

**ASSOCIATIONS OF SELF-REPORTED
PHYSICAL ACTIVITY LEVELS AND LIFESTYLE
RISK FACTORS WITH IRRITABLE BOWEL
SYNDROME SEVERITY SCORES**

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by

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LIST OF ABBREVIATIONS

CNS	Central nervous system
FGIDs	Functional gastrointestinal diseases
GI	Gastrointestinal
HUSM	Hospital Universiti Sains Malaysia
IBS	Irritable bowel syndrome
IBS-A	IBS with alternating constipation and diarrhoea
IBS-C	Constipation-predominant IBS
IBS-D	Diarrhea-predominant IBS
IBS-SSS	IBS-Severity Scoring System
IPAQ	International Physical Activity Questionnaire
PA	Physical activity
QoL	Quality of Life

HUBUNGAN ANTARA TAHAP AKTIVITI FIZIKAL YANG DILAPORKAN SENDIRI DAN FAKTOR-FAKTOR RISIKO GAYA HIDUP DENGAN SKOR KEKERAPAN SINDROM IRRITASI USUS

ABSTRAK

Objektif: Tujuan kajian ini adalah untuk meneroka hubungan antara pelbagai komponen tahap aktiviti fizikal yang dilaporkan sendiri, faktor-faktor gaya hidup dan skor keparahan sindrom gangguan usus pada pesakit sindrom iritasi usus (IBS).

Kaedah: 38 pesakit IBS yang pernah mendapatkan rawatan dari Hospital Universiti Sains Malaysia telah direkrut dalam kajian ini. Mereka diminta untuk menjawab soal selidik Aktiviti Fizikal Antarabangsa (IPAQ), Sistem Permakaian Keparahan IBS (IBS-SSS) dan, soal selidik gaya hidup dan diet serta borang data demografi peribadi. Kami menggunakan analisis regresi berganda untuk menyiasat hubungan antara aktiviti fizikal, faktor gaya hidup dan skor keparahan IBS. **Keputusan:** Tidak ada perbezaan yang signifikan dalam tahap-tahap aktiviti fizikal yang dilaporkan sendiri dalam kalangan pesakit IBS ($p > 0.05$). Kami tidak dapat mencari hubungan yang signifikan antara tahap-tahap aktiviti fizikal yang dilaporkan sendiri pada skor keparahan pesakit IBS ($p > 0.05$). Tidak ada hubungan yang signifikan antara faktor-faktor gaya hidup pada skor keparahan IBS pesakit IBