool samples using fluorescent *in situ* hybridisation technique. **Results:** It was found that energy intake of mothers was only 66% of the recommended Thai Dietary Reference Intakes (DRIs). Most micronutrient and dietary fibre intakes were below the Thai DRIs. Vitamin A (VA)-rich fruits and vegetables food group correlated positively with *Lactobacillus* species (spp). The association between gut microbiota and nutrient intake of lactating women showed that total protein, phosphorus, and VA were positively correlated with *Bifidobacterium* spp.; while β-carotene and vitamin C were also positively correlated with *Lactobacillus* spp. In contrast, consumption of eggs and calcium correlated negatively with *Clostridium* spp./ *Enterobacter* spp. *Bifidobacterium* spp. and *Lactobacillus* spp. of lactating women and breastfed infants showed strong correlations. **Conclusion:** Food and nutrient intakes of lactating women were correlated with their *Clostridium* spp./*Enterobacter* spp., *Bifidobacterium* spp. and *Lactobacillus* spp. Furthermore, *Bifidobacterium* spp. and *Lactobacillus* spp. of mothers and breastfed infants showed strong correlations.

Keywords: correlation, exclusively breastfed infants, food group, gut microbiota, lactating women, nutrient intakes

INTRODUCTION

Formerly, newborn infants were considered to be in a sterile intrauterine environment (Karakochuk *et al.,* 2017), with their first exposure to microbes occurring during breastfeeding. However, recent studies have suggested that the foetus does not reside in a sterile intrauterine environment, since commensal bacteria from the maternal

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gut/bloodstream can enter the amniotic fluid by crossing the placenta (Walker, 2017). In addition, newborns are also exposed to microbes at birth. The first gut microbiota that interact with an infant have significant roles in stimulating the immune system, facilitating maturation of the immune system, programming a healthy immune development, and metabolic programming (Karakochuk *et al.,* 2017).

The bacterial composition of gut microbiota in breastfed infants is closely related to their mothers'. González *et al.* (2013) found a positive correlation between maternal milk and infant's faecal microbiota for *S. epidermidis* group, analysed by polymerase chain reaction (PCR). There are several reasons why a correlation exists between a lactating woman and her infant's gut microbiota. The maternal gut microbiota may promote microbiota colonisation of the infant gut prior to birth *in utero*, after delivery, or later through breastfeeding (McDonald & McCoy, 2019). Oligosaccharides in breast milk promote the growth of *Lactobacillus and Bifidobacterium*, which dominate the infant gut (Mueller *et al.*, 2015). Maternal microbiota at different body sites and in the gut provide exposure to an infant at the initial stages of life from holding, cuddling and kissing (Farren & Turner, 2017), supplying viable microbiota.

An association between the gut microbiota and the infant's nutritional status was found for *Streptococcus, Clostridium leptum,* and *Clostridium coccoides*, which were significantly increased in infants with malnutrition (González *et al.*, 2013). A recent study has shown that changes in gut microbiota profile among Thai urban children were related to the types of food consumed (Nakayama *et al.*, 2015). The types of food and nutrients consumed in the dishes are primary factors influencing gut microbiota. For example, fermentation of undigested dietary components generates short-chain fatty acids (SCFA) that are essential for the growth of beneficial bacteria in the intestine (Telle-Hansen, Holven & Ulven, 2018). Polyphenols, fibres, and carbohydrates are dietary factors that can modify the balance of gut microbiota, whereas illness, stress, ageing, bad dietary habits, and lifestyle can cause changes in the gut microbiota (Zhang *et al.*, 2015).

Recently, a study of the interrelation between nutrient/nutritional status and gut microbiota has recognised this as a determinant of human health (Hills *et al.,* 2019). However, there are needs of supporting evidence, especially of the relationship between gut microbiota in lactating women with their diet and nutrient intakes; as well as of the gut microbiota in their exclusively breastfed infants. Our focus was on southern peninsular Thailand, where the culture and eating habits differ from other parts of the country. Thus, this study aimed to correlate the gut microbiota in lactating women with their food/nutrient intakes, and with their exclusively breastfed infants' gut microbiota.

MATERIALS AND METHODS

Study site and participants

A descriptive cross-sectional study was conducted in a sample of 27 Thai Muslim lactating women and their exclusively breastfed infants. This study was part of a main study named "the efficacy of vitamin A (VA) fortified rice in lactating Thai women". The details of the study protocol and sample size calculation are described in a previous report (Pinkaew *et al.*, 2021). Briefly, healthy women with single birth, no gestational diseases, in the age range of 20-40 years old, and their exclusively breastfed infants with a birth weight of >2,500g, were recruited for the study from January 2017 to

February 2018. The study site was located in the Muang district of Pattani province, in southern Thailand.

Before recruitment, details of the study protocol were explained to the potential participants. Informed consent was obtained from the participants, as well as on behalf of their infants.

Data collection

Dietary intake

Dietary intakes of the lactating women were assessed by 24-hour recall for three non-consecutive days (two weekdays and one weekend). The data consisted of food items, types of food, food components, cooking method, and the amount (weight/size) of the consumed portion. The data were analysed by INMUCAL V3 programme (Mahidol University, Thailand) for nutrient intakes and reported in % Thai Dietary Reference Intake (DRI).

In addition to that, data of food items from the 24-hour recall were also grouped. The nine food groups assessed were according to the Food and Agriculture Organization (FAO) guidelines (FAO, 2011). The amounts consumed for (1) starchy staples, (2) dark green leafy vegetables, (3) other VA-rich fruits and vegetables, (4) other fruits and vegetables, (5) organ meat, (6) meat and fish, (7) eggs, (8) legumes, nut and seeds, and (9) milk and milk products, were estimated by using the same programme (INMUCAL V3 programme).

Gut microbiota determination

Stool samples of lactating women and their breastfed infants were collected during the first month of breastfeeding. At the time of stool sample collection, the participants were informed about instructions that must be followed on collecting the stool samples. Stool samples of both mother and infant had to be collected on the same day by using a sterile plastic teaspoon and placed into a sterile small plastic box. Then they were brought to the laboratory and kept in a freezer at -80°C for gut microbiota analysis.

All stool samples were analysed specifically for the bacteria *Bifidobacterium* species (spp.) and *Lactobacillus* spp. as representatives of beneficial bacteria, and *Clostridium* spp./*Enterobacter* spp. as representative of pathogenic bacteria, using DNA probes (Bif164, Lab158, Chris150) (Lucigen, Wisconsin, USA). The fluorescent *in situ* hybridisation (FISH) technique was used to measure the gut bacteria in stool samples following laboratory protocols of the Nutraceutical and Functional Laboratory (Faculty of Agroindustry, Prince of Songkla University, Hatyai, Thailand) (Plongbunjong *et al.*, 2017). Data were reported as $\log_{10}$ cell/g faecal sample.

Ethical clearance

The study protocol was approved by the Research Ethics Committee for Science, Technology and Health Science, Prince of Songkla University, Pattani campus (ERC No. psu.pn.1-005/59). The protocol was registered with ClinicalTrials.gov (ID: NCT03056625.)

Statistical analysis

The gut microbiota enumeration by FISH technique was presented as $\log_{10}$ cell/g faecal sample. Data on nutrient intakes were analysed with INMUCAL V-3 programme (Mahidol University, Thailand) and were presented as % Thai DRI. Data were normally distributed as checked by Shapiro-Wilk test (p>0.05) and were expressed as mean±standard deviation (*SD*). The correlation between gut microbiota in lactating women versus nutrient intakes, amount of food consumption (nine groups), and gut microbiota of infants were assessed

using Pearson's correlation. All data were statistically analysed with R programme i386 version 3.5.2.

RESULTS

The average age of mothers and infants were 29.2 years old and one month old, respectively. All infants were exclusively breastfed, and 70.4% were born via vaginal delivery. All of the participants were Muslim. The average *Bifidobacria* spp., *Lactobacillus* spp., and *Clostridium* spp./*Enterobacter* spp. in lactating women were 9.70±0.28, 9.75±0.36, and 9.76±0.42 $\log_{10}$ cell/g faecal sample, respectively. For infants, the average *Bifidobacria* spp., *Lactobacillus* spp., and *Clostridium* spp./*Enterobacter* spp. were 9.82±0.35, 9.71±0.36, and 9.70±0.60 $\log_{10}$ cell/g faecal sample, respectively.

Dietary intake of lactating women

Food group consumption of lactating women

The amounts of daily consumption (per day) for the nine groups of food, as presented in Table 1, were assessed following the FAO guidelines (FAO, 2011). A total of 642 g of starchy staple food was consumed daily, and this was the main food group consumed by lactating women. This was followed by other fruits and vegetables (117.8 g), milk and milk products (113.8 g), and meat and fish (112.0 g). Other VA-rich fruits and vegetables group had the lowest (11.5 g) intake.

Nutrient intakes of lactating women

On average, the energy intake of the participants was 1,476 kcal/ day and this only accounted for 66% of the Thai DRI. The energy distribution of carbohydrate:protein:fat was in the normal range (64:15:21). Figure 1 showed that both the energy and protein intakes of participants were below the Thai DRIs and estimated average requirement (EAR≈80% of Thai DRIs).

Most of the micronutrients (Figure 1) and dietary fibre consumed were below the Thai DRIs. Daily VA and iron consumption, which are essential for lactating women, were found to be deficient compared to the recommendation (14% and 17% of Thai DRIs, respectively). The consumption of other important micronutrients by

Table 1. The average consumption of each food group by lactating women (g/day)

Food group	*Total (n=27)*
Starchy staples[†] (g)	642.0±217.3
Dark green leafy vegetables (g)	13.1±2.6
Other vitamin A-rich fruits and vegetables[‡] (g)	11.5±4.3
Other fruits and vegetables[§] (g)	117.8±50.8
Organ meat (g)	41.8±10.4
Meat and fish[¶] (g)	112.0±41.4
Eggs (g)	36.8±9.7
Legumes, nuts and seeds (g)	18.9±3.0
Milk and milk products (g)	113.8±28.8

[†]The starchy staples food group is a combination of cereals and white roots and tubers.
[‡]The other VA-rich fruits and vegetables group is a combination of VA-rich vegetables and tubers and VA-rich fruits (e.g. the plants with red, yellow, orange colour).
[§]The other fruits and vegetables group is a combination of other fruits and other vegetables (excluding dark green leafy vegetables and other vitamin A-rich fruits and vegetables[‡]).
[¶]The meat group is a combination of meat and fish.

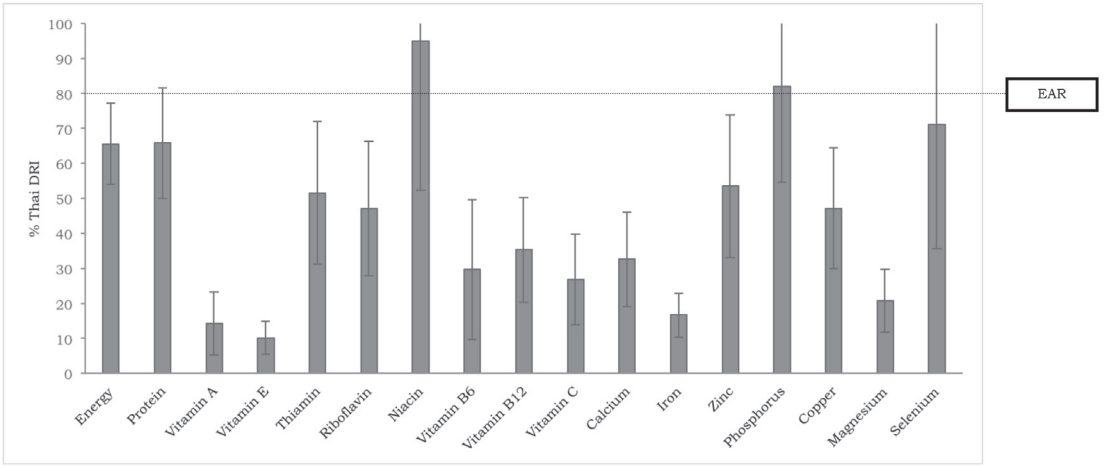

Figure 1. The nutrient intakes of lactating women relative to Thai DRIs.
The dotted line stands for EAR=estimated average requirement (IOM, Food and Nutrition Board, 1998)

lactating women, such as calcium, zinc, thiamine, and vitamin C, were also below the EARs (33%, 53%, 52%, and 27% of Thai DRIs). The intake of dietary fibre was only 6.8 g/day compared to the recommended daily intake of 25 g/day. Phosphorus and niacin were the only two nutrient intakes higher than the EARs (>80% of Thai DRIs.)

Correlation of gut bacteria and dietary intake of lactating women

Correlation of gut bacteria and food group intakes of lactating women

Table 2 shows the associations between the group of foods consumed by lactating women and *Bifidobacterium* spp., *Lactobacillus* spp., and *Clostridium* spp./*Enterobacter* spp. Among the nine

Table 2. Correlation coefficients (cc) of food group consumption and gut bacteria in lactating women

Food group	*Correlation coefficients*		
	Bifidobacterium spp.	*Lactobacillus spp.*	*Clostridium spp./ Enterobacter spp.*
Starchy staples	-0.15	0.31	0.09
Dark green leafy vegetables	0.23	-0.05	-0.19
Other vitamin A rich fruits and vegetables	-0.03	0.47*	-0.03
Other fruits and vegetables	-0.16	-0.26	-0.23
Organ meat	-0.18	0.03	-0.27
Meat and fish	0.05	-0.15	-0.14
Eggs	-0.03	0.07	-0.45*
Legumes, nut and seeds	0.13	0.004	0.32
Milk and milk products	0.13	-0.15	0.11

*correlation (Pearson's correlation) is significant at the 0.05 level (2-tailed)

groups of food consumed, *Lactobacillus* showed a positive correlation with "other VA-rich fruits and vegetables". However, lactating women with high egg consumption showed a negative correlation with *Clostridium* spp./ *Enterobacter* spp.

Correlation of gut bacteria and nutrient intakes of lactating women

The correlations of *Bifidobacterium* spp., *Lactobacillus* spp., and *Clostridium* spp./*Enterobacter* spp. and nutrient intakes are shown in Table 3. Proteins, protein from animal, phosphorus, and VA were positively correlated with *Bifidobacterium,* while β-carotene and vitamin C were positively correlated with *Lactobacillus* spp. However, *Clostridium spp./Enterobacter* spp. was negatively correlated with calcium.

Correlation of gut bacteria between lactating women and their breastfed infants

As shown in Table 4, *Bifidobacterium* spp. and *Lactobacillus* spp. of lactating women and infants were positively correlated. However, no correlation was detected for *Clostridium* spp./ *Enterobacter* spp.

Table 3. Correlation coefficients (cc) of nutrient intakes with gut bacteria in lactating women

Nutrient	*Correlation coefficients*		
	Bifidobacterium spp.	*Lactobacillus spp.*	*Clostridium spp/ Enterobacter spp.*
Energy	0.21	0.06	0.28
Carbohydrate	0.31	0.18	0.39
Protein	0.55*	0.27	0.17
Protein-animal	0.55*	0.22	0.23
Protein-vegetable	0.39	0.31	0.32
Fat	-0.19	-0.21	-0.35
Calcium	-0.20	0.15	-0.50*
Phosphorus	0.50*	0.19	0.02
Iron	0.31	-0.08	0.07
Copper	-0.07	-0.15	0.28
Magnesium	0.27	0.32	-0.12
Selenium	0.33	0.15	0.31
Zinc	0.22	-0.10	-0.06
Vitamin A	0.50*	0.37	0.27
Retinol	-0.21	0.06	-0.07
Beta-carotene	-0.32	0.49*	-0.16
Thiamin	0.15	0.01	0.01
Riboflavin	-0.08	-0.37	-0.39
Vitamin B6	0.34	-0.14	0.01
Vitamin B12	0.25	-0.10	-0.09
Vitamin C	-0.29	0.47*	0.24
Niacin	0.28	0.20	0.08
Vitamin E	-0.16	-0.40	-0.29
Dietary fibre	0.13	-0.07	0.04

*correlation (Pearson's correlation) is significant at the 0.05 level (2-tailed)

Table 4. Correlation coefficients (cc) of gut bacteria in lactating women and in their infants

Bacteria	*Lactating women bacteria*		
	Bifidobacterium (cc)	*Lactobacillus (cc)*	*Clostridium/ Enterobacter (cc)*
Infant bacteria			
Bifidobacterium (cc)	0.53**	0.47*	0.36
Lactobacillus (cc)	0.62**	0.51*	0.29
Clostridium/Enterobacter (cc)	0.17	0.40	0.01

*correlation (Pearson's correlation) is significant at the 0.05 level (2-tailed)
**correlation (Pearson's correlation) is significant at the 0.01 level (2-tailed)
cc, correlation coefficient

DISCUSSION

Data on the average food consumption (nine food groups) and nutrient intakes of mothers revealed that lactating women in this study area may have a risk of undernutrition, especially a lack of vitamin A. This is because most of the nutrient and energy intakes of lactating women were below the Thai DRIs and EARs. The average energy intake was only 1,476 kcal/day, which accounted for 66% of the Thai DRI, while the average VA intake of participants was only 14% of the Thai DRI. The percentage of VA was lower than in other developing countries such as Indonesia and China. VA intake of lactating women in Indonesia was 64% of Angka Kecukupan Gizi (AKG), while China had 100.1% of its Chinese Recommended Nutrient Intake (RNI) (Chen *et al.,* 2012; Madanijah *et al.,* 2016). The main study had revealed that almost 50% of subjects had VA deficiency based on total VA liver reserve (Pinkaew *et al.*, 2021), while the average body mass index (BMI) was 22.5±3.9 kg/m^2 (Azis, Pinkaew & Wichienchot, 2021). However, according to Swalarz *et al.* (2018), BMI is not the best indicator of malnutrition, because malnutrition already occurs much earlier and there is no cut-off for lactating women. The subjects had low energy intake compared to the requirement for lactating women, mainly due to low socio-economic status with an average family income of USD500 per month to support around five people in a family (Azis *et al.*, 2021). Moreover, food taboos of the Muslim people in the study area, which only allowed the consumption of rice and grilled or fried fish during the first period of lactation (30 days – three months) may have further contributed to the lack in energy intake.

Among the nine food groups consumed by lactating women (FAO, 2011), rice was the main starchy staple with the highest amount of consumption (642 g/day). This was the food group that contributed the main portion of calories and other nutrients to these lactating women.

The correlations between gut bacteria in lactating women and food groups showed that the "other VA-rich fruits and vegetables" was positively correlated with *Lactobacillus* spp. A study showed that *Lactobacilli* are able to use foods as their carbon source to support their growth and maintain the environmental pH (Walter, 2008). Previous *in vivo* and *in vitro* studies have found an interrelationship between *Lactobacillus* spp. and VA group of foods (Lee & Ko, 2016). However, the underlying mechanism has not been clearly elaborated. Cell differentiation and maintenance of healthy skin, mucous membranes, and soft tissues,

are the major functions of VA (Huang *et al.,* 2018). Therefore, VA could potentially help in promoting differentiation of healthy villi in the gastrointestinal tract. Moreover, fruits and vegetables are known as important sources of carbohydrates and prebiotics, such as fructooligosaccharides, oligofructose, inulin, galactose, and xylose, which contain oligosaccharides as energy sources used by the gut microbiota (Azad *et al.*, 2018).

The results revealed that *Bifidobacterium* spp. was positively associated with total protein, protein from animal sources, phosphorus, and VA intake. Garcia-Mantrana *et al.* (2018) reported that protein-rich foods have significantly high bifidobacteria counts and significant positive correlations with various groups of butyrate-producing bacteria within the faecal microbial composition, along with higher concentration of SCFA. In haemodialysis patients, *Bifidobacteriaceae* was positively correlated with phosphorus. *Bifidobacterium* spp. may regulate the absorption of phosphate in the intestine and use it as one of their energy sources (Miao *et al.*, 2018).

Lactobacillus spp. was positively correlated with β-carotene and vitamin C. β-carotene is a good source of VA. Therefore, this could support our finding of a positive correlation between "other VA-rich fruits and vegetables" and *Lactobacillus* spp. A prior study found that beta-carotene as pro-VA carotenoid promoted *Bifidobacteria* and *Lactobacillus* via fermentation of the substances bound with β-carotene in the food matrix (O'Callaghan & van Sinderen, 2016). The proposed mechanism of the correlation between vitamin C and *Lactobacillus* spp. is that vitamin C might stimulate the growth of *lactobacilli* by increasing the acidity of the medium, as probiotics prefer an acidic gastric environment (Stadler & Viernstein, 2003). *Lactobacilli* of intestinal origin are considered intrinsically resistant to acidic environments and are often employed in fermented foods as probiotics (Corcoran *et al.*, 2005). On the other hand, calcium was negatively correlated with *Clostridium* spp./*Enterobacter* spp. Previously, calcium was also reported to be negatively correlated with *Clostridium coccoides* and *Clostridium leptum* in obese mice, which is in line with our finding. Calcium can modulate gut microbiota in a specific and prebiotic manner (Chaplin *et al.*, 2016).

The association between gut microbiota of lactating women and those of their breastfed infants has been confirmed in our Muslim population. *Bifidobacterium* spp. and *Lactobacillus* spp. in lactating women and infant pairs were positively correlated. According to Karakochuk *et al.* (2017), the gut microorganisms in mothers are closely similar with their infants'. This is because of their food pattern, environment, activity, and daily interaction, as well as the mode of delivery. *Bifidobacteria* species e.g. B. *breve*, B. *longum* spp., B. *bifidum*, B. *adolescentis*, B. *dentium*, and B. *pseudocatenulatum*, which were all identified in infant faeces, were also found in the corresponding milk samples of the mother (Duranti *et al.,* 2017). The transmission of *Bifidobacteria* and *Lactobacillus* of lactating women to her infant suggests that human milk is a potential vehicle to facilitate this acquisition.

This is the first study on Thai Muslim population that presented a correlation between gut bacteria and dietary/nutrient intakes of lactating women, and also of gut bacteria in their exclusively breastfed infants. Our data showed that *Lactobacillus* spp. of lactating women was positively correlated with VA-rich fruits/vegetables food group

(providing carotenoids), β-carotene (major source of carotenoids in the diet), and *Lactobacillus* spp. of their breastfed infants. Thus, VA/ β-carotene in the diet of mothers could be a factor promoting the growth of *Lactobacillus* spp., not only in the mothers themselves, but also in their infants.

A limitation of this current study was the rather small sample size (27 pairs of lactating women and breastfed infants) due to the high rate of dropouts, mainly caused by inability to exclusively breastfeed. As a limitation of descriptive cross-sectional study, it was not possible to establish a true cause and effect. Therefore, a longitudinal or experimental study should be conducted to confirm this finding. In addition to that, aside from diet/nutrients, several other factors such as maternal size, mode of delivery, feeding practices, and body contact are also known to affect the gut microbiota of lactating women and infants; these could be addressed by a future study together with nutritional factors.

The findings from this study supported the need for encouraging exclusive breastfeeding for the first six months of a newborn's life, together with giving nutrition education to mothers. These strategies could shape the nutritional status and promote the growth of beneficial bacteria (*Lactobacillus* spp. *and Bifidobacterium* spp.) in both mothers and infants.

CONCLUSION

Based on the dietary assessment, the lactating women in this study area were at risk of undernutrition and rice was consumed as the main staple food. The "VA-rich fruits and vegetables" food group correlated positively with *Lactobacillus* spp. Egg consumption correlated negatively with *Clostridium* spp./*Enterobacter* spp. Regarding associations between gut microbiota and nutrient intakes in lactating women, total protein, protein from animal sources, phosphorus, and VA were positively correlated with *Bifidobacterium* spp. Beta-carotene and vitamin C were also positively correlated with *Lactobacillus* spp., but calcium was negatively correlated with *Clostridium* spp./*Enterobacter* spp. Finally, *Bifidobacterium* spp. and *Lactobacillus* spp. of lactating women and their breastfed infants showed strong correlations.

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Authors' contributions

LA, conducted the dietary assessment, measured gut microbiota enumeration, statistically analysed the data, and drafted the manuscript; SW, designed the research and supervised gut microbiota determination; SP, designed the research, conducted the dietary assessment, and statistically analysed the data. All authors read and approved the final manuscript.

Conflict of interest

LA, SW and SP have no conflicts of interest.

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Association between stress and eating behaviour among nurses in Hospital Universiti Sains Malaysia

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ABSTRACT

Introduction: Stress is a factor that may affect dietary behaviour among nurses, which can contribute to a risk of overweight or obesity in the future. The aim of this study was to determine the association between stress and eating behaviour among nurses at Hospital Universiti Sains Malaysia, Kelantan, Malaysia. **Methods:** A cross-sectional analysis was performed among 105 nurses (30-50 years of age; 84.8% females and 15.2% males) and participants were assessed using a self-administered questionnaire consisting of socio-demographic data, body mass index (BMI), Perceived Stress Scale-10 (PSS-10), and the Dutch Eating Behaviour Questionnaire (DEBQ). Data were analysed using descriptive statistics and the associations were determined by Kruskal-Wallis Test. **Results:** Based on descriptive data, 73.3% of nurses (n=77) were moderately stressed and 49.5% had normal BMI (n=52). Furthermore, according to three eating domains, the emotional eating score was the highest (30.0±16.0). An association was found between emotional eating [$\chi^2(2)=10.305$, $p=0.006$], while external eating [$\chi^2(2)=5.103$, $p=0.078$], and restrained eating [$\chi^2(2)=2.335$, $p=0.311$] did not display a significant difference. The Bonferroni test was further used and there was a significant difference between low and moderate stress levels only ($p<0.01$), while others were not significantly different (low-high and moderate-high) ($p>0.05$). The results showed that nurses in the low stress group had lower scores of emotional eating behaviour than nurses with moderate stress levels. **Conclusion:** Stress has an impact on emotional eating behaviour and more research is needed to fully understand this link.

Keywords: stress, eating behaviour, nurses

INTRODUCTION

Nursing is a health science profession that plays an important role in management of patient care in hospitals, clinics, institutions or even in the community. According to statistics, it was reported that there is a total of 74,788 registered nurses in Malaysia under the Ministry of Health, not including community and dental nurses (WHO, 2014). Nursing is considered to be an exceptionally difficult occupation compared to other professions because it is highly stressful (Chou, Li & Hu, 2013). Nursing job stress is caused by a variety of factors including the need for patient care, professional issues, the workplace, and organisational policies and procedures (Bai & Ravindran, 2019). In Malaysia, the prevalence of job stress among nurses was reported to be between 41.0% and 49.3% (Emilia & Noor Hassim, 2007;

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Ghawadra *et al.,* 2019). In the meantime, 41.2% of Australian nurses reported being stressed at work (Maharaj, Lees & Lal, 2019). Furthermore, a study from Iran reported that the prevalence of job stress among nurses has been reported to be high, at 90.0% (Gheshlagh *et al.,* 2017).

Stress is defined as the body and mind's attempt to adapt to a changing environment, or in other words, stress is the internal response to external events (Johan, Sarwar & Majeed, 2017). Most notably, uncontrollable stress changes eating habits and increases consumption of hyperpalatable foods, particularly those high in fat, sugar, or salt (Yau & Potenza, 2013). Moreover, stress can lead to an increase in the consumption of high-fat snacks and fast foods, as well as a lower intake of energy from carbohydrates (Barrington *et al.* 2014). In the long run, this can promote weight gain and body fat mass, increasing the risk of obesity among nurses (Bowman & Vinyard, 2004). Previous research has found a high prevalence of overweight and obesity among nurses due to dietary habit, especially skipping of meals and physical inactivity, which can increase the risk of poor health conditions such as diabetes, cardiovascular disease, high blood pressure, and high cholesterol. Aside from a hectic work schedule, a sedentary lifestyle and a lack of physical activity can contribute to weight gain or unhealthy food choices (Aryee *et al.,* 2013).

Thus, it is essential to understand the prevalence of stress and its association with eating behaviour among nurses, as it is an important issue to explore in order to overcome and develop appropriate interventions or potential strategies for obesity prevention. The objective of this study was, therefore, to determine the association between stress and eating behaviour among nurses in Hospital Universiti Sains Malaysia, Kelantan, Malaysia.

MATERIAL AND METHODS

Study population

This research was a cross-sectional study performed between January 2019 and March 2019. A cross-sectional study design was used to (1) examine the level of stress and eating behaviour; (2) determine the status of body mass index (BMI); (3) determine the association between stress and eating behaviour among nurses at Hospital Universiti Sains Malaysia. The study setting was at Hospital Universiti Sains Malaysia, a teaching hospital in the Northeastern state of Kelantan, Malaysia.

Nurses who worked at the Hospital Universiti Sains Malaysia's inpatient wards (13 wards), clinics, and other departments (dental, oncology, radiotherapy, psychiatric and haemodialysis units) were eligible for the study if they were present on the day of data collection, interested in participating, and could read and understand Bahasa Malaysia. The exclusion criteria were trainee and student nurses.

Sampling method

Convenience sampling method was used to recruit all eligible nurses working in Hospital Universiti Sains Malaysia. The sample size needed for this study was calculated based on the formula by Daniel (1999) $n = \frac{Z^2 P(1-P)}{d^2}$ (n=sample size, Z=z statistic for a level of confidence at 95%, P=expected prevalence stress among nurses, d=precision) with the value of P being equal to 93.4% (Mwinga & Mugala, 2015). The calculation considered a 20% drop-out rate in the study. Accordingly, the total participants required for this study was 114.

Measuring tools

The measurement tool used in this study was a self-administered questionnaire. The questionnaire consisted of four parts (A, B, C and D) as described below.

Part A (demographic data)
Part A contains questions related to the demographic data that included information on age, gender, ethnicity, and marital status.

Part B (anthropometric data)
Part B comprises anthropometric data which included weight, height, and BMI. In order to determine BMI, the weight and height of participants were collected using the dial mechanical weighing scale with height rod that was located in each department, ward, or clinic at the hospital. The current weight and height were self-recorded based on the average of two measurement readings. For weight measurement, participants were advised to empty their pockets before, and reading was recorded to the nearest 0.1 kg. Meanwhile, for height measurement, participants were instructed to remove their shoes or others related footwear, stand upright and look forward with both hands at the sides. The measurement of height was recorded to the nearest 0.1 cm. Subsequently, BMI was calculated using the formula of BMI = weight (kg)/ height $(m)^2$. Based on the World Health Organization (WHO) classification, BMI was then classified as underweight, normal, overweight, or obesity (WHO, 2000).

Part C (Perceived Stress Scale-10)
In Part C, stress level was determined using the Perceived Stress Scale-10 (PSS-10). The Malay version of the PSS-10 is a reliable and accurate measure of stress among nurses in Malaysia (Sukhvinder Singh, Noor Hassim & Krishna Gopal, 2015). The PSS-10 has ten items on a 5-Likert scale and the scale was scored as 0=never, 1=almost never, 2=sometimes, 3=fairly often, and 4=very often. Out of the ten items, there were four positive items (items 4, 5, 7, and 8) that were graded in reverse (0=very often, 1=fairy often, 2= sometimes, 3=almost never, 4=never). The total score ranged from 0 to 40, with a higher score indicating a higher level of perceived stress (0-13=low, 14-26=moderate, and 27-40=high). The Cronbach's alpha coefficient value was 0.82 for the first factor (six items) and 0.72 for the second factor (four items). The overall alpha value was 0.63, demonstrating a satisfactory level of validity and reliability in assessing stress perception among nurses in Malaysia (Sukhvinder Singh, Noor Hassim & Krishna Gopal, 2015). Permission to use the Malay versions of the PSS-10 was granted by the researchers who translated and validated these survey instruments.

Part D (Dutch Eating Behaviour Questionnaire)
The final section of part D involved using the Dutch Eating Behaviour Questionnaire (DEBQ) to determine eating behaviours. DEBQ is a 33-item self-reported questionnaire designed to determine eating styles that can contribute to or slow the occurrence of overweight. It consists of three scales: emotional (13 items), external (ten items), and restrained eating (ten items). Emotional eating was defined as eating in response to a negative emotion; external eating was defined as eating in response to the appearance of foods; and restrained eating was defined as an effort to avoid eating due to weight concerns (Van Strien *et al.,* 1986). However, according to Subramaniam and colleagues, three items (items 21, 27, and 14) were removed from the Malay version of the DEBQ due to low reliability coefficient values (Subramaniam *et al.*, 2017). Thus, in total, only 30 items were used in the DEBQ Malay version, which was reported as a suitable instrument to be used to identify eating behaviours among adult Malaysians due to good construction validity and reliability. The internal consistency for emotional

eating scale, external eating scale, and restrained eating scale were 0.914, 0.819, and 0.856, respectively (Subramaniam *et al.*, 2017). All items must be completed on the basis of the Likert scale (1=never, 2=seldom, 3=sometimes, 4=often, and 5=very often). A higher total score indicated a greater tendency for poor eating behaviours. The researchers that translated and validated the DEBQ gave permission to use the Malay versions of these survey instruments.

Data collection procedures

After receiving ethical approval from the Ethics Committee of Universiti Sains Malaysia (USM/JEPeM/18100522), the researcher began collecting data by meeting with the participants. The purpose of the study, procedures, benefits, and potential risks of participating in this study were all explained to the participants. All eligible participants provided informed consent prior to the survey. Participants' confidentiality was guaranteed, and they could withdraw from the study at any time with no negative effects.

The participants completed a four-part questionnaire that took about 20 minutes. The researchers collected the questionnaire from the participants a week later to give them sufficient time to complete it. The hypothesis was that there is an association between stress and eating behaviour among nurses at Hospital Universiti Sains Malaysia.

Data analysis

The analysis was carried out using the SPSS (version 24, SPSS Inc, Chicago, IL, USA) statistical software. The Shapiro-Wilk Test was used to determine if the distribution was normal. Participants' socio-demographic characteristics were summarised using descriptive data. Based on normality distribution, numerical data were presented as mean (standard deviation, *SD*) or median (interquartile range, *IQR*), while categorical data were presented as frequency and percentage. The association between stress and eating behaviour was evaluated using the Kruskal-Wallis Test. Statistical significance was determined at $p<0.05$.

RESULTS

Demographic characteristics of study groups

Prior to the study, there was a total of 114 participants, but nine were excluded due to incomplete questionnaires. Finally, only 105 participants completed the study. Females (n=89, 84.8%) and Malays (n=103, 98.1%) made up the majority of the participants. Furthermore, majority of the participants (n=78, or 74.3%) were married, followed by 21.0% (n=22) who were single and 4.8% (n=5) who were divorced.

Table 1. Demographic characteristics of participants (n=105)

Characteristics	*n (%)*
Age	
<30 years	38 (36.2)
30-39 years	42 (40.0)
40-49 years	16 (15.2)
>50 years	9 (8.6)
Gender	
Male	16 (15.2)
Female	89 (84.8)
Ethnic	
Malay	103 (98.1)
Non-Malay	2 (1.9)
Marital Status	
Single	22 (21.0)
Married	78 (74.3)
Divorced	5 (4.8)
Body Mass Index (BMI)	
Underweight (<18.5 kgm^{-2})	5 (4.8)
Normal (18.5-24.9 kgm^{-2})	52 (49.5)
Overweight (25- 29.9 kgm^{-2})	33 (31.4)
Obese (>29.9 kgm^{-2})	15 (14.3)

According to the WHO classification, approximately 49.5% of participants

(*n*=52) were in the normal body weight category, followed by overweight (*n*=33, 31.4%), obese (*n*=15, 14.3%), and underweight (*n*=5, 4.8%) (Table 1).

Stress level among nurses

Table 2 shows the perceived stress score for participants classified as low, moderate, or high stress levels. Most nurses reported moderate stress levels (*n*=77, 73.3%), followed by low stress levels (*n*=26, 24.8%), and high stress levels (*n*=2, 1.9%). In the meantime, the overall mean total score was 16.1 (*SD*=4.5).

Table 2. Stress level among participants (*n*=105)

Characteristics	*n (%)*	*Range*
Level of stress		
Low	26 (24.8)	4.0-13.0
Moderate	77 (73.3)	14.0-26.0
High	2 (1.9)	27.0-28.0
Overall PSS score	16.1 (4.5)	-

Perceived Stress Score (PSS): 0-13=low, 14-26=moderate, and 27-40=high

Eating behaviour among nurses

Table 3 shows the scores of eating behaviours in three domains: emotional, external, and restrained among participants. The results indicated that total emotional eating score (30 points, *IQR*=16) was higher than external eating score (27 points, *SD*=5.8) and restrained eating behaviour score (25 points, *SD*=7.2).

Association between stress and eating behaviour

Kruskal-Wallis Test showed that the stress level of participants (low, moderate, or high) differed significantly from that of emotional eating behaviour only [$\chi^2(2) = 10.305$, $p=0.006$]. In the meantime, both external eating [$\chi^2(2)=5.103$, $p=0.078$] and restrained eating [$\chi^2(2)=2.335$, $p=0.311$] did not show a significant difference (Table 4).

Specifically, based on the post-hoc Bonferroni correction test, there was a significant difference between low and moderate stress levels with emotional eating score ($p<0.01$) only, while others were not significantly different ($p>0.05$). It has been shown that nurses in the low stress category had lower scores of emotional eating behaviour compared to nurses with moderate stress level.

DISCUSSION

This current study is important to find an association between stress level and eating behaviour among nurses since stress may promote unhealthy eating behaviours, and this can lead to many health complications such as obesity and cardiovascular risk. Majority of the participants in this study were females, with the remaining participants being males. Due to the nature of this profession, which is usually associated with females, there was naturally a higher proportion of female participants (Pudney & Shields, 2000). Furthermore, the prevalences of overweight (32.4%) and

Table 3. Eating behaviour scores of participants (*n*=105)

Eating behaviour categories	*Mean±SD*	*Median (IQR)*	*Range*
Emotional		30.0 (16.0)	13.0-57.0
External	27.0±5.8		15.0-40.0
Restrained	25.0±7.2		9.0-41.0

Table 4. Comparison of eating behaviour score categories with stress level among participants in Hospital Universiti Sains Malaysia (n=105)

Parameter	*Stress level*	*Median (IQR)*	*Chi-square statistic (df)*	*p-value*[†]
Emotional score	Low	23 (16.8)	10.305 (2)	0.006*
	Moderate	33 (14.0)		
	High	37 (NA)		
External score	Low	25 (6.5)	5.103 (2)	0.078
	Moderate	28 (8.5)		
	High	27 (NA)		
Restrained score	Low	22 (12.5)	2.335 (2)	0.311
	Moderate	26 (9.5)		
	High	30 (NA)		

[†]Tested using Kruskal-Wallis Test, significant at p<0.05
*Post-hoc with Bonferroni's correction: low vs. moderate (p<0.01), low vs. high (p>0.05), moderate vs. high (p>0.05)

obesity (14.3%) were high among nurses in this study, which was consistent with a study conducted among registered Malaysian nurses (overweight 33.5% and obese 17.1%) (Coomarasamy, Wint & Sukumaran, 2015).

In terms of stress prevalence among nurses, the mean overall stress level was moderate, with the majority falling into this category (73.3%). The prevalence was reportedly within the range according to a meta-analysis study from Iran at 69-90% (Gheshlagh *et al.*, 2017), but higher in Zambian nurses at 93.4% (Mwinga & Mugala, 2015). When compared to other health workers, the nursing profession appears to be more stressful (Yeboah *et al.*, 2014). In addition, nurses working in public hospitals in Thailand are more stressed than those working in private hospitals, according to a study by Tyson & Pongruengphant (2004).

The greater number of nurses experiencing moderate stress may be caused by many factors such as patient, occupational, organisational or personal factors (Bai & Ravindran, 2019). In addition, other possible explanations for this variation may be different countries, hospital settings either teaching or non-teaching hospital, and convenience sampling that can increase in inaccuracy. The causes of job stress in nurses according to a previous study is the job itself. It was reported that heavy workload, repetitive work, and poor working environment were among the factors that trigger stress among nurses, especially in the public health services in Malaysia (Beh & Loo, 2012). A most significant finding was that job factors, rather than demographic factors, are more involved in job stress (Najimi, Goudarzi & Sharifirad, 2012). However, in this study, factors that led to stress among nurses were not determined.

In this study, three domains of eating behaviours were assessed: emotional, external, and restrained. Stress was found to have a significant relationship with emotional eating behaviour in this study, but not in the other domains. This contrasts with findings of a Saudi Arabian study, which found that stress was positively associated with all three domains of emotional, external, and restrained eating (Almajwal, 2016). Prior study also found that the associations between stress and eating behaviours were usually different in each of the eating behavioural domains and were gender-influenced (Ohara *et al.*, 2019).

The different outcomes of the studies may be due to the different versions and items used to assess psychological stress and eating behaviours. In terms of psychological stress, the current study used the Malay version of PSS and had ten items compared to the previous study that used the English version that consisted of four items only. Meanwhile, for eating behaviour, the tool used was dietary eating behaviour in Malay version that consisted of 30 items compared to the previous study that used the original English version that consisted of 33 items in the questionnaire (Almajwal, 2016).

This study found that nurses with moderate stress had higher scores of eating behaviours relative to those with low stress. Higher scores of eating behaviours indicates poor eating behaviours. Emotional conditions, such as anxiety, depression and sadness, stimulates dietary behaviours that do not conform to dietary guidelines (e.g. increased food intakes or poor food choices) (Devonport, Nicholls & Fullerton, 2019). Furthermore, previous research has shown that stressed emotional eaters consume more sweets, high-fat foods, as well as energy-dense meals, than unstressed and non-emotional eaters. Besides that, stressed workers are more likely to develop negative eating habits such as overeating and gaining weight (Nishitani & Sakakibara, 2007). This will exacerbate overweight or obesity issues, having an impact on nurses' health and wellbeing. However, this study did not assess the dietary intake of nurses.

The current research included analysis of classification of body weight or BMI with stress level, which might provide some additional information as an example, there was a similar pattern showing that the majority of participants in each BMI category (underweight, normal, overweight and obesity) had a moderate stress level. A meta-analysis study to determine the association between BMI with stress reported that stress was associated with increasing BMI, which was not consistent with the current study. The reason for differences might be due to the complexity of how humans react towards stress with foods because some may eat more or less as a response to stress (Wardle *et al.*, 2011), therefore this may lead to weight problems – either under- or overweight. In addition, self-reported weight and height may be biased and therefore needs precaution in its interpretation. Importantly, given the scarcity of published research on emotional eating, its impact on the stress-eating relationship would require further investigation.

Meanwhile, the lack of significant differences in terms of stress and external eating behaviour could be attributed to different backgrounds of environmental factors, as this study drew nurses from a variety of backgrounds, including inpatient, outpatient, and dental nurses. This was supported by the fact that external eating behaviour is defined as a shift in attitude towards environmental factor cues during times of stress, and people are compelled to eat (Almajwal, 2016). The wide differences in environmental factors of a diverse working environment may give rise to this pattern of results. In addition, previous studies have shown that although nurses realised they could face problems of overweight or obesity, many have not practised weight management behaviours (Zapka *et al.*, 2009). This may explain why there were no significant differences in stress with respect to restricted eating behaviour. As mentioned earlier, restrained eating behaviour is an attempt to refrain from eating because of concerns about weight gain.

There were some limitations in this study. This was a cross-sectional study

that prevented the possibility of assessing causality. In addition, this study also involved nurses from all departments, either inpatient or outpatient setting, which could confound the findings since other factors, such as work shifts, may influence outcome. Aside from that, the participants' dietary intakes were not measured and analysed in this study, while the measurements of weight and height were self-recorded by the nurses.

Despite these limitations, this current study added knowledge by providing information on the current prevalence of stress, eating behaviours, BMI and the significant association between stress and emotional eating behaviour among nurses at Hospital Universiti Sains Malaysia. It is necessary to evaluate the level of stress among nurses because further research are needed on appropriate interventions to reduce the burden of health and obesity among this population.

For nurses, it is important to have better stress management in the future because this is essential to their mental wellbeing. The hospital nursing management should take proactive actions by designing tailored stress management programme, provide continuous psychological support system for the nurses, appreciate the contributions of nurses, and take responsibility in the mental health of their staff by providing them with a conducive working environment that is less stressful (Salilih & Abajobir, 2014). In terms of promotion of healthy eating, nurses can also receive individual dietary advice from the hospital dietitians to improve their eating practices in order to reduce stress-related over-eating. More research is needed to confirm the link between stress and eating behaviour by taking into consideration other factors, such as shift works, disease, working place (Salilih & Abajobir, 2014), years of work experience and total working hours.

CONCLUSION

In conclusion, only emotional eating was linked to stress in nurses. The other domains – external and restrained eating – had no links to stress. As a result, drawing a firm conclusion about the relationship between stress and eating behaviour in general is difficult and requires further investigation.

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Authors' contributions

NHNMS, conducted the study, data analysis, and interpretation of the data with the support from JS; JS, helped supervise the study, prepared the draft of the manuscript, and reviewed the manuscript. All authors approved the final manuscript.

Conflict of interest

The authors declare that they have no conflicting financial or non-financial interests in this study.

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Improvement in body composition of adult post-bariatric surgery patients at one-year follow-up at a public hospital in United Arab Emirates

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ABSTRACT

Background: Data on postoperative follow-ups and bariatric surgery (BS) outcomes performed in the United Arab Emirates (UAE) are crucial for registry. This study assessed the one-year postoperative changes in body composition and metabolic profiles in BS patients. **Methods**: The medical and dietetics records of 51 adult patients who underwent BS in the largest public hospital in Sharjah, UAE were reviewed. Data on body weight and composition, as well as metabolic profile (blood glucose and lipid levels) from the initial until the last hospital visit were recorded. **Results**: The median (interquartile range) follow-up period was 6.0 (8.0) months. The patients had significant total weight loss [19.3 (12.6)%] and reduction in body mass index (BMI) [18.0 (13.6)%] of approximately 7 BMI points. Moreover, the patients' body composition improved significantly; loss was the highest in fat mass [–30.9 (22.1)%] and the least in lean body mass [–8.6 (8.4)%]. There was a steady decline in all body composition variables with a longer duration of follow-up visits from 1–3 months to 10–12 months. The fat mass (–40.3%):lean body mass (–10.7%) loss ratio was 3.8:1 at 10–12 months. The patients' metabolic status was normal during the last postoperative visit. **Conclusions**: Incremental improvements in body composition of patients were evident with longer follow-up visits up to one year after BS. Hence, patients should attend regular follow-up visits after BS. Moreover, accurate and complete documentations of medical and dietetics visits are mandated.

Keywords: bariatric surgery; body composition; postoperative

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INTRODUCTION

The prevalence rates of overweight and obesity (43.0% and 32.3%, respectively) are high in the United Arab Emirates (UAE) (Sulaiman *et al.,* 2017). Recently, the risk of metabolic complications according to waist circumference and waist-to-hip ratio (52.4% and 56.5%, respectively) have substantially increased in the UAE (Sulaiman *et al.,* 2017). Any type of bariatric surgery (BS) is considered a frontline treatment for severe obesity, thereby leading to superior weight loss and maintenance along with improvements in medical morbidities, compared with non-surgical interventions (Pareek *et al.,* 2018; Ruban *et al.,* 2019). A previous report showed that the number of BS performed worldwide from 2011 to 2013 had significantly increased (98.0%) (Angrisani *et al.,* 2015). Globally, the most common procedure is sleeve gastrectomy (SG) (58.6%), followed by Roux-en-Y gastric bypass (RYGB) at 31.2% (Ramos *et al.,* 2019).

Studies have shown improvements in body composition after BS (Andersson *et al.,* 2019; Maïmoun *et al.,* 2019). Specifically, significant improvement in glycemic control and reduced 10-year cardiovascular risk were reported at 12–24 months after RYGB (Andersson *et al.,* 2019; Pareek *et al.,* 2018). The mechanisms seem to extend beyond the magnitude of weight loss alone and include improvements in incretin profiles, insulin secretion, and insulin sensitivity, which all lead to improved patient outcomes and reduced cardiovascular risk factors (Prateek *et al.,* 2018).

The UAE is a member of the BS group/society under the International Federation for the Surgery of Obesity and Metabolic Disorders. There were 2,843 BS procedures conducted in the UAE from 2015 to 2018; the most common being SG (84.0%), followed by RYGB (13.0%), adjustable gastric banding (AGB) in 3.0%, and mini gastric bypass (MGB) in 3.0% (Ramos *et al.,* 2019). Although thousands of BS are performed annually in the UAE, data in the national registry of BS cases are incomplete (Ramos *et al.,* 2019). Moreover, information on the outcomes of BS in patients in the UAE is limited.

To the best of our knowledge, only one study was conducted at a single BS centre in the UAE. This research focused on the outcomes (weight and metabolic profiles) of BS after one year (Abusnana *et al.*, 2015). Such information is important not only for healthcare providers, but also for patients, as it can help build confidence in BS and its health benefits. There was a substantial decrease in the patient follow-up rate (39.0%) at the end of one year after BS in the UAE study (Abusnana *et al.*, 2015).

Hence, the current study aimed to assess the postoperative changes in body composition and metabolic profiles in BS patients during their last visit one year after the surgery in one of the largest public hospitals in UAE.

METHODS

We retrospectively assessed the medical and dietetics records of patients in the largest public hospital in Sharjah under the Ministry of Health and Prevention (MOHAP), UAE. This hospital is among the 19 BS centres in the country (Ramos *et al.,* 2019) and adopts the international standards for the eligibility criteria for BS set by the National Institutes of Health and American Society for Metabolic and Bariatric Surgery (MOHAP, 2019).

SG and MGB were the most common BS procedures carried out. The surgical procedures (Karamanakos *et al.,* 2008; Lee *et al.,* 2012) were conducted according to the BS Management Guidelines published under the Clinical

Practice Guidelines by the MOHAP-UAE (MOHAP, 2019). SG was performed laparoscopically, and it involved the dissection of the stomach with a linear stapler starting 3 cm from the pylorus up to the angle of His. A 60–80-mL gastric sleeve tube was placed, and 85% of the stomach was excised. MGB was performed by creating a long-sleeved gastric tube that is approximately 2.0-cm wide along the lesser curvature starting below the incisurae angularis to the angle of His. Then, antecolic Billroth II-type loop gastroenterostomy was conducted in the small intestine 200 cm distal to the ligament of Treitz. Patients could choose the type of procedure based on their medical condition and the surgeon's preference.

The medical and dietetics records of all male and female adult patients aged 18 years and above who underwent BS between January 1, 2014 and April 30, 2014 were reviewed in April 2015. Electronic and paper records of all medical and dietetics data from the initial visit (time of surgery) until the last visit (April 30, 2015) were reviewed. At least one post-BS follow-up visit was considered for inclusion. On the contrary, patient records without any follow-up visits after BS were excluded. Accordingly, the medical and dietetics records of 66 patients who underwent BS during the above-mentioned period were reviewed. However, due to the lack of follow-up visits/data, only 51 patients were included in the analysis. Figure 1 shows the recruitment process and follow-up visits of patients after BS.

To elaborate, patients' records were reviewed to collect the following information: demographic characteristics, including age, sex, marital status, and nationality; medical records of the date and type of BS, blood pressure, and metabolic profile based on the biochemical tests [lipid profile (total cholesterol, TC; triglyceride, TG; low density lipoprotein, LDL; and high density lipoprotein, HDL), blood glucose, and glycosylated haemoglobin (HbA1c) levels]; and dietetics records on physical measurements, including body weight, height, body mass index (BMI), body composition in terms of fat mass (FM), body fat percentage (%BF), lean body mass (LBM), total body water (TBW), and waist-to-hip ratio (WHR). Body weight and height measurements were collected using the appropriate equipment (SECA, Model 286, Germany) and BMI was calculated accordingly using the information on body weight and height. Body composition analysis (BCA) was conducted via bioelectrical impedance using the eight-electrode method (SECA, Model mBCA514, Germany). WHR was automatically calculated on the BCA machine (ACCUNIQ BC 360). The comorbidity data of patients were not included.

Data analysis was performed using the Statistical Package for the Social Sciences software version 24.0 (IBM SPSS, Chicago, IL, the USA). Non-parametric tests were used after assessing the normality distribution of data using the Shapiro–Wilk test. Descriptive statistics were presented as frequencies and percentages, medians, and interquartile range (IQR). The Wilcoxon signed-rank test was used to compare the changes in body composition variables between the initial (preoperative period) and the last follow-up visits. All data were tested at a 5% significance level ($p<0.05$).

This study was conducted in accordance with the Code of Ethics of the World Medical Association (Declaration of Helsinki). The research protocol was approved by the Research Ethics Committee of the Al Qassimi Clinical Research Centre, Ministry of Health and Prevention, Sharjah, United Arab Emirates (UG004/2015-02-19) that

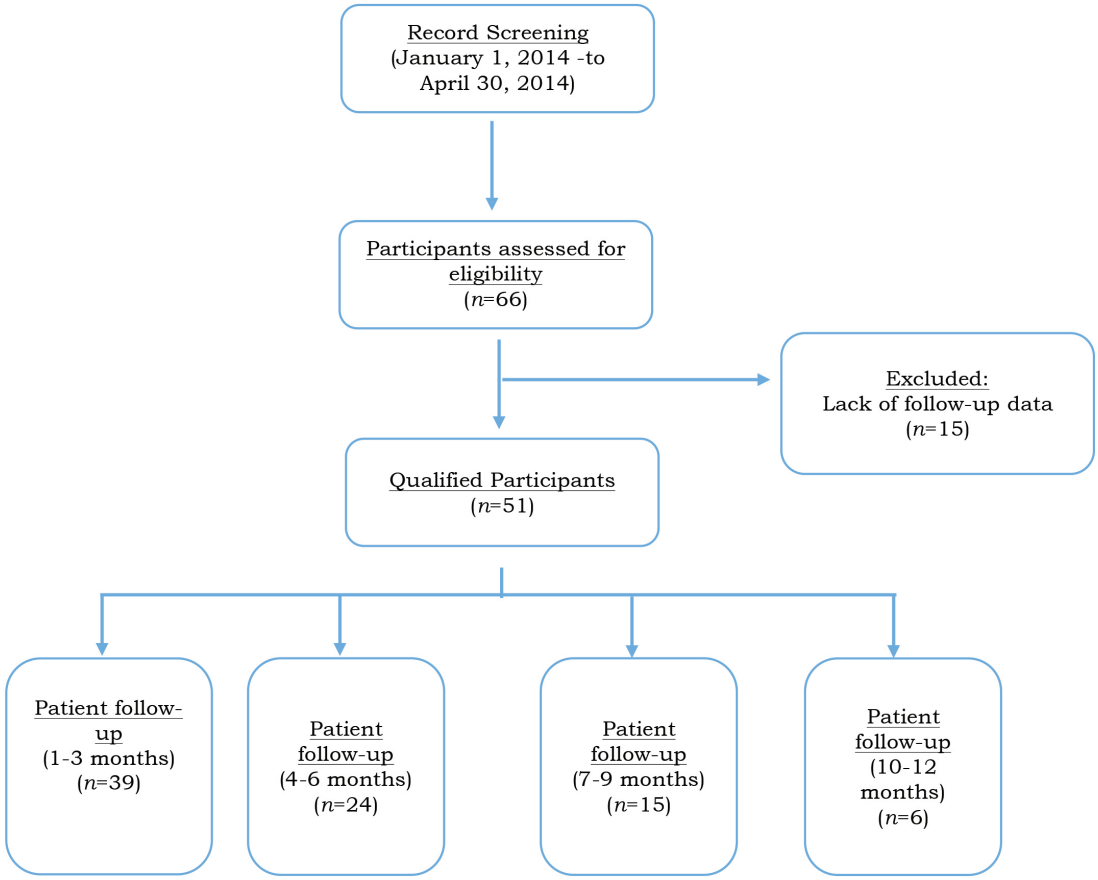


Figure 1. Flowchart of patient recruitment process and follow-up after bariatric surgery

considered patients' consent for their data to be used in future retrospective studies.

RESULTS

The demographic characteristics of BS patients (*N*=51) are summarised in Table 1. There were 47 (92.2%) women and 4 (7.8%) men; 38 of 51 patients were married and 13 were not. Most patients were UAE nationals (Emiratis; *n*=45, 88.2%), while six (11.8%) were expatriates from other Arab and Southeast Asian countries. The median (IQR) age of the patients was 32.0 (10.0) years. In total, 38 underwent SG and 13 MGB surgery.

The median (IQR) follow-up period was 6.0 (8.0) months. Moreover, the average number of postoperative patient visits for medical consultation was 4.8 (maximum of 16), and the average number of dietary counselling visits during the follow-up period was 3.5 (up to 8 visits). None of the patients visited the hospital beyond one year after BS. Based on the records, their visits were limited within the first few months after BS.

Table 2 shows the changes in the physical measurements and body composition measures of patients during the postoperative follow-up period. The average weight of the patients was 98.9

Table 1. Demographic characteristics of the participants (*N*=51) and type of surgery

Characteristics of the participants	*Median (IQR)*	*Patients n (%)*
Sex		
Female		47 (92.2)
Male		4 (7.8)
Marital status		38 (74.5)
Married		13 (25.5)
Single		
Nationality		
UAE nationals (Emiratis)		45 (88.2)
Expatriates		6 (11.8)
Age (years)	32.0 (10.0)	
Type of bariatric surgery		
Sleeve Gastrectomy		38 (74.5)
Mini Gastric Bypass		13 (25.5)
Follow-up period after BS (months)	6.0 (8.0)	

(23.4) kg at the time of surgery and 81.1 (15.1) kg during the last follow-up visit. Total weight loss [19.3 (12.6)%] during the postoperative period was significant (p<0.001).

The preoperative median (IQR) BMI of all patients was 39.5 (7.1) kg/m^2, which indicated borderline morbid obesity. However, it decreased to 32.8 (5.6) kg/m^2; hence, the patients were categorised under grade I obesity during their last visit. The value reduced by 18.0% (almost 7 BMI points), which was highly significant (p<0.001).

During the postoperative period, body FM significantly reduced [30.9 (22.1)%] (p<0.001). Moreover, FM decreased from 44.9 (18.1) kg in the initial visit to 31.1 (9.0) kg during the last follow-up visit. Patients' %BF reduced from 43.9 (7.1)% at the time of surgery to 36.1 (6.7)% on the last follow-up visit. Concurrently, there was a significant decrease in LBM from 56.7 (9.7) kg to 52.4 (8.2) kg in the postoperative period. In addition, TBW significantly decreased from 41.0 (7.3) kg to 37.6 (6.0) kg. Conversely, there was a significant reduction in WHR from

Table 2. Medians and interquartile ranges (IQRs) for changes in body composition after bariatric surgery

Variables	*Median (IQR)*			*p-value*
	Initial visit	*Last visit*	*Difference (%)*	
Weight (kg)	98.9 (23.4)	81.1 (15.1)	–19.3 (12.6)	<0.001
BMI (kg/m^2)	39.5 (7.1)	32.8 (5.6)	–18.0 (13.6)	<0.001
FM (kg)	44.9 (18.1)	31.1 (9.0)	–30.9 (22.1)	<0.001
BF (%)	43.9 (7.1)	36.1 (6.7)	–18.3 (15.4)	<0.001
LBM (kg)	56.7 (9.7)	52.4 (8.2)	–8.6 (8.4)	<0.001
TBW (kg)	41.0 (7.3)	37.6 (6.0)	–8.9 (7.8)	<0.001
WHR	1.0 (0.1)	0.9 (0.1)	–9.1 (6.8)	<0.001

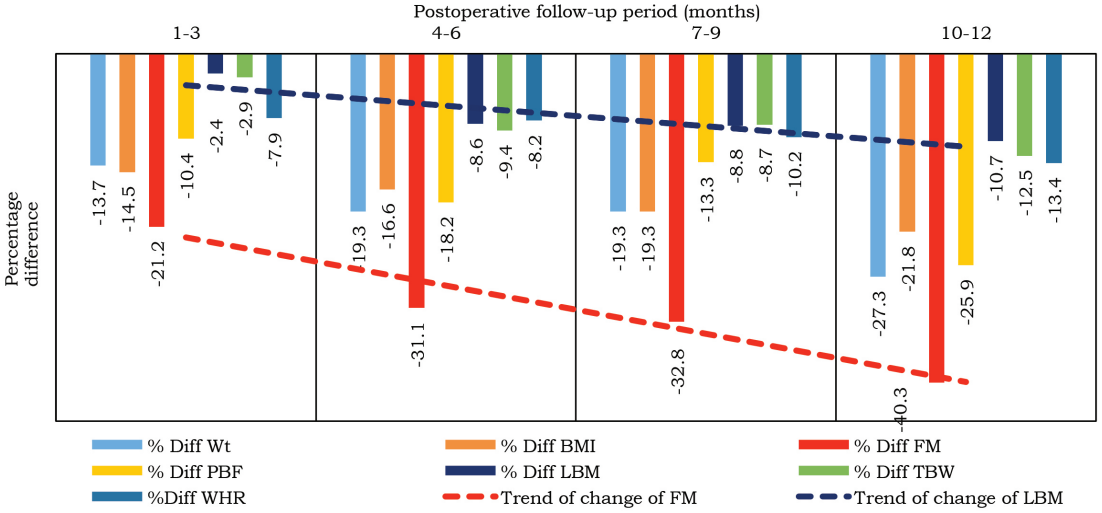
BMI, body mass index; FM, fat mass; %BF, body fat percentage; LBM, lean body mass; TBW, total body water; and WHR, waist-to-hip ratio

0.96 (0.07) at the time of surgery to 0.90 (0.10) during the last visit.

Figure 2 shows the postoperative changes in the body composition measures of patients, which were expressed as percentage, during the follow-up visits. There was a constant decline in all body composition measures from 1–3 to 10–12 months. Moreover, there was a linear reduction in FM by 40.3% in patients who visited the hospital up to one year. Meanwhile, there was only a 21.2% reduction in FM within 1–3 months after BS during the follow-up period. LBM consistently decreased (2.4% at 1–3 months after BS vs. 10.7% at 10–12 months after BS). The FM:LBM loss ratio at 10–12 months was 3.8:1. Similar trends of amplified improvements in other body composition measures were observed in patients who had postoperative follow-up until 10–12 months.

The systolic and diastolic blood pressures of the patients were normal from the time of surgery until the last follow-up visit. The average haemoglobin level significantly improved from 10.4 (2.5) g/dL to 11.8 (1.92) g/dL (p<0.05) one year after BS.

Only biochemical measurements available during the last visit were considered. The averages of these selected biochemical variables showed that the metabolic profiles of patients were within the normal ranges (Table 3). However, LDL cholesterol level was 2.86 (1.0) mmol/L at the end of the follow-up visit, which was still marginally above the normal range (<2.5 mmol/L). Moreover, total cholesterol level was within the normal range [4.4 (1.2) mmol/L; reference value: <5.2 mmol/L]. Triglyceride level was 0.9 (0.4) mmol/L, which was lower than the normal reference value (<1.7 mmol/L),



%Diff Wt, percent difference in weight; %Diff BMI, percent difference in body mass index; %Diff FM, percent difference in fat mass; %Diff PBF, percent difference in percent body fat; %Diff LBM, percent difference in lean body mass; % Diff TBW, percent difference in total body water; %Diff WHR, percent difference in waist-to-hip ratio
Follow-up period after BS: 1–3 months (n = 39); 4–6 months (n = 24); 7–9 months (n = 15); 10–12 months (n = 6)

Figure 2. Body composition of patients at different follow-up periods after bariatric surgery

Table 3. Medians and interquartile ranges (IQRs) of metabolic profiles at the last follow-up visit after bariatric surgery

Variables	*Median (IQR)*	*Reference value*
Total cholesterol level (mmol/L)	4.4 (1.2)	<5.2
Triglyceride level (mmol/L)	0.9 (0.4)	<1.7
LDL level (mmol/L)	2.9 (1.0)	<2.6
HDL level (mmol/L)	1.4 (0.2)	Men: 1.0–1.3 Women: 1.3–1.50
FBG level (mmol/L)	5.4 (0.6)	<5.6
HbA1c (%)	5.7 (0.4)	<6.0

LDL, low density lipoprotein; HDL, high density lipoprotein; FBG, fasting blood glucose; HbA1c, glycosylated haemoglobin

while HDL cholesterol level was 1.3 (0.2) mmol/L, which was at a desirable level (normal reference values: 1.0–1.3 mmol/L in men and 1.3–1.5 mmol/L in women). Similarly, the patients' blood glucose level was within normal range after surgery. Fasting blood glucose level and HbA1c were 5.4 (0.6) mmol/L and 5.7 (0.4)%, respectively, thus within the normal values (<5.6 mmol/L and <6.0%, respectively).

DISCUSSION

In the Eastern Mediterranean region, the UAE is one of the countries with the highest proportion of overweight and obese adults (World Health Organization/ Regional Office for the Eastern Mediterranean, 2018). The incidences of obesity, type II diabetes mellitus, and metabolic syndrome among young adults in the UAE have been a cause of concern (Alzaabi *et al.,* 2019). Concurrently, the number of individuals who underwent BS has significantly increased in the country based on global statistics (DHA, 2019; Ramos *et al.,* 2019). According to the demographic characteristics of our population, younger individuals (aged 32 years) and women (92.2%) were more likely to undergo BS; this was similar to the trend reported in earlier studies in the UAE (40 years and 65.1%, respectively) (Alia *et al.,* 2019) and other countries worldwide (39.0 years and 72%, respectively) (Luca *et al.,* 2021).

This retrospective study focused on the one-year postoperative changes in body composition and metabolic profiles of BS patients in 1 of the 19 registered clinical sites for BS in the UAE. Previous studies with short-term follow-up until 12 months have shown substantial weight loss and improvements in comorbidities after BS procedures, such as RYGB, SG, and AGB (Andersson *et al.,* 2019; Schwoerer *et al.,* 2017). The current study revealed that about 74.5% and 25.5% of patients underwent SG and MGB. SG is the most commonly performed BS procedure in countries worldwide and in the Middle East region (Nimeri *et al.,* 2017; Ramos *et al.,* 2019).

In the current study, the average post-BS follow-up period was 6.0 months. None of these patients visited the hospital for clinical consultations beyond one year after BS. In fact, consultations with healthcare professionals after BS were insufficient; the average number of physician visits was 4.8, and the average dietitian visits during the follow-up period was only 3.5. Data in literature have shown that higher adherence to physician visits after BS was associated with better weight loss outcomes (Lujan *et al.,* 2020). In one report, although there was

a need for postoperative care, only 34% patients completed their recommended follow-up visits in person, and 66% were lost to follow-up before one year post-BS (Lujan *et al.,* 2020). In another study, only 44.7% committed to follow-ups during the first five years after BS (Luca *et al.,* 2021). The actual reason for such low retention is unknown. Perhaps, the patients who have undergone BS did not feel the need for further intervention after surgery (29.5%) or they believed that behavioural interventions have minimal effects because these might not have resulted in long-term weight loss prior to surgery (Luca *et al.,* 2021).

Patients lost an average of almost one-fifth (19.3%) of their initial body weight and one-third of body FM (30.9%) during the follow-up period. Similar to the findings of a previous study on individuals in the UAE (Abusnana *et al.*, 2015), the reduction in FM was most remarkable after BS. However, the patients in the current study had a lower reduction in body FM than those in the previous study (30.9% vs. 35%). Moreover, compared to an earlier study (Abusnana *et al.*, 2015), the current study had lower reductions in LBM (8.6% vs. 26.8%) and TBW (8.9% vs. 32%). The percentage of muscle mass loss one year after SG was reportedly up to 22% (Palacio *et al.,* 2019). Our results showed that the decline in body composition measures increased with the duration of follow-up period. That is, the lowest decline was observed within 1–3 months and the highest within 10–12 months after BS. Furthermore, FM reduction reached up to 40.3% in patients who attended the follow-up sessions up to 10–12 months, but those who attended the follow-up sessions within 1–3 months after BS only reached a reduction of up to 21.2% in FM.

There is a lack of consensus regarding the loss of fat-free mass (FFM) that is considered excessive in terms of undesirable metabolic outcomes (Nuijten *et al.,* 2020); following which they proposed around 25% of total weight loss as the cut-off point for excessive FFM loss. Overall, FM loss has been reported to exceed lean mass loss by threefold in a cohort of adults (aged 45 ± 12 years) at 12 months of follow-up (FM: –49% ± 12% vs. FFM: –14% ± 6%; $p<0.05$ compared with the baseline values for both) (Alba *et al.,* 2019). In the current study, the ratio of FM:LBM loss was 3.8:1 at 10–12 months after BS. In a previous study, patients who had the highest weight loss had accelerated losses of both LBM and FM with incremental LBM loss, with lean-to-fat loss ratios of 1:4.0, 1:3.6, and 1:3.0 among the respective tertiles based on the reduction in BMI per month (Zalesin *et al.*, 2010). Nonetheless, aggressive nutritional and behavioural interventions are required to preserve lean mass after BS.

There was an improvement in central obesity among patients as reflected by the significant reduction in WHR from 0.96 to 0.90, thereby reaching a 13.4% loss within 10–12 months after BS. In a prospective study on Hispanic adults, the presence of abdominal obesity was highlighted as predictive of mortality risk; therefore, loss of central obesity indicated a reduced risk (Gnatiuc, 2020).

Data from the literature showed that weight loss of about 25%, along with improvements of comorbidities, indicated surgical success (Masnyj, Shea & Khaitan, 2020; Tu *et al.,* 2021). In a recent study, the success criteria called for the consideration of clear goals regarding health improvement, which include the metabolic aspects of the patients. Therefore, moving beyond a weight-centric approach to define the success and the cost–benefit of BS is recommended (Unamuno, Portincasa & Frühbeck, 2019). In a sample of 80 Emirati adults with diabetes, weight loss was within the recommended success

rate postoperatively (32% after two years of follow-up); however, patients also experienced significant drops in HbA1c, systolic and diastolic blood pressures, and LDL cholesterol and total cholesterol ($p<0.001$ for all metabolic markers) (Alnageeb *et al.,* 2018).

The lipid profiles of the patients were within normal ranges, except for LDL, which was still marginally higher [2.86 (0.96) mmol/L] than the normal limit during the last follow-up visit. Our findings on better lipid profiles one year after BS were supported by a previous study conducted in the UAE. Patients in the current study also showed improved glucose control (FBG: 5.40 mmol/L, HbA1c: 5.74%), similar to the patients in another study (FBG level: 5.0 mmol/L and HbA1c: 5.3%) (Andersson *et al.,* 2019). Although the comorbidity data from the medical records of patients were not included in the study, improvements in their lipid profile after surgery can reduce cardiovascular risk. Indeed, such improvements have been found to significantly reduce the 10-year cardiovascular risk, according to the Framingham risk equation, during the 12–24 months follow-up after RYGB surgery (Andersson *et al.,* 2019).

To the best of our knowledge, this was one of few studies in the UAE that showed steady improvements in body composition and metabolic profile one year after BS. However, the current study had certain limitations. That is, the study used a retrospective design, and it was conducted at a single public health facility, thereby leading to restrictions in patient recruitment and inclusion of a small sample size. Moreover, the postoperative follow-up visits were not sufficient. Thus, only patients who had a minimum of one year of follow-up record after BS were included. Missing/incomplete patient data might be attributed to the transition phase of patient records/follow-ups from manual documentation to the use of an electronic system in the hospital during the survey period. The low return rate might have been caused by the fact that patients who had a successful weight loss did not feel the need to visit the hospital or felt the burden of additional cost for follow-up sessions. Furthermore, our study was restricted to one hospital, which was a referral clinical site. Thus, patients could have returned to their respective primary health care facilities for subsequent postoperative follow-ups in the absence of any complications, thereby adding to the missing data in such cases. Lastly, the small sample size limited in-depth data analysis of the follow-up visits, and comparison of outcomes one year after BS according to the types of bariatric procedures (MGB and SG) conducted in the specific hospital. Nevertheless, MGB, which is similar to RYGB, acts via the principle of restriction and malabsorption. However, MGB was reported to be superior to RYGB as it is a simpler technique and it had greater efficacy, reversibility, and revisability (Rutledge *et al.,* 2017). Similarly, SG has emerged as a standalone procedure that can achieve weight reduction and remission of comorbidities (Mittal *et al.,* 2021).

In the UAE, clinics conduct thousands of BS annually. However, the incomplete data in the national registry of BS cases in the country (Ramos *et al.,* 2019) underscored the significant impact of these interventions. Therefore, documentation among health facilities should be completed and updated to reflect the outcomes of bariatric surgeries in the UAE in the context of global scenario.

CONCLUSION

The findings of this study were based on the medical and dietary records of BS patients during their last follow-up visits.

This might have camouflaged the actual effect of BS because not all patients had regular follow-up visits until one year after surgery. Nonetheless, body weight and body composition parameters were significantly reduced after surgery. In addition, almost all biochemical markers depicted improved metabolic profiles as represented by values within the normal ranges. The importance of preoperative education inclusive of strict adherence to postoperative follow-up protocols and complete documentation cannot be overemphasised. Hence, future studies should be conducted to evaluate bariatric procedures that are most effective in improving body composition and metabolic outcomes among patients undergoing BS in hospitals in the UAE according to global statistics.

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Authors' contributions

AA, principal investigator, led the conceptualisation of the study, data collection, investigation, methodology, project administration, resources, supervision, validation, visualisation, writing (original draft, review and editing); HH, led the conceptualisation of the study, data collection, formal analysis, investigation, methodology, project administration, resources, software, supervision, validation, visualisation, writing (original draft, review and editing); LMR, led the data collection, resources, writing-review and editing; MAH, led the data collection, resources, supervision, writing-review and editing; AWAW, led the data collection, resources, supervision, visualisation, writing-review and editing. All authors have critically reviewed and approved the final draft and are responsible for the content and similarity index of the manuscript.

Conflict of interest

Each author declares that he or she has no commercial associations (e.g., consultancies, stock ownership, equity interest, patent/licensing arrangement, etc.) that might pose a conflict of interest in connection with the submitted article.

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The *in vivo* glycaemic response of different rice varieties in Sri Lanka

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ABSTRACT

Introduction: Diabetes poses a heavy economic burden in Sri Lanka. High glycaemic index (GI) diets are known to promote a higher risk of diabetes. This study was aimed to determine the GI values of nine improved and three traditional rice varieties of Sri Lanka including Bg406, H.H.Z.36, Ld368, Bw367, Bg94-1, At405, At362, Bg300, Bg352, Sudu heenati, Madathawalu, and Pachchaperumal. Furthermore, comparisons of GI values between improved and traditional varieties, as well as the effect of subject gender and colour of pericarp on GI were described. **Methods:** Fourteen healthy subjects consisting of seven males and seven females were fed with a reference food and cooked rice varieties containing 50 g available carbohydrate; GI were calculated. **Results:** The GI of 12 rice varieties varied from 40-69. All traditional varieties including Sudu heenati, Madathawalu and Pachchaperumal were in the low GI category presenting GI values of 51, 54, and 41, respectively. Rice with red pericarp obtained significantly lower GI compared to those with white pericarp. Yet, GI values obtained in males were significantly higher than females. **Conclusion:** The result of this study suggested that all traditional varieties and improved rice H.H.Z 36, Ld368, and Bg406 could have beneficial effects on lowering the glycaemic response in healthy subjects. Glycaemic index can be predicted from the colour of the rice grain. Gender should be considered in the determination of GI.

Keywords: glycaemic index, glycaemic response, rice, Sri Lanka

INTRODUCTION

All over the world including Asia, Africa, America and the Pacific, rice is the predominant staple food which provides 20 percent of the global dietary energy supply (Saragih *et al.*, 2019). There are thousands of varieties grown all over the globe, having genetic diversity and available in various colours, including brown, red, purple, black etc., in its natural non-milled state. These varieties of colourful rice are also prized for their health properties and there is a wide variation of preference among consumers based on the colour of pericarp.

Starch is the storage form of carbohydrate in rice grain, and it is a homopolymer of glucose. Since rice is rich in starch as its major nutrient, it contributes to blood glucose level.

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Glycaemic response (GR) means the appearance of glucose in the bloodstream after taking a meal, and it is a normal physiological process that depends on the rate of glucose intake, absorption, and hepatic glucose release. The GR of a food is expressed as a percentage of GR of the reference food (usually a glucose solution or white bread). In fact, the glycaemic index (GI) value is expressed as a relative to GR. The concepts of GI, glycaemic load (GL) determination and their relationship with common metabolic diseases, such as diabetes and obesity, have been investigated. Presently, low GI diets have a favourable effect on the prevention and management of diabetes, heart disease, and obesity (Augustin *et al.*, 2015; Suara *et al.*, 2019). Both the amount and types of carbohydrates in the diet should be considered in conjunction with formulating dietary advices for patients with type 2 diabetes (Vlachos *et al.,* 2020).

The GI of the various rice varieties in the world may be different, and it depends on several factors including the degree of processing, amylose content, cooking time, and other botanical structure variations. Several studies have shown inconsistencies in GI of the same variety due to the difference in processing, cooking time, and geographical variation, which may affect the physical and chemical properties of the rice grain (Gunathilaka & Ekanayake, 2015). According to the Food and Agriculture Organization (FAO)'s Food and Nutrition Division (2004), unmilled rice has a higher nutrient content than milled or polished white rice. Rice varieties grown in Sri Lanka are usually categorised as white and red rice based on pericarp colour.

The knowledge of GI may provide consumers and health professionals with accurate and reliable information about the GI of foods and its application needs to be developed. Owing to the fact that most studies done on Sri Lankan foods have been conducted among non-diabetic healthy volunteers with mixed carbohydrate meals (Hettiaratchi *et al.,* 2012; Nisanka & Ekanayake, 2016; Pirasath *et al.,* 2015), the influence from side dishes to GI calculation have been discounted (Sandrasegarampillai & Arasaratnam, 2010). Only a few studies have been done with single meal among healthy volunteers.

The objective of this study was to determine the GI and GL of 12 selected traditional and improved varieties of rice grown in Sri Lanka, namely Bg94-1, At405, Bw367, H.H.Z.36, Ld368, Bg406, At362, Bg300, Bg352, Madathawalu, Suduheenati, and Pachchaperumal; and to compare the GI in order to determine its association with the colour of the pericarp of rice and effect of gender.

MATERIALS AND METHODS

Study subjects

A group of 14 healthy volunteers of both genders was selected for the study. Blood pressure was measured using a sphygmomanometer. Volunteers with normal body mass index (BMI) (18.5-24.5 kg m^{-2}) and aged between 20-30 years were selected for the study. Those who were diagnosed with diabetes or any other signs and symptoms of medical co-morbidity, dieting or restricting their carbohydrate intake, with fasting blood glucose of more than 120 mg dL^{-1}, and under any medication were excluded from the study. The volunteers were advised to maintain their customary dietary intake for three days prior to the testing date (Bur *et al.*, 2003). They were also requested to refrain from smoking, alcohol, and strenuous exercise during the study period. Before being admitted to the study, a detailed written and oral explanation of the different procedures involved in the study was provided and written informed consent was obtained

from all subjects. The protocol was approved by the Ethics Committee, Postgraduate Institute of Science, University of Peradeniya.

Rice varieties and reference food

Dehulled rice samples of improved (Bg94-1, At405, Bw367, H.H.Z.36, Ld368, At362, Bg300, Bg352, and Bg406) and traditional rice varieties (Madathawalu, Suduheenati and Pachchaperumal) (Table 1) were obtained from the Rice Research and Development Institute, Bathalagoda. The twelve tested rice varieties consisted of 6 red and 6 white. The rice was washed well in water and cooked (1:2; rice:water) for about 20 minutes until palatable (Hettiaratchi *et al.,* 2009).

Glucoline (GSK Glaxco Wellcome Ceylon Ltd., Sri Lanka) dextrose monohydrate, after being dissolved completely in 250ml of water, was used as the reference food (containing 50 g glucose) (Gunathilaka & Ekanayake, 2015).

Experimental design

The subjects were studied on fifteen separate occasions: twelve occasions on which they consumed different test foods and three occasions (first, seventh, and fifteenth sessions) were dedicated to the reference food. According to the randomisation list established prior to the commencement of the study, the twelve varieties of rice were provided to each participant in a randomised order in between the three reference food tests. The tests were carried out one week apart for each participant.

In the morning of each session, the subjects were instructed to report to the laboratory following a period of 10 hours fasting. Capillary blood glucose levels were measured two times using a glucometer (Prodigy pocket blood glucose meter, Prodigy Diabetes Care, NC USA). The average blood glucose level was considered to be the baseline concentration (fasting). The cooked rice portion containing 50 g of available carbohydrates (Table 2) together with

Table 1. Total carbohydrate content and weight of raw and cooked rice containing 50g carbohydrate

Rice variety	*Colour of pericarp*	*Available starch content (g) in 100g*	*Weight of consumed raw rice containing 50g of carbohydrate (g)*	*Weight of cooked portion containing 50g of carbohydrate (g)*
At405	White	77.54	64	158.7
Bg94-1	White	74.34	67	214.5
Bg300	White	70.21	71	153.3
Bg352	White	74.74	67	151.6
Bw367	White	73.99	68	211.0
H.H.Z.36	White	73.11	69	181.8
At362	Red	68.71	73	173.0
Bg406	Red	69.63	71	172.6
Ld368	Red	69.28	72	132.0
Madathawalu	Red	72.30	69	192.1
Pachchaperumal	Red	71.36	70	124.3
Sudu heenati	Red	77.70	64	189.7

250 ml of water were served for each subject and these were consumed within 10 to 15 minutes duration. After that, capillary blood glucose levels were measured at 30, 60, 90, 120 minutes following ingestion of the test food.

Table 2. Baseline measurements of participants (Mean±*SE*)

	Male	*Female*
Number (*n*)	7	7
Age (year)	25.7±2.4	27.0±3.0
Height (m)	1.7±0.1	1.6±0.1
Weight (kg)	63.0±4.8	53.7±7.5
BMI (kg m^{-2})	21.5±2.4	21.0±2.2
Fasting blood glucose (mg dL^{-1})	93.6±2.3	88.7±3.0
Blood pressure		
Systolic (mm Hg)	115±8	110±6
Diastolic (mm Hg)	80±0	75±5

For each variety of rice and reference food, GI was calculated using the incremental area under the curve (IAUC), following the equation below and presented by taking the average of the ratios (Wolever *et al.*, 1991).

$$GI = \frac{IAUC\ of\ rice}{IAUC\ of\ glucose}\ X100$$

The GL corresponds mathematically to GL = GI × available carbohydrate (g) /100 (Brand-Miller *et al.*, 2003). The maximum increase in blood glucose (MIBG) was an increase in the postprandial blood glucose subtracted by fasting blood glucose (FBS) (Olausson *et al.*, 2014).

Statistical analysis

The Graph Pad Prism 5.0 (Graph Pad Software Inc., San Diego, CA, USA) statistical software was used for calculating the IAUC. Data obtained from each subject were fitted into a completely randomised design (CRD). The results were considered significant at $p<0.05$. To determine the significance of the rice pericarp colour, gender, traditional/ improved breeding on GI, the Student's *t*-test was performed, considering an α error of 0.05 to be statistically significant at 95% confidence interval. Unpaired *t*-test was applied to test the group differences between males and females.

RESULTS

Baseline measurements of subjects

The anthropometric measurements of the subject group (n=14) indicated that they were within the acceptable normal limits. There were no significant gender differences in BMI, anthropometric measurements, fasting blood glucose level, and blood pressure (Table 2). All participants were between 20-30 years old, with the average age of males (n=7) and females (n=7) being 25.7±2.4 years and 27.0±3.0 years, respectively.

Glycaemic index (GI), glycaemic load (GL) and maximum increase in blood glucose (MIBG) of tested rice

The GI of the 12 tested rice varieties varied from 40-69, with a mean value of 53.5±8.5. The highest GI was reported in At405 (GI= 69) and the lowest was in Ld368 (GI=40). The variations in the mean GI among the 12 varieties were statistically different (p=0.003) (Table 3). Sudu heenati, Bg406, H.H.Z.36, Ld368, Madathawalu, and Pachchaperumal were at the low GI category, while the other six varieties, namely BW367, Bg94-1, At405, At362, Bg300, and Bg352, had medium GI. Interestingly, among the tested varieties, all the three traditional varieties were referred as low GI. Average GI values of traditional varieties and new varieties were 49±6.8 and 55±8.6, respectively. Yet, there was no significant difference in the GI of both traditional and new rice varieties (p=0.196). The GL of the selected rice varieties varied from 20-34. Similar to GI, the highest and lowest GL could be identified in At405 and Ld368, respectively. All rice

Table 3. Maximum increase in blood glucose (MIBG), glycaemic load (GL) and glycaemic index (GI) with their category for each test rice

Rice variety	*GI*	*Glycaemic category*	*GL*	*GL category*	*MIBG (mg dL^{-1})*
At405	69±10.2^{b}	Medium	34	High	45±9.1
Bg94-1	56±9.1^{ab}	Medium	28	High	36±15.3
Bg300	64±1.6^{ab}	Medium	32	High	47±11.3
Bg352	56±8.3^{ab}	Medium	28	High	62±15.6
Bw367	58±13.2^{ab}	Medium	29	High	30±17.4
H.H.Z.36	50±11.3^{ab}	Low	25	High	36±13.9
At362†	56±7.6^{ab}	Medium	28	High	47±33.9
Bg406†	47±11.4^{ab}	Low	24	High	38±13.8
Ld368†	40±11.6^{a}	Low	20	High	30±10.7
Madathawalu†	54±6.7^{ab}	Low	27	High	38±15.6
Pachchaperumal†	41±11.0^{a}	Low	20	High	28±13.3
Sudu heenati†	51±9.2^{ab}	Low	26	High	31±10.2
Mean±*SE*	53.5±8.5				39±9.8
Probability	0.003				0.006

Data are mean±*SD*, unless otherwise indicated
†rice varieties with red pericarp, while others are white
GI value is referred as low (≤ 55), medium (≥ 56 - ≤ 69) and high (≥ 70)
GL is categorised as low (≤ 10), medium (≥ 10 - ≤ 20) and high (≥ 20)
Means in each group, followed with a different superscript letter in each column were significantly different (p<0.05), as analysed by one-way ANOVA

varieties were categorised as high in GL. The MIBG in 12 rice varieties varied from 28-62 mg dL^{-1}, with a mean value of 39±9.8 mg dL^{-1} (Table 3). Further, the MIBG was observed within 30 minutes after the ingestion of all rice varieties and a significant variation was observed among the rice varieties (p=0.006).

Effect of pericarp colour on GI and GL

Among the six tested white and red varieties, the GI of white rice ranged from 50-69, while the GI of red varieties ranged from 40–56. The mean GI of white rice varieties showed a significantly higher value (p=0.001) compared to red rice, with mean GIs of 59.3±10.2 and 49.02±10.1, respectively (Figure 1). GL of white and red rice varieties varied from 25-34 and 20-28, respectively. Similar to GI, a significantly higher GL (p=0.023) was seen in white rice varieties (29.3±1.3; n=6) in comparison to red rice varieties (24.2±1.4; n=6).

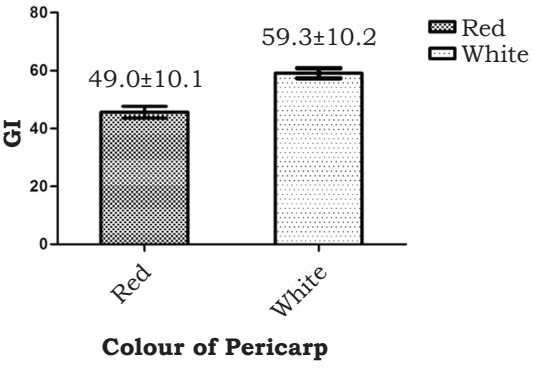

Figure 1: Comparison of GI among red and white rice varieties

Effect of subject gender on GI and MIBG

The GI obtained from all the rice varieties on males ranged between 32-87, with a mean value of 57.6 ±17.0; the GI obtained for 12 rice varieties on females ranged between 20-58, with a mean value of 38.9±12.3. The GI values obtained on males were significantly higher than those of females (p=0.006). The MIBG level between males and females varied between 31-73 mg dL^{-1} and 22-51 mg dL^{-1}, respectively; the MIBG values of males were significantly higher than females (p=0.016), with mean values of 45.3±14.5 mg dL^{-1} and 32.7±8.3 mg dL^{-1}, respectively (Figure 2).

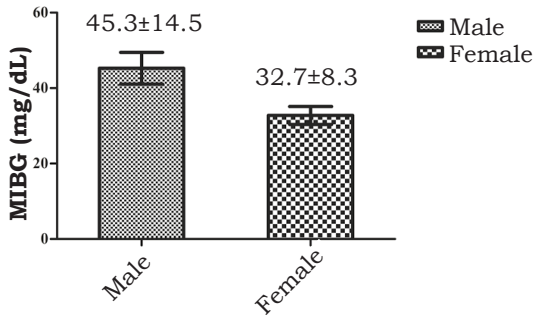

Figure 2: Comparison of MIBG level among male and female subjects

DISCUSSION

A group of 14 healthy volunteers of both sexes (female=7, male=7), aged 20-30 years, with normal BMI (BMI=21.5±3 kg/m^2) were recruited for the study, as it has been reported that high BMI or obesity are directly affected with hormonal regulation of blood glucose, especially with increased insulin secretion rate and decreased insulin clearance rate (Jung *et al.,* 2018).

The results of this study showed that different Sri Lankan rice varieties has a wide range of GI. Some of the commercial rice cultivars of Sri Lanka have shown GI values ranging from 67% to 72%, with the majority of them classified as medium GI rice (Darandakumbura *et al.*, 2013). Studies in other countries have also shown that there is a wide variation in the GI of different varieties of rice (Kaur *et al.,* 2016; Prasad *et al.,* 2018). In this study, six out of 12 varieties were categorised as "low GI" and six were categorised as "medium GI". The variation in the mean GI among the 12 varieties was statistically different (p=0.003), and the variation could be due to the resistant starch content of each variety. Darandakumbura *et al.* (2013) showed that resistant starch content of variety At405 was significantly higher than Bg300 and Bg358. Thus, in the mentioned research, At405 was categorised as a medium GI rice, while Bg300 and Bg358 were categorised as high GI rice. Further, the result of this study has also proven that the colour of pericarp has a significant effect on the variation of GI.

All the 12 rice varieties were categorised as "high" in GL in this study. GL can be influenced either by changing GI or by changing the amount of carbohydrates consumed, or both. In this study, the amount of carbohydrates consumed was equal in all rice varieties, which was 50g. As GI of all rice varieties were more than 40, and their GLs were also more than 20, which is the cut-off value, they were categorised as "high". A previous study indicated the GI for Bg352 (parboiled) as 40±13 (Nisanka and Ekanayake, 2016), while GI for the same variety was indicated as 60±2 for parboiled rice and 67±3 for raw rice (Pathiraje *et al.*, 2010); in this study, it was 56.0±8.3 for Bg352 (raw). Furthermore, the GI for Bg300 was reported as 61±3 and 73±2 for Bg406 in a previous study (Pathiraje *et al.*, 2010), whilst this study indicated a GI of 64.0±1.6 for Bg300 and 47.0±11.4 for Bg406. Therefore, this indicated that the GI obtained for similar rice varieties

were slightly varied in different studies. The differences between the GI values obtained for rice in published research could be mainly due to differences in the food item itself, processing method, the methodologies employed in calculating the carbohydrate content, as well as the variations in subject characteristics, such as gender, age, metabolic state etc.

Pathiraje *et al.* (2010) used different methods to calculate the carbohydrate content in rice, while Nisanka & Ekanayake (2016) adapted the Holm's method to calculate digestible carbohydrate. In this study, available carbohydrate was calculated by polarimetry method (US ISO 6493: 2000). Meanwhile, the accompaniment of test food with different side dishes and water, such as 5 g of chilli paste and 250 mL of water (Pathiraje *et al.,* 2010) or 25 g of coconut sambol (scraped fresh coconut kernel mixed with chilly, onion, salt and lime) and 250 ml of water (Nisanka & Ekanayake, 2016) may contribute to a difference. It is well informed that the co-ingestion of rice with fat and protein in mixed meals can reduce the glycaemic response compared to rice alone, thus the estimation of GI in mixed meal using predicted or adjusted formula has provided contradictory findings (Osman *et al.,* 2017). In the current study, the test food was accompanied with only 250 ml of water, which minimised the interference from side dishes when calculating GI (Sandrasegarampillai & Arasaratnam, 2010). Further, it has been shown that the GI for the same rice variety can vary based on the variation of subject's metabolic state (Vrolix & Mensink, 2010).

In addition to the new rice varieties grown in Sri Lanka, there are traditional rice varieties which fuel the diet of the Sri Lankan people in the past. However, consumers still believe that traditional rice varieties have better nutritional properties, and they tend to keep them under satiety condition for a longer time. All three traditional varieties tested were referred as low GI compared to the new varieties. As such, this result revealed that traditional rice produced a non-significant (p=0.196), lower postprandial glycaemic effect than did the new varieties. Further, Pathiraje *et al.* (2010) confirmed this fact as they reported that the traditional varieties of Rathkaral, Wedaheenaty, and Heendikwel produced lower postprandial glycaemic effect over the new varieties. However, according to his finding, GI of fully polished traditional rice varieties belonged to medium GI category. This difference is due to the high fibre content of unpolished rice, which has been confirmed to negatively affect the GI value of rice (Somaratne *et al.*, 2017).

This study implied that GI can be predicted from the colour of pericarp as there were significant differences between the mean GI of white and red rice varieties. In general, nutritionists and medical professionals believe that for patients with diabetes, the consumption of red raw rice varieties is better than white rice. The results of the present study further confirmed that most of the red rice varieties had a low GI compared to white rice (p=0.001). A similar conclusion has been made by earlier studies of Somaratne *et al.* (2017) and *Saleh et al.* (2019), indicating the higher levels of total phenolic content and total anthocyanin content in red rice than white rice, which are also negatively correlated with GI. As reported in several studies, higher levels of total phenol and anthocyanin in the red rice bran layer could affect the digestion of starch in rice by inhibiting the activity of enzymes such as α-glucosidase, β-glucosidase, and α-amylase (Boue *et al.,* 2016; Somaratne *et al.,* 2017).

Moreover, the current study disclosed the significantly higher GI obtained by the male subjects than the females

(p=0.001). Simultaneously, the MIBG glucose in males was higher compared to females (p=0.006). However, there were no significant differences in the BMI and age between males and females. In 2015, the National Survey of Health and Nutrition in Japan indicated that 15.5% of Type 2 diabetes mellitus patients were men and that 9.8% were women (Ishii *et al.,* 2016). Probably, a higher sensitivity to insulin upon glucose and dietary starch in females, as shown in the present research, may be one of the reasons for the above findings. In addition to that, it was reported that men had significantly higher fasting plasma glucagon concentrations and glucagon-like peptide (GLP)-1 (Carroll *et al.*, 2007), which further justify the results. In males, as glucagon and GLP-1 levels were higher throughout the 2-hour study period, MIBG could be higher in this study. Thus, it would directly affect the high GI obtained in male subjects. Therefore, the results of this study suggested that it is necessary to consider gender when measuring the GI of foods.

CONCLUSION

Based on the results of the present study, it can be concluded that GI values varied according to rice variety. Therefore, there is a necessity for formulating and implementing a policy on food labelling in Sri Lanka, so that consumers can easily obtain information about the glycaemic indices of different varieties of rice. Traditional rice varieties raised blood glucose levels slower than new varieties. The results of this study also suggested that gender should be considered in the determination of GI.

Only certain varieties of red raw rice, such as Pachchaperumal and Ld368, can be specially recommended for patients with obesity, diabetes, and coronary heart disease compared to the white varieties. The results of this study are applicable to normal weight young adults that are not hyperglycaemic or hypertensive. Future studies are needed to observe the relationship between amylose:amylopectin ratio, resistant starch, and GI of rice varieties. Furthermore, a large sample size including both males and females is needed to validate and generalise the results of gender variation.

Acknowledgement

We thank the Rice Research Development Institute Bathalagoda for providing the required quantities of rice and the Department of Medical Laboratory Science, Faculty of Allied Health Sciences, University of Peradeniya for allowing us to carry out this research.

Author's contribution

RMHWR, carried out the experiments and wrote the manuscript with input from all authors; JGSR, conceived the study and was in charge of overall direction, planning and supervised the project; SSPS, performed the analysis and helped supervise the project. All authors provided critical feedback and helped shape the research, analysis and contributed to the final manuscript.

Conflict of interest

The authors of the current study certify that they have no affiliations with or involvement with any organisation or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript.

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BOOK REVIEW

Krause and Mahan's Food and the Nutrition Care Process – 1st Southeast Asia Edition

Janice L. Raymond & Kelly Morrow
Elsevier Inc., Singapore, 2022. ISBN: Softcover 978-981-4920-46-9

Globally, the interest on knowledge related to food, nutrition and dietetics has increased significantly, particularly in Southeast Asia. The increasing interest in this area could be driven by the surging incidence and prevalence of diseases related to poor nutrition throughout the life-course. Nutrition and dietetics is a dynamic area and its application differs between each population and region due to biological and cultural reasons. Hence, the publication of this book is timely, with its updated content according to the latest evidence-based science, latest nutrition guidelines, and current nutrition trends. There is a lack of books that are updated and tailored according to the practical needs of nutritionists and dietitians in this region. Fortunately, this issue is resolved with the introduction of the 1st Southeast Asia edition, which is edited according to the Asian Body Mass Index (BMI) cut-offs, nutrition guidelines of Southeast Asia, and nutrition information according to the Southeast Asian context.

The 15th edition editors are Janice Raymond and Kelly Morrow, both highly experienced dietitians and academicians. There are a total of 69 contributors, comprising experts based in the United States of America from various institutions. The Southeast Asia edition has three Southeast Asia content contributors, namely Professor Dr. Bee Koon Poh, Associate Professor Dr. Nik Shanita Safii, and Dr Mohd Redzwan Sabran. All of them are academicians from Malaysia, who are local and regional experts in the area of nutrition and dietetics. This new edition has also been reviewed by Dr. Dian Novita Chandra (Indonesia), Assistant Professor Diane Salazar Mendoza (The Philippines), Assistant Professor Dimitrios Spanos (Singapore), Associate Professor Wantanee Kriengsinyos (Thailand) to ensure that the new content has comprehensive Southeast Asia representation.

With a total page number of 1172, this book can be considered as the most comprehensive textbook covering all areas related to nutrition and dietetics with great depth of information that is applicable for students and professionals related to dietetics, nutrition, nursing, medicine, dentistry and other health sciences. This book covers important areas such as nutrition assessment, nutrition diagnosis and intervention, nutrition in the life cycle, nutrition for weight management, sports nutrition, and also medical nutrition therapy with an additional section on paediatric specialties. Some updates were introduced in this chapter, notably in areas that

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are rapidly changing, such as nutritional genomics and the latest dieting trends, including intermittent fasting. Each chapter begins with the list of key terms to indicate the importance of words within the chapter. It is then followed by general information presented in simple English sentences, colourful tables and graphics, as well as a useful website section. The useful website section is very important to help readers browse through the right websites as some internet websites may contain misleading information. The clinical insight and clinical case study section, which is edited according to Southeast Asia scenarios, may help readers relate and apply their clinical skills according to local settings.

I would strongly recommend this book for anyone who is interested to learn about topics related to nutrition and dietetics. It is not only a good text book for students, but also a comprehensive resource for medical and health care professionals who deal with these issues related to nutrition and dietetics.

Review by: Prof. Dr. Hamid Jan B. Jan Mohamed
Dated: 1 November 2021

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REVIEW

Status of probiotic regulations in Southeast Asia countries

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ABSTRACT

This review summarises the key components of the available probiotic regulations in six Southeast Asia countries (Indonesia, Malaysia, Philippines, Singapore, Thailand and Vietnam). Diverse approaches have been undertaken by the countries in regulating the marketing and sale of probiotics in foods and health supplements. Only Indonesia, Malaysia, Philippines and Thailand have enacted specific regulations which include their respective legal definition of probiotics. Only Malaysia, Philippines and Thailand publish a list of microorganisms permitted to be used as probiotics in foods or health supplements; the approved microorganisms are not harmonised among these countries. All six countries allow the application for new microorganisms to be used, but have adopted differing requirements and approaches. A common requirement is that all applications must be accompanied by scientific data to demonstrate clinically that the microorganisms are safe and provide health benefits. All the countries, except Indonesia and Vietnam permit the use of a small number of pre-approved generic function claims. It is noted that the countries have different specific labelling requirement for products containing probiotics. The divergent probiotic regulations in the region, either for foods or health supplements, creates inconsistencies and difficulties for all stakeholders including regulators, academia, industries and consumers, as well as impacting trade among countries. This review highlights the importance of having regulatory control to ensure consumers have access to safe, genuine and efficacious probiotic products. We propose working towards a harmonised probiotics regulation in the region to enable further development and progress of probiotics in the region.

Keywords: probiotics, regulations, harmonisation, health supplements, functional foods

INTRODUCTION

The Food and Agriculture Organization/ World Health Organization (FAO/WHO) Joint Expert Consultation report has defined probiotics as live microorganisms which when administered in adequate amounts confer a health benefit on the host (FAO/WHO, 2001). This definition was "reinforced as relevant and sufficiently accommodating for current and anticipated applications" by a consensus statement of the

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International Scientific Association for Probiotics and Prebiotics (ISAPP) (Hill *et al.,* 2014). Probiotics have become an increasingly popular functional foods, with growing clinical evidence supporting the effectiveness of probiotics in general health maintenance and disease treatment, especially conditions related to digestive tract, the immune system and respiratory functions (Nomoto, 2021; Hill *et al.,* 2014).

According to the Mordor Intelligence (2021) report, during the forecast period 2020-2025, Asia Pacific is the largest as well as the fastest growing probiotics market. Probiotics have become a part of functional foods and beverages, consumed by people of all ages. The exogenous shock presented by the COVID-19 pandemic in early 2020 has contributed to a surge in demand for products that provide immune health, including probiotics. According to the report, the complexity of regulatory, legislative, and technological aspects may be major hurdles impeding market growth. Hill *et al.* (2014) noted that amidst the rapid progress in clinical evidence and growth in probiotic products, misuse of the term probiotic has become a major issue, with many products exploiting the term without meeting the required criteria.

There is clearly a need for regulatory control of probiotics to facilitate research and development in probiotics and to make sure effective and safe products reach the consumers. Regulations should clearly spell out the definition of probiotics, their characteristics, safety requirements and specific labelling requirements of foods and dietary supplements containing these live microbes.

In view of these developments, the Southeast Asia Probiotics Scientific and Regulatory Experts Network (SEA PROBIOTICS SREN) carried out a review of the available probiotic regulations in countries in the region, covering the use of probiotics in foods and beverages as well as in dietary or health supplements.

METHODOLOGY

A template was prepared by the authors, with the following key aspects of the probiotic regulations or documents:

- regulatory framework including legal definition of probiotics
- requirement for minimum number of probiotic microorganisms
- positive list for approved probiotic microorganisms
- requirements and procedure for applications for use of new probiotics
- specific labelling requirements for probiotic products
- probiotic health claims and procedure for application

Regulatory officials and relevant regulatory experts from Indonesia, Malaysia, Philippines, Thailand and Vietnam who have been participating in periodic meetings of the SEA PROBIOTICS SREN were requested to assist in providing the information required in the template based on the available official documents in their respective country. These officials and experts were also requested to provide the official regulations or documents related to the use of probiotics as an ingredient in foods and beverages, as well as for use as dietary or health supplements. For the other countries in Southeast Asia (SEA), a search for any relevant documents were made on the official regulatory websites.

The authors scrutinised the entries for the template and compared these with the information in the official documents from the regulatory authorities. After compilation and editing by the authors, they were returned to the officials for verification.

RESULTS

Regulations or related documentations (for example guideline, decree or circular) for the control of the sale and marketing of probiotics in foods and dietary or health supplements were obtained from six countries in SEA, namely Indonesia, Malaysia, Philippines, Singapore, Thailand and Vietnam. For convenience of presenting the regulatory status of the use of probiotics in foods and beverages (hereinafter referred to as foods) as well as in dietary/health supplements (hereinafter referred to as dietary supplements) in the six countries, this review is presented based on the key aspects as listed in the methodology section above.

Regulatory framework including legal definition of probiotics

Probiotic-containing foods and health supplements in **Indonesia** are regulated by two different divisions of the National Agency for Drug and Food Control (NADFC).

The sale of probiotics as food is being regulated under the Directorate for food standardization. A specific regulation on probiotic-containing foods was enacted in early 2016 concerning Controlling of Claims on Processed Food Label and Advertising, specifically Annex XI on Guidelines for the Assessment of the Use of Probiotics in Processed Food (NADFC, 2016). In this regulation, probiotics are defined as "Live microorganisms which when administered in adequate amounts confer a health benefit on the host". Probiotic-containing foods under this regulation include fermentation products containing one or more probiotic bacteria; or dried food products containing one or more dried bacteria in the form of granules or powder which can be consumed as a food or beverage; or non-fermented liquid food product containing one or more probiotic bacteria.

On the other hand, probiotics as supplements are regulated under Directorate for Traditional Medicine, Health Supplement and Cosmetics Standardization. A recently enacted Regulation 17 of 2021 serves as a Guideline on Evaluation of Health Supplement Products Containing Probiotics for NADFC in registering new products and the business community (NADFC, 2021). The legal definition for probiotics in health supplements is the same as for probiotics in foods.

In **Malaysia,** probiotics can be used in food, beverages, and health supplements, and regulated by two different divisions of the Ministry of Health Malaysia.

The Food Safety and Quality Division (FSQD), Ministry of Health Malaysia is the regulatory authority responsible for sale of probiotics in foods and beverages. A specific regulation (Regulation 26A – Probiotic culture) to permit probiotic cultures to be added to foods and regulate their use was gazette in April 2017, under Malaysia Food Regulation 1985 (MOH Malaysia, 2017). Through this regulation, the legal definition given to probiotic culture is: live microorganisms which when administrated in adequate numbers confer health benefits on the host'.

The control of probiotic health supplements is under the National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health Malaysia. A specific regulation on probiotic supplements has not been developed. Probiotics in health supplements fall under the definition of "product" in Control of Drugs and Cosmetics Regulations (CDCR) (MOH Malaysia, 1984). The term 'product' as used in this law refers to 'a drug to be used as an

ingredient of a preparation for a medicinal purpose'. In this regard, probiotics fall under the medicinal purpose for 'general maintenance or promotion of health or wellbeing'. Probiotics are listed as health supplements in the Drug Registration Guidance Document (MOH Malaysia, 2021). The definition for probiotic in health supplements follows the generally recognised definition by WHO: "live microorganisms which when administered in adequate amounts confer a health benefit on the host".

The sale and use of probiotics in foods and dietary supplements in the **Philippines** are regulated by the Food and Drug Administration (FDA) Philippines through regulation Bureau of Food and Drug (BFAD) Circular No. 16s 2004 (BFAD, 2004). Through this regulation, Philippines has provided the following definition for probiotics, which followed the definition by Guarner & Schaafsma (1998): "a dietary supplement based on living organisms which when administered in sufficient quantity, has a beneficial effect on the host organism, improving the equilibrium of the intestinal microflora". There is no requirement for minimum number of microorganisms that must be present.

The use of probiotics in **Singapore** can be regulated either under the food regulations or as health supplements, by two separate authorities.

The sale of probiotic-containing foods is regulated by the Singapore Food Agency (SFA). However there is no specific regulation on probiotics and current food regulations do not use or define the term 'probiotics'. Nevertheless, strains of *bifidobacteria* and *lactobacillus* that have a proven long history of safe use may be used as probiotics in suitable categories of food products. These include cultured milk drink and yoghurt (SFA, 2021).

Complementary health products containing probiotics (classified as health supplements) are under the purview of the Health Sciences Authority (HSA) which has not provided a specific regulation or definition of probiotics (HSA, 2021). Health supplements are not subject to product approvals, registration nor dealer licensing. Dealers of health supplements are responsible for the safety and quality of their products and compliance with the guidelines prescribed by the HSA.

The FDA, Ministry of Public Health, **Thailand** is the regulatory authority responsible for probiotics classified as food or dietary supplement. Two Notifications of the Ministry of Public Health, no. 339 (2011) and no. 346 (2012) regulate the use of probiotic microorganisms in both food and supplements (MoPH, 2011; MoPH, 2012). Through Notification no. 339, Thailand has provided the following legal definition for probiotics: "Probiotic Microorganisms means viable microorganisms that are beneficial to body if intake in sufficient amount" (MoPH, 2011).

In **Vietnam**, there is no specific regulation or legal definition of probiotics. The sale of probiotics in foods and supplements is regulated through several government agencies, including the Vietnam Food Administration (VFA) and inspectors of the Ministry of Health, Department of Health and Food Safety Management Agencies, Vietnam Directorate of Market Surveillance (Ministry of Industry and Trade) and its agencies at the provincial levels. The Food Safety Law of Vietnam has listed probiotics as a dietary supplement (Decree 15/2018/ND-CP) (Government of Vietnam, 2018). More details on the management of probiotics under functional foods, which includes supplemented foods and dietary supplements is provided in Circular No. 43/2014/TT-BYT (MOH Vietnam, 2014).

Supplemented food has been defined as conventional food supplemented with micronutrients and other healthful

components for the body such as vitamins, minerals, amino acids, fatty acids, enzymes, probiotics, prebiotics and other biologically active substances. Dietary supplement refers to a product used as a supplement to the daily diet to maintain, enhance and improve health functions and disease risk reduction, and can be in the form of soft gels, pellets, tablets, granules, powder, liquid and other dosage form divided into smaller doses (MOH Vietnam, 2014).

Requirement for minimum number of probiotic microorganisms

NADFC **Indonesia** has indicated that if there is no claim for a probiotic-containing food product, it is not required to declare the number of organisms on the label (NADFC, 2016). On the other hand, if there is a claim on the label, it is required to declare the number of organisms in terms of colony forming unit, cfu/g or ml, based on the clinical study for that claim.

The NADFC guideline for health supplements has indicated that the probiotics must be live cultures, but has not specified the minimum number of microorganisms that must be present in the product.

For **Malaysia**, one of the conditions in the FSQD regulation is that the probiotic cultures added shall remain viable and the viable probiotic count shall not be less than 10^6cfu/ml or cfu/g during the shelf life of such food. For probiotic health supplements, NPRA has not indicated that there must be a minimum number of microorganisms in the products.

The BFAD circular of the **Philippines** does not specify the minimum number of probiotics that must be present in a food or dietary supplement product (BFAD, 2004).

The minimum number of viable probiotic microorganisms is not specified in the **Singapore** food regulations. The onus is on companies to ensure that the viable count of the probiotic microorganisms present in the product throughout its shelf life is able to bring about the claimed effect. The HSA too does not specify the minimum number of organisms that must be in a health supplement that contains probiotics. Dealers are required to ensure that the probiotic strains used and the recommended doses are safe and meet the dosing recommendations stated in the evidence or references for the claimed intended effects for the target consumers.

In Notification no. 339 of 2011 of **Thailand**, the number of viable probiotic microorganisms in the product shall be not less than 10^6cfu/g food at the end of its shelf life. In products in which there are more than one kind of probiotics used, each kind of microorganisms shall be viable and not less than 10^6cfu/g food at the end of its shelf life.

In **Vietnam**, there is no specific requirement to declare the minimum number on the label. But the minimum number must be declared if required by Codex or other international organisations or if there is a dosage recommendation.

Availability of positive list of approved probiotic microorganisms

Indonesia has not issued a positive list of approved probiotic species/ strains for use in foods (NADFC, 2016). The recent regulation for health supplements containing probiotics has also not provided a list of approved microorganisms (NADFC, 2021. Manufacturers or importers may apply to the NADFC for use of probiotic microorganisms (see next section).

The FSQD **Malaysia** currently lists 13 *Bifidobacterium* strains and 19 *Lactobacillus* strains in regulation 26A that may be recognised as probiotic cultures and permitted to be added to

foods (Table 1) (MOH Malaysia, 2017). Manufacturers or importers may apply for additional probiotics to be added to the list (see next section).

In terms of probiotic use in health supplements in **Malaysia**, NPRA has not provided a list of probiotic microorganisms approved to be used (MOH Malaysia, 1984). However, probiotics allowed in the registered health supplements that are currently on the market can be checked in NPRA website under product search. Prior approval from NPRA is required before the use of probiotics strain in health supplements that are not currently registered (see next section).

An approved list of five genera/ species of microorganisms to be used as probiotics in the **Philippines** is provided in the Bureau Circular (BFAD, 2004). Current list comprises *Lactobacilli, Bifidobacteria*, non-pathogenic strains of *Streptococcus*, *Sacchromamyces boulardi* and *Bacillus causii* (Table 1).

SFA has not published a list of probiotics allowed for use in foods in **Singapore**. However, strains of *bifidobacteria* and *lactobacillus* that have a proven long history of safe use in food (such as *Bifidobacterium bifidum, Lactobacillus acidophilus, Lactobacillus delbrueckii, Lactobacillus casei Shirota strain*) are allowed to be used as probiotics in suitable categories of food products (SFA, 2021).

Similarly, HSA **Singapore** has not published a list of approved probiotic microorganisms in health supplements (HSA, 2021). Health supplements containing probiotics are permitted in Singapore. As previously indicated, they are not subject to approvals and licensing by HSA for their importation, manufacture and sales.

The **Thailand** FDA Notification no. 339 of 2011 has provided a list of 23 species of microorganisms for use on foods and supplements. This comprises 9 *Bifidobacterium,* 2 *Enterococcus*, 9 *Lactobacillus*, 1 P*ropionibacterium*, 1 *Staphylococcus*, and 1 *Saccharomyces* species (Table 1) (MoPH, 2011).

Vietnam Food Authority (VFA) has not established a positive list of approved probiotic microorganisms for use in foods and supplements. Manufacturers may register a bacteria strain for use under supplemented food or as a health supplement (see next section).

Requirements and procedure for applications for use of new probiotics

In **Indonesia**, manufacturers or importers may apply to the NADFC for use of microorganisms as probiotics in foods. Each new probiotic strain must go through a review process, which includes detailed functional characterisation and safety evaluation before it can be used in food (details of requirements given in Table 2) (NADFC, 2016). It is mandatory for companies/manufacturers to conduct phase two clinical trials on Indonesian population in Indonesia. The regulation also stipulates that the trials shall be conducted in each finished product where data obtained from one type of processed food containing specific probiotics cannot be extrapolated to other processed food products containing the same probiotic strains. Details of the assessment process, including clinical trial requirements are given in Annex XII of the regulation (NADFC, 2016). NADFC has in place a process to receive an review all applications. Data in all submissions will first be verified by the Agency and assessed based on the above mentioned Annex.

Similarly, manufacturers may apply for a new probiotic strains to be used in health supplement products. All applicants must be supported by documents that demonstrate safety and beneficial effects and quality of the products. The NADFC (2021) guideline has provided a flow chart for the

Table 1. Positive list of probiotic cultures approved for use in foods and dietary/health supplements in SEA countries

Indonesia		*Malaysia*		*Philippines*	*Singapore*		*Thailand*	*Vietnam*
Foods	*Health supplements*	*Food*	*Health supplements*	*Food & dietary supplements*	*Food*	*Health supplement*	*Food & dietary supplements*	*Food & dietary supplements*
(NADFC, 2016)	(NADFC, 2021)	(MOH Malaysia, 2017)	(MOH Malaysia, 1984)	(BFAD, 2004)	(SFA, 2021)	(HSA, 2021)	(MoPH, 2011)	(MOH Vietnam, 2014)
No positive list published	No positive list published	***Bifidobacterium sp.*** *B. bifidum* Bb-02 *B. breve* strain Yakult *B. breve* M-16V *B. animalis* subsp. *lactis* (BB-12) *B. lactis* HN019 *B. lactis* Bl-04 *B. lactis* Bi-07 *B. lactis* 420 *B. lactis* CNCM I-3446 *B. longum* BB536 *B. longum* BB-46 *B. longum* Rosell-175 *B. longum* ATCC BAA-999 ***Lactobacillus sp.*** *L. acidophilus* LA-5 *L. acidophilus* NCFM *L. acidophilus* La-14 *L. acidophilus* Rosell-52 *L. casei* Shirota *L. johnsonii* La 1/Lj 1 *L. johnsonii* CNCM I-1225 *L. paracasei subsp. paracasei* (L.CASEI 01) *L. paracasei subsp. paracasei* (L.CASEI 431) *L. paracasei* Lpc-37 *L. paracasei* CNCM I-2116 *L. plantarum Lp-115* *L. rhamnosus* (LGG) *L. rhamnosus* Lr-32 *L. rhamnosus* HN001 *L. rhamnosus* Rosell-11 *L. rhamnosus* CGMCC 1.3724 *L. salivarius* Ls-33 *L. reuteri* DSM 17938* *The addition only allowed in infant formula, follow-up formula and formulated milk powder for children. A statement "THIS PRODUCT CONTAINS *L. reuteri* DSM 17938 AND NOT RECOMMENDED FOR INFANTS WITH A HISTORY OF GASTROINTESTINAL SURGERY" shall be written in the principal display panel in the label of a package containing infant formula and follow-up formula, in not less than 4 point lettering and in bold	No positive list published	*Lactobacilli* *Bifidobacteria* Non-pathogenic strains of *Streptococcus* *Sacchromamyces boulardi* *Bacillus causii*	No positive list published	No positive list published	*Bacillus coagulans* ***Bifidobacterium sp.*** *B. dolescentis* *B. animalis* *B. bifidum* *B. breve* *B. infantis* *B. lactis* *B. longum* *B. pseudolongum* ***Enterococcus sp.*** *Enterococcus durans* *Enterococcus faecium* ***Lactobacillus sp.*** *L. acidophilus* *L. crispatus* *L. gasseri* *L. johnsonii* *L. paracasei* *L. reuteri* *L. rhamnosus* *L. salivarius* *L. zeae* ***Propionibacterium sp.*** *Propionibacterium arabinosum* ***Staphylococcus sp.*** *Staphylococcus sciuri* ***Saccharomyces sp.*** *Saccharomyces cerevisiae subsp. Boulardii*	No positive list published

categorisation of a probiotic product to determine if it is to be registered as a drug or a health supplement. A separate flow chart provides the principles of assessment of such products, including probiotic strain identification, functional characterisation and quality evaluation. The requirements for the phases of clinical trials for the evaluation of health effects of probiotics are also provided in the chart (Table 2).

In addition to the 23 probiotic strains in the positive list in the **Malaysia** probiotic regulation, food companies may apply to FSQD for additional strains to be added to the list. Applications can be made using an application form that is available from FSQD website: http://fsq.moh.gov.my/v6/xs/page.php?id=72. FSQD takes into consideration the probiotic characteristics, history of consumption, the safety of the strain to human and beneficial to health as demonstrated in human studies. Several safety requirements and other supporting requirements that should be documented for FSQD review are listed in Table 2. FSQD emphasises that the documents provided must be comprehensive to fulfil all the requirements and must be strain specific.

In the FSQD regulatory review process, scientific data and supporting documents submitted would first be screened by a regulatory officer before being reviewed extensively by an expert working group on microbiology. The expert working group presents all proposals for review by the Advisory Committee on the Food Legislation, and lastly the approved document is handled by the legal department for gazettement.

Probiotic health supplements that are not yet registered by the NPRA **Malaysia** must apply for registration. Applications are required to meet the strain specific safety and health beneficial requirements as demonstrated in human studies, as well as the requirement on probiotic characterisation (Table 2). NPRA has also outlined the documents required to support the safety of probiotics as well as other requirements for the use of probiotics in health supplements (Table 2) (MOH Malaysia 2021). The review process for probiotics in health supplements involves four steps: screening of product registration application, evaluation of product registration application, table application in product evaluation committee meeting and table application in drug control authority meeting in which a decision on approval or rejection of product registration will be taken.

In the **Philippines**, companies may apply for the use of probiotics not in the current list of BFAD (2004) using the electronic registration system under FDA Circular 2016-014 (FDA, 2016). The new bacterial strain must provide evidence of safe use as food supplement, undergo probiotic characterisation, and demonstrate effectiveness as a probiotic (Table 2). The review process undertaken in the evaluation of probiotic food use include strain identification through phenotypic and genotypic methods, deposition of strain in international culture collection, determination of functional characterisation of identified strain through *in vitro* tests and animal studies, and safety assessment of the strain through *in vitro* tests and/or animal studies as well as phase one human study.

For the use of new microorganisms for use as probiotics in foods in **Singapore**, an application may be submitted to SFA. All needed documents must be submitted, including complete identification and characterisation of the microorganism. Manufacturers are required to ensure that the strains used, as well as the quantities of probiotic bacteria present in their food products are safe and suitable for consumption by the target group of consumers and are sufficient throughout its shelf life to

deliver the intended function as claimed. Details of requirements are given in Table 2.

The review process for the assessment of a new microorganism for use in food can be summarised into three steps: (1) the applicant submits an application for the assessment of a new microorganism to SFA for review; (2) SFA reviews the information provided and may request further information from the applicant; and (3) if the outcome of the review is positive, SFA issues an approval letter to the applicant for the use of the new microorganism in food.

The sale of health supplements in **Singapore**, including those containing probiotics, are not subject to pre-market approvals, registration nor dealer licensing by HSA. Nevertheless, the onus of responsibility on the safety and quality of their health supplement products rest on importers. Thus, for probiotic-containing health supplements, dealers are required to ensure that the probiotic strains used, and the recommended doses are safe and meet the dosing recommendations stated in the evidence or references for the claimed intended effects for the target consumers (HSA, 2021).

In **Thailand,** manufacturers or importers may apply for the use of probiotic microorganisms other than those specified in the available list. Applications can be submitted using a form which can be accessed via: http://www.fda.moph.go.th/sites/food/manual/9.3.3-2_Probiotic(Eng).pdf. Information that must be submitted are as indicated in Table 2, including identity report, safety assessment results and characteristics of such probiotic microorganisms. The requirements are similar to those in the FAO/WHO Guidelines for the Evaluation of Probiotics in Food (FAO/WHO, 2002). Thai FDA has also stipulated that at least two well-designed human intervention studies from different institutes should be provided. Publications on clinical trials from outside of Thailand may be submitted for consideration (MoPH, 2011). Thai FDA has in place a process to review all applications. Upon confirmation that the application has provided all the required information as mentioned above, it is submitted to the FDA and subsequently submitted for expert consultation. All views are considered by the sub-committee and a decision made forwarded to the FDA.

Manufacturers may register a bacteria strain for use under supplemented food or as a health supplement in **Vietnam**. The VFA is the highest competent authority to evaluate and approve registration of products. Information required to be submitted are as indicated in Table 2. Permission for the use of the bacteria strain is given based on the strength of scientific evidence of the product or ingredient. Dossiers are to be submitted online. Upon evaluation by the regulatory authority, the applicant will be informed via online (Government of Vietnam, 2018; Au *et al.,* 2019).

Specific labelling requirements for probiotic products

The probiotic regulation for food of **Indonesia** (NADFC, 2016) has listed the information that must be provided on the label of a food containing probiotics: clear description of the genus, species and strain; factual information about the benefits of the strain; the minimum number of live probiotic strains in terms of cfu/g or ml at the end of shelf life; the serving size that should provide an effective minimum amount of probiotics to ensure the claim is in accordance with the result of clinical tests; health claims (if any); proper storage instructions; and address of the company that can be contacted for consumer information.

Table 2. Requirements for application for use of new probiotics in foods and dietary/health supplements

	General requirement/ characteristics	*Safety requirement*	*Requirements for clinical trials*	*Other requirements*
Indonesia				
In foods (NADFC, 2016)	General requirements: a. The term probiotics is solely used for products containing live microorganisms that are beneficial to health; b. It is necessary to determine the right amount for each probiotic bacteria to provide health effects. The minimum amount of probiotics must be defined as probiotics are strain-specific, as well as its relation to dosage and benefits to health. The amount and benefits to health must be proven with conclusive results of clinical trials; c. For use in processed foods, probiotic microorganisms must be able to survive in the digestive tract, and also must be able to proliferate in the gastrointestinal tract (gut); d. The ability of probiotic microorganisms to survive and proliferate in the gastrointestinal tract shall be highly dependent on the strain, gastrointestinal microbiota profile and environmental conditions of the digestive tract which in turn is influenced by the local environment and living habits; e. The use of probiotics as ingredients of food must be based on scientific evidence including identification of the strain, quantity, duration of use recommended by the manufacturer, desired health benefits and possible side effects; f. Living microorganisms that have antibiotic resistant genes should not be used. Assessment guideline: a. Identification of Probiotics strains – The scientific evidence available must demonstrate the effect of specific probiotics produced by each strain (strain-specific). The genus and species of probiotic strains need to be identified, to be linked to the specific effects, for accurate surveillance and epidemiological studies. – Nomenclature of the bacteria must be in accordance with the scientific name. Misleading bacteria names should not be used. b. Methods of identification of strain must be done through a combination of valid phenotypic and genotypic methods; c. All strains derived from outside Indonesia shall be stored in international culture collections in accordance with correct storage procedures; d. *In vitro* tests to determine the characteristics of probiotic strains: (i) Resistant to gastric acidity; (ii) Resistant to bile acids; (iii) Able to stick to mucus and/or epithelial cells and cell line and colonize the human gut; (iv) Antimicrobial activity against potentially pathogenic bacteria; (v) Having the ability to reduce the adherence of pathogens on the surface of the intestinal wall; (vi) Bile salt hydrolase activity and antibiotic resistance.	Clinical tests in humans phase one shall be conducted to determine whether the probiotic products that will be consumed by humans are proven safe and not contaminated during the transportation process. The following safety assessment must be carried out: a. Determination of the pattern of antibiotic resistance; b. Testing of specific metabolic activity (for example, D-lactate production, bile salts deconjugation); c. Evaluation of side effects that arise during clinical tests in humans; d. If the strains evaluated are associated with a species known to produce toxin for mammals, the toxin production must be tested. The schemes that can be used for testing toxin production are, among others, the EU Scientific Committee on Animal Nutrition (SCAN, 2000); and e. If the strains evaluated are associated with a species known to potentially cause haemolysis, it is necessary to conduct haemolysis activity test; f. It is required to prove that a preparation of probiotic strains is safe and free from contamination. Other safety considerations are as follows: a. The strains are proven safe for human consumption, among other fermented foods that are empirically proven safe for consumption; b. Strains that carry antibiotic resistance genes that can be transferred should not be used; c. The origin of isolation of the strain must be identifiable.	Scientific evidence must be the result of experimental tests on Indonesian subjects in Indonesia. No specific number of studies is mentioned. However, it is mentioned that in accordance with the recommendation of the FAO/WHO (2002), the results of clinical test Phase two in humans must be redone by more than one testing institute to confirm the result. In this case, the confirmation clinical test Phase one must be done in Indonesia on Indonesian subjects. Clinical test phase two must be conducted in humans with the following requirements: a. Double-blind, randomised, placebo-controlled test (DBPC), which aims to establish the efficacy of a probiotic product compared with the placebo and to determine the adverse effects that may result; b. Placebos are processed foods that do not contain probiotics; c. The number of samples shall be calculated based on the statistically minimum number of samples; d. Data obtained from one type of processed food containing specific probiotics cannot be extrapolated to other processed food products containing the same probiotic strains; e. The important probiotic efficacy study result shall be proven to be beneficial in human studies in terms of significant improvement in terms of health conditions, symptoms of disease, decreased risk of disease or prolongs relapse or accelerates the healing time both statistically and biologically. Each of these benefits must be shown to be associated with the probiotics tested; f. When the processed food is consumed, there are no adverse effects for the use of the probiotics. The adverse effects should be monitored and any incidents should be reported.	The result of clinical tests shall be published in a peer-reviewed scientific journal, and the result should be confirmed with the result of other independent institutions both in Indonesia and abroad.

Table 2. Requirements for application for use of new probiotics in foods and dietary/health supplements (continued)

	General requirement/characteristics	*Safety requirement*	*Requirements for clinical trials*	*Other requirements*
In health supplements: (NADFC, 2021)	General requirements: Probiotics are live microorganisms which, when consumed in adequate amounts, can confer health benefits for consumers a. Methods of identification of strain must be done through a combination of valid phenotypic and genotypic methods b. Identified strains stored in international culture collections Functional characteristics determined by: a. *In vitro* test b. Tests on animals The quality documents as referred to above include: a. source of the probiotics; b. product specification test; c. microorganism contaminants; d. minimum number of live bacteria at the end of the shelf life; e. appropriate dosage conditions	The supporting documents submitted by applicants must include: a. safety and efficacy; and b. quality. Safety and health benefit documents must be in accordance with the provisions stipulated by the WHO or the FAO. Safety assessment by: a. *In vitro* and animal tests; b. Phase one clinical trial	Appendix II of the Guideline provides a flow chart for the evaluation of probiotic health supplements. Randomized Controlled Trial (RCT) phase two or appropriate design with suitable sample size and primary outcome to determine product efficacy	Other requirements are in accordance with the Health Supplement Quality Requirements and other regulations in the field of health supplements
Malaysia				
In foods (MOH Malaysia, 2017)	a. Evaluated for its safety to human and beneficial to health as demonstrated in human studies; b. Resistant to gastric acidity; c. Resistant to bile acid; d. Adhered to mucus and/or human epithelial cells and cell line; e. Able to hydrolyse bile salt; f. Clear strain identification which conformation of the methodology; g. Has long history of consumption.	Safety evaluation of probiotic strains in food: a. Assessment of metabolic activity; b. Safety evaluation derived from both chronic and acute studies conducted on the probiotic culture; c. Transmissible antibiotic resistance gene; d. Epidemiological surveillance for undesired incidents among consumers; e. Side effects found in clinical studies conducted in human subjects	There is no specific number of clinical studies set by FSQD. However, the supporting documents provided must be comprehensive to fulfil all the requirements and must be strain specific.	a. Name of the media used for the culture and maintenance of the probiotic culture; b. Functional role(s) of the probiotic culture; c. Minimum viable number of the probiotic culture at the end of the shelf life; d. Stability and bioavailability of the probiotic culture in the food(s) in which it is to be added' e. Analytical method (validated method) to identify the purity of the probiotic culture; f. Information on regulation / approval by other countries; g. Combination with other strain and the safety evidence of the strains combination.

Table 2. Requirements for application for use of new probiotics in foods and dietary/health supplements (continued)

	General requirement/characteristics	*Safety requirement*	*Requirements for clinical trials*	*Other requirements*
In health supplements (MOH Malaysia, 1984)	Submission of product registration application via online system (QUEST 3+ System) (https://www.npra.gov.my/index.php/en/) Applications for probiotics strains in health supplements are required to meet the following requirements: a. Evaluated for its safety to human and beneficial to health as demonstrated in human studies; b. Antibiotic resistance data on the probiotic strain; c. Genus, species and strain designation in the Certificate of Analysis of Active Ingredient; d. Resistant to gastric acidity; e. Resistant to bile acid; f. Adhered to mucus and/or human epithelial cells and cell line; g. Able to hydrolyse bile salt.	Documents to support the safety of probiotics in health supplements:- a. Standard / established references such as monograph, pharmacopoeia; b. Clinical studies or scientific evidences to evaluate the safety on long term use in human; c. Information from other reference country such as registration status, type of claims and maximum registered daily dose as health supplements; d. Antibiotic resistance data for the specific strain.	Publications on clinical trials from outside of country (international data) is adequate. There is no specific number of clinical studies set by NPRA. However, the supporting documents provided must be comprehensive to fulfil all the requirements and must be strain specific.	a. Stability data to identify the minimum viable cfu at the end of shelf life at the proposed storage condition and shelf life; b. Certificate of Analysis of Finished Product; c. Certificate of Good Manufacturing Practice (GMP) of product manufacturer; d. Certificate of Free Sale (for imported product); e. Complete product label; f. Complete batch manufacturing formula.
Philippines				
In foods and dietary supplements (BFAD, 2004)	Probiotics have to be in the list of bacterial strains as specified, otherwise substantiation is required in accordance with FAO/WHO guidelines (FAO/WHO, 2002). For a probiotic to the effective, the following properties should be demonstrated: a. beneficial effect on the host organism; b. should be able to survive in the digestive tract; c. should adhere to the mucosal epithelial cells; d. should exhibit enhancement and protection of the intestinal ecology; e. should remain viable during periods of storage and use.	The following documents should be submitted: a. Determination of antibiotic resistance patterns; b. Assessment of certain metabolic activities (e.g., D-lactate production, bile salt deconjugation); c. Assessment of side-effects during human studies; d. Epidemiological surveillance of adverse incidents in consumers (post-market); e. If the strain under evaluation belongs to a species that is a known mammalian toxin producer, it must be tested for toxin production. One possible scheme for testing toxin production has been recommended by the EU Scientific Committee on Animal Nutrition (SCAN, 2000); f. If the strain under evaluation belongs to a species with known hemolytic potential, determination of hemolytic activity is required.	Food or food supplement products do not require any clinical trials.	When a probiotic makes a claim of altering disease or as an immunomodulator, the said product shall be classified as drug.

Table 2. Requirements for application for use of new probiotics in foods and dietary/health supplements (continued)

	General requirement/characteristics	*Safety requirement*	*Requirements for clinical trials*	*Other requirements*
Singapore				
In foods (SFA, 2021)	The following information should be submitted when applying for the use of new microorganisms in food: a. Complete identification and characterisation for the microorganisms intended for use in food, purity of the microorganism preparation, including percentages of the major components and impurities present; b. Information on the manufacturing process of the microorganisms; c. Information on the proposed types of food which the microorganisms will be added to, and the proposed usage levels for the microorganisms in food; d. Reasons for addition of the microorganisms in food (e.g. as a starter culture or as a food ingredient).	All ingredients and additives used in food must be safe, including probiotics. SFA evaluates the safety of the microorganism added to food but does not endorse its probiotic properties. Applicants need to show evidence that the microorganisms used in food have a long history of safe use in food production. If the microorganism does not have a history of safe use, applicants will need to demonstrate safety through safety studies. When evaluating the safety of the new microorganisms intended to be added to food, SFA take reference from European Food Safety Authority Panel on biological hazards qualified presumption of safety (QPS) list and International Dairy Federation inventory of microbial food cultures with history of safe use, to assess whether the microorganism is safe for food use. SFA also takes reference from the guidelines from FAO/WHO (2001; 2002).	When the safety evaluations is unavailable, relevant published scientific information such as toxicity studies, ADME (absorption, distribution, metabolism and excretion) studies and human clinical trials demonstrating the safety of the microorganisms in food may be considered. International recommendations on the use of the microorganisms in food (e.g. relevant Codex standards) and/or regulatory approvals in Australia, Canada, New Zealand, Japan, and the European Union (e.g. approval letters on the use of the microorganisms in infant formula issued by the respective food safety authorities) may be acceptable.	
In health supplements (HSA, 2021)	Health supplements (including those containing probiotics) are not subject to pre-marketing approval by the HSA. Dealers are not required to obtain pre-market approval to import and sell their health supplements in Singapore. Dealers are required to ensure that the strains used are safe and the recommended daily dosages for the product is within levels that are safe and appropriate for the consumers.	Dealers of health supplements are responsible for the safety and quality of their products and compliance with the guidelines on the health supplements set out by the HSA. This includes ensuring the products they supply do not contain any prohibited substances or substances controlled under the Poisons Act. Dealers are also required to hold on to evidence to support the safety and quality of their products, including the ingredients used in the products.	No specific requirements stated.	

Table 2. Requirements for application for use of new probiotics in foods and dietary/health supplements (continued)

	General requirement/characteristics	*Safety requirement*	*Requirements for clinical trials*	*Other requirements*
Thailand In foods and dietary supplements (MoPH, 2011)	Safety assessment results and characteristics of probiotic microorganisms are to be evaluated according to Guidelines for the Evaluation of Probiotics in Food (FAO/WHO, 2002) as follows: a. Testing of identity of genus, species, strain using the most current, valid methodology and nomenclature of microorganisms; b. Nomenclature of the bacteria must conform to the current, scientifically recognized names; c. Tests for probiotic characteristics: • resistance to gastric acidity • bile salt resistance • adherence to mucus and/or human epithelial cell and cell line • bile salt hydrolase activity; and • other characteristics (if any) as the case maybe	*In vitro* or *in vivo* tests and human studies for safety evaluation and human adverse reaction to new probiotics strain as follows: a. Antimicrobial resistance; b. Metabolic effect assessment such as D-lactate or bile salt deconjugation; c. Side effects in human intervention studies; d. Epidemiological surveillance of adverse incidents after marketing; e. Tests for toxin production, if the strain under evaluation belongs to a species that is a known toxin producer; f. Test for haemolytic activity if the strain under evaluation belongs toa species with known haemolytic potential.	At least two well designed human intervention studies from different institutes; international data may be adequate Specific requirements for clinical trial: a. Well-designed human intervention studies; or b. other appropriately designed human intervention studies with enough sample size and result of preliminary studies of the strains or food.	a. Stability and bioavailability of the probiotic culture in the food(s) in which it is to be added; b. Analytical method (validated method) to identify the purity of the probiotic culture; c. Combination with other strains (if applicable) and the evidence of safety of the combination; d. Information on approval by other countries.
Vietnam In food and dietary supplement (MOH Vietnam, 2014)	A probiotic strain can be registered under supplemented food or dietary supplement. The documents submitted must provide information on: • Composition • Specification • Certificate of analysis valid for 12 months, issued by accredited ISO 17025 certified laboratory • Label artworks • GMP certificate (applicable for dietary supplements) • Certificate of free sale (applicable for dietary supplements) • Scientific documents to support functions of the probiotic, claims	The product must meet safety specifications for heavy metals, mycotoxin, microbiological content.	a. Clinical trials may not be necessary. Scientific documents of ingredients, translated into Vietnamese, may be accepted; b. Scientific documents of effectiveness of the probiotics from outside of Vietnam must be published in scientific journals.	Other technical characteristics provided by the manufacturer

The same labelling requirements also apply to probiotic health supplements (NADFC, 2021).

For probiotic-containing foods in **Malaysia**, the Regulation 26A on probiotic culture has provided conditions dealing with labelling of foods with added probiotic cultures. These food products must be labelled with: the term probiotic cultures, as well as the genus, species and strain of the probiotic cultures; the quantity of the culture in cfu/ml or cfu/g; direction for storage before and after package is opened. In addition, where the media used for propagation and maintenance of the probiotic cultures are derived from animal, the common name of such animal shall be stated on the food label. These labelling requirements are in addition to the general labelling requirements.

In Malaysia, all approved probiotic health supplements must adhere to the standard labelling requirement for health supplement as stipulated in the Drug Registration Guidance Document (GRDG) (MOH Malaysia, 2021). These include the usual information required for pharmaceutical products. NRPA highlights that all information on the label must be truthful and not misleading to the consumers.

Labelling aspects of probiotic-containing foods and dietary supplements in the **Philippines** should comply with the mandatory general labelling information required for a food. In addition to this, labels for a probiotic food or dietary supplement must also include the information on bacteria contents (genus, species, strain designation), minimum numbers of viable bacteria at end of shelf life, proper storage conditions and corporate contact details for consumer information.

In **Singapore**, both SFA and HSA have not specified any specific labelling requirements for probiotics in foods or health supplements. All prepacked food products and health supplements for sale in Singapore must be labelled according to the general labelling requirements for food and complementary health products prescribed by these regulatory authorities.

The label of all food products containing probiotic in **Thailand** must first adhere to the general labelling and nutrition labelling requirements of pre-packaged foods in the country. The label of the product containing probiotics shall have the approval statement (if relevant), the term 'probiotic microorganism' or 'probiotics', as well as the genus, species and strain of the probiotics. For probiotic products carrying a health claim statement, the following additional information/statement must be provided: "This product is not intended to treat, heal, cure or prevent diseases"; amount to be consumed and time needed for health claim effect, instruction of use and appropriate condition for storage (MoPH, 2011).

For dietary supplements, depending on the ingredients contained therein, additional statements are required to appear on the label (MoPH, 2019). These statements include "Should eat varieties of five categories of food"; "No effect for prevention or cure diseases"; "Should not be consumed by children and pregnant women".

For a probiotic-containing food or supplement for sale in **Vietnam**, the manufacturer shall specify that the probiotic strain name as well as the amount per serving size or 100 g on the product label. For probiotic-containing product registered as supplemented food, there must be a phrase expressing the food group as "Supplemented foods" on the main part of the label, whereas for product registered as health

supplement, there must be a phrase on main part of the label expressing the food group as "Health supplement" to distinguish ordinary foods from medicines. For probiotic registered as health supplement, the following warning statement must be given on the label: "This product is not a medicine, and it is not a substitute for medicines" (MOH Vietnam, 2014).

Probiotic function and health claims and procedure for application

Probiotic-containing foods in **Indonesia** are permitted to make health claims if they are supported by sufficient scientific evidence. The requirements for such applications are similar to those prescribed for applications for use of new probiotic strains (NADFC, 2016). Similarly, publications from clinical trials carried out on Indonesian population must be submitted to substantiate the application. The specific health claims approved may be listed on the label and used in advertising. It is pointed out that specific health claims for certain strains should not be used for other strains, and do not apply to a combination of various strains or synbiotic (probiotics with prebiotics).

Similarly, for health supplements in Indonesia, applications for products with probiotics may include claims. The requirements for such applications are similar to those prescribed for applications for use of new probiotic health supplements (NADFC, 2021).

In **Malaysia**, a pre-approved generic function claim for foods containing probiotics is permitted under the Regulations for probiotics, namely: "Probiotic cultures help in improving intestinal or gut function" or any other words of similar meaning (Table 3) (MOH Malaysia, 2017). Malaysia does not allow disease risk reduction health claims to be made on foods, although 'other function claims' may be considered, if supported by scientific substantiation.

Health claims on probiotic health supplements are permitted in Malaysia. Probiotics in health supplements can make general claims, functional claims and disease risk reduction claims if the relevant requirements for such claims stated in the Drug Registration Guidance Document (DRGD) can be fulfilled (MOH Malaysia, 2021). The current approved functional claim for probiotic is 'helps to improve a beneficial intestinal microflora' (Table 3). Companies applying for health claim must provide comprehensive publications on clinical trials to fulfil all the requirements and must be strain specific. Stability data is required to support the label claim amount of probiotic microorganism in the finished product at the proposed shelf life and storage condition.

The BFAD Circular in the **Philippines** has allowed the use of four pre-approved claims related to probiotics and can be reflected on the product labels, used for advertisement and product promotion (BFAD, 2004) (Table 3). These claims include enhancement of intestinal ecology, improvement of lactose malabsorption, improvement of digestion and aid to the enhancement of natural resistance to intestinal infections. Companies are permitted to apply for the use of these specified health claims on probiotics by going through the same review process as the procedure for evaluation of probiotics for food use.

In **Singapore**, only the list of pre-approved health claims permitted under the Guide to Food Labelling and Advertisements (SFA, 2019) and regulation 9A of the Food Regulations (SFA, 2021) may be used on foods that meet the respective criteria. For probiotic-containing foods, four nutrient function claims relating to the role of probiotics in

helping to maintain a healthy digestive system through suppressing the growth of harmful bacteria may be used (Table 3). The exact species of the probiotic present in the product must be specified on the label. The viable count of the probiotic present in the product that is able to bring about the claimed effect must also be indicated.

Health supplements in **Singapore** (including those containing probiotics) are not subject to pre-marketing approval by the HSA. The onus of ensuring that the health claims made for a probiotic health supplement is accurate, not false or misleading is on the dealer. All claims made should be adequately support by relevant evidence to provide truthful information to ensure consumers to make informed decisions when purchasing and consuming the products. In general, the health claims used on probiotic health supplements must be consistent with a product that is used to support or maintain the healthy functions of the human body. The claims made should not indicate that the product helps or implies that the product is necessary or play a role in diseased states. Claims such as "support/promote/maintain healthy digestion", or "support/promote/maintain digestive health" may be used, but treatment claims such as "relief of constipation" or "treat diarrhoea" are not permitted (HSA, 2019).

Probiotic health claims are permitted in **Thailand**. A generic pre-approved health claim: "Beneficial microorganism to the body" or words of similar meaning may be used with prior approval by the Thai FDA (MoPH, 2011) (Table 3). Manufacturers or importers may apply for probiotics health claims using a form which can be accessed via: http://www.fda.moph.go.th/sites/food/manual/9.2_checklist_Health_claims(Eng)pdf. The regulation has provided clear guidelines for the criteria, procedure and conditions when submitting a health claim on probiotics (MoPH, 2011). Scientific substantiation of the intended claim should be obtained from well-designed human intervention studies from at least two different institutes. The guideline also listed the specific requirements for the clinical trials, including the details that should be covered in the design and results of the human intervention study.

There are no pre-approved claims, but companies may apply for health claims on probiotics in **Vietnam.** The application for health claims follows the same procedure and requirements for application of a probiotic strain to be registered for use under supplemented food or health supplement.

DISCUSSION

Regulations in SEA countries for use of probiotics in foods and health supplements

The six countries in this review have taken on different approaches in regulating the marketing and sale of probiotics in foods or dietary supplements. Only Indonesia, Malaysia, Philippines and Thailand have enacted specific regulations for this purpose. Two different divisions within the regulatory authorities in Indonesia and Malaysia are responsible for these products. In the Philippines and Thailand, both categories of products are controlled by the Food and Drugs Authority in these countries. Authorities in these countries have provided a legal definition of 'probiotics' which is basically similar to that of FAO/WHO consultation report (FAO/WHO, 2001).

Singapore and Vietnam have not enacted a specific regulation on probiotics but the use and sale of probiotics-containing foods and dietary supplements are permitted. There is also

Table 3. List of health claims approved for probiotic-containing foods and dietary/health supplements in SEA countries

	List of permitted health claims
Indonesia	
Foods	No pre-approved claims. Applications may be made to BPOM, supported by scientific evidence. Requirements are similar to those prescribed for applications for use of new probiotic strains as indicated in Table 2.
Health supplements	No pre-approved claims. Same as for foods, applications may be made to BPOM, supported by scientific evidence.
Malaysia	
Foods	A pre-approved function claim: *Probiotic cultures help in improving intestinal or gut function;* words of similar meaning may be used. Malaysia does not allow disease risk reduction health claims to be made on foods, although other function claims may be considered.
Health supplements	A pre-approved function claim: *Helps to improve a beneficial intestinal microflora.* Companies applying for health claims must provide comprehensive publications to substantiate the proposed claims.
Philippines	
Foods and supplements	Four (4) pre-approved function claims: • *Enhancement of intestinal ecology.* • *Helping improve lactose malabsorption.* • *Improving digestion.* • *Aid to the enhancement of natural resistance to intestinal infections.* Companies may apply for use of health claims using the same process as when applying for use of new probiotic strains.
Singapore	
Foods	The following five (5) pre-approved function claims relating to the role of probiotics (exact name of probiotic must be specified) in helping to maintain a healthy digestive system through suppressing the growth of harmful bacteria may be used, as long as they are truthful and can be substantiated. • *Helps to maintain a healthy digestive system.* • *Helps in digestion.* • *Helps to maintain a desirable balance of beneficial bacteria in the digestive system.* • *Helps to suppress / fight against harmful bacteria in the digestive system, thereby helping to maintain a healthy digestive system.*
Health supplements	No pe-approved list of permitted claims. Claims such as *"support/promote/maintain healthy digestion", or "support/promote/maintain digestive health"* may be used Probiotic health supplements and their product claims are not subject to pre- marketing approval by the HSA. The onus of ensuring that the health claims made for a probiotic health supplement is accurate, not false or misleading is on the dealer.
Thailand	
Foods and supplements	A pre-approved function claim may be used: *Beneficial microorganism to the body.* Words of similar meaning may be used with prior approval by the Thai FDA. Manufacturers or importers may apply for health claims with scientific substantiation.

no legal definition of the term 'probiotics' in these two countries. In Singapore, the sale of probiotics in food and supplements are controlled by separate health authorities. In Vietnam, the sale of probiotics in foods and supplements is regulated by several ministries, including health and trade.

The microorganisms approved to be used as probiotics are not harmonised among the SEA countries. Malaysia listed a numbers of approved bacterial strains for use in foods, but there is no approved list for use in dietary supplements. Philippines and Thailand, on the other hand have published lists for probiotics approved to be used in foods and dietary supplements, but up to the genus and species level, respectively. Indonesia, Singapore and Vietnam do not have positive list of probiotics that may be used either for foods or dietary supplements. For countries with a positive list of bacteria strains, it is observed that the lists comprise mainly strains from *Bifidobacterium sp.* and *Lactobacillus sp.* Only Malaysia and Thailand have mandated that probiotic-containing products must contain a minimum number of probiotic microorganisms, i.e. at least 10^6cfu/ml or cfu/g during the shelf life of such products.

All six countries in this review allow the application for new probiotics to be used, with varying requirements to be met, and have adopted differing regulatory approach. There are, however, several generally similar requirements among several the four countries with specific regulations, i.e. Indonesia, Malaysia, Philippines and Thailand. These four countries have provided clear guidelines to intending applicants. Clear identification of probiotic strains must be carried out. Tests to be carried out to determine the characteristics of probiotic strains include ability to survive in the digestive tract, adherence to the mucosal epithelial cells, and ability to hydrolyse bile salts. There are also rather similar safety assessments that must be conducted on the probiotic strains, e.g. determination of antibiotic resistance patterns and assessment of metabolic activities. Assessment of side effects of the cultures during clinical studies conducted in human subjects must also be conducted.

These four countries also require that all applications be accompanied by scientific evidence on functional roles or potential health benefits of the probiotic culture, demonstrated through human clinical studies. NADFC of Indonesia requires that these data must be obtained through local studies conducted on local population; details for the conduct of such clinical trials are provided in the regulation. The other three countries accept international data published in peer-reviewed journals.

Pre-approved generic function/ health claims related to intestinal or gut function; or digestive health/ healthy digestive system; or intestinal microflora/microorganisms/ecology; or desirable balance of beneficial bacteria are permitted for use in foods and health supplements containing probiotics in Malaysia, Philippines, Singapore and Thailand. Applications for additional health claims can be submitted to the regulatory authorities in all countries except Malaysia. Applications must be accompanied by scientific evidence obtained from human clinical trials. In the case of NAFDC, such data must be obtained through local studies conducted on Indonesian population. However, there is a lack of clarity in the requirements for application in some countries with no clear regulation for probiotic, such as Vietnam.

Countries in the review have adopted differing approaches with regard to the specific labelling requirement for

products containing probiotics. Except for Singapore, all the other five countries (Indonesia, Malaysia, Philippines, Thailand, Vietnam) require the product label to have clear identification of the genus, species and strain of the probiotics, the number of live microorganisms in terms of cfu/g or ml at the end of shelf life, as well as storage instructions. Singapore, on the other hand, does not have specific labelling requirements for probiotic containing foods or health supplements.

In addition, Thailand and Vietnam have mandated the requirement to have cautionary statements for probiotic health supplement products, for example that the supplement is not a medicine and not a substitute for medication.

Global probiotic regulations

In a review of 11 Asian countries and Australia and New Zealand, Au *et al* (2019) had demonstrated that there is no harmonised regulations or guidelines on probiotics in foods and dietary supplements. Each country has its unique regulatory approach to these products. Probiotic-containing foods have also been placed in different categories, e.g. general foods (Indonesia, Malaysia, Singapore, Thailand), functional foods (China, Vietnam), nutraceuticals (India), health supplements (Indonesia, Malaysia, Singapore, Vietnam), Food for Specified Health Use (FOSHU) (Japan), health foods (Taiwan) and novel foods (China, India, Australia New Zealand). There are also divergent approaches in the other aspects of the regulatory framework including approved probiotic strains, permitted claims, procedure for application for new probiotic strains.

More recently, Nomoto (2021) has provided a review of the status of probiotic regulations in several continents. In North America, only Canada and Brazil have enacted regulations for these beneficial microorganisms. In Europe region, there is no specific regulations or guidelines in the European Union, although some countries in the region have provided for this. These countries include Italy, Czech Republic and the Netherlands. In Asia, China, Korea and India have legislations regulating probiotics. There is no specific probiotic regulation in Japan, but the Food for Specified Health Uses (FOSHU) system permits claims related to gastrointestinal tract using probiotics *Lactobacilli* and *Bifidobacterium* (Au *et al*, 2019; Iwatani & Yamamoto, 2019).

Harmonisation of probiotic regulations in SEA countries

Several years ago, Arora & Baldi (2015) had pointed out that probiotic products have been introduced into the international market as food supplements, dietary supplements, natural health products, functional foods and many other categories. The status of probiotic-based products was full of ambiguities because various regulatory agencies in different countries are defining and categorising probiotics differently. As a result, there was considerable confusion and scepticism amongst regulatory bodies, producers and consumers, for the associated claims of probiotic products. A single definition of probiotics and use of consistent terminologies were lacking. There was also a lack of regulatory framework and harmonisation of guidelines on an international basis. The authors called for a common regulatory framework to enable future safe and efficacious use of probiotics.

This review has indicated that there is no harmonised probiotic regulations, either for use in foods or dietary supplements in SEA countries.

The diverse implementation of probiotic regulations across countries creates inconsistencies and difficulties for all key stakeholders including government authorities, academia, industry and consumers. Without a common understanding and harmonised use of the term 'probiotic' and characteristics of such products, there could be misuse of the term and products not meeting the required criteria may be available to consumers.

Having a harmonised regulation on probiotics in the region is expected to be beneficial to the trading of probiotic products within the SEA region as well as outside the region. It will also have a positive impact on research and development of probiotics by the academia and the industry. Consumer confidence on probiotic products will also be enhanced.

In this regard, the SEA PROBIOTICS SREN has provided a platform for discussion among key stakeholders to explore opportunities for harmonisation of some aspects of the regulatory framework for probiotics in SEA countries. It was felt that five aspects of the probiotic regulations in foods and supplements could be considered, namely: definition of probiotics, positive list of probiotics, general health claims on probiotics, labelling of probiotics and procedure for applications for use of new probiotic strains. The Network is currently working on developing a common framework and guideline for the evaluation of probiotic cultures for use in foods, beverages and dietary supplements in the region. The guideline will include the following aspects of the probiotic strains: identification and nomenclature, characteristics, safety evaluation including in humans and functional role/beneficial health effects.

Recognising that there are no harmonised regulations on probiotics in foods or dietary supplements globally, there has been an effort to develop a harmonised probiotic guideline for use in foods and dietary supplements within the Codex Alimentarius system. At the last session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) in 2019, a Discussion Paper on Harmonised Probiotic Guidelines for Use in Foods and Dietary Supplements (CX/NFSDU 19/41/11) (FAO/WHO, 2019a) was tabled for discussion. This discussion paper has been revised jointly by Argentina and Malaysia, based on comments made by delegations during the CCNFSDU session in 2019 (FAO/QWHO, 2019b), and is expected to be considered in the next session of the CCNFSDU at the end of 2022.

CONCLUSION

All indications are that the demand for probiotics in foods and beverages and dietary supplements will continue to increase in the SEA region. It is important for countries to have clear regulatory control, to ensure consumers have access to safe and efficacious probiotic containing foods or dietary supplements. Clear regulations or guidelines by authorities will provide guidance to consumers on choosing genuine probiotic-containing products. Hopefully, products that do not meet the criteria for probiotics will eventually be weeded out. Similarly, this will enable the industry to have a clear understanding of the requirements when submitting new probiotic strains for approval. Information from this review can serve as reference to countries in the region intending to establish regulations or update existing regulations.

The review has indicated that only four countries in SEA region have enacted clear regulations for the use of probiotics

in foods or dietary supplements. There are significant benefits for all stakeholders if there are harmonised regulations for use in the region. The SEA PROBIOTICS SREN will continue to make effort to harmonise some aspects of the probiotic regulations. The Network will also continue to provide a platform for the key stakeholders in the region (from government, academia, professional organization and private sector) to share updates on scientific and regulatory aspects of probiotics and microbiome research. In the meantime, it is hoped that the proposed harmonised probiotic guideline will be accepted as new work in the Codex Alimentarius system.

Further development of probiotics in the region can continue to improve and progress so that more probiotic products can be made available for the health and wellbeing of the consumers. This would require capacity building in research and development, regulatory development and harmonisation, and even consumer education on appropriate choice and use of probiotic products. Collaboration among the main players, namely the regulatory authorities, the research groups, professional bodies and the relevant industry will facilitate these development.

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All authors contributed to the conceptualisation of paper, obtained regulations for analysis, analysed available information, drafted manuscript, finalised manuscript for publication.

Conflict of interest

TES and H declare that they have no conflicts of interest; CASS is the staff member of DuPont Nutrition & Biosciences.

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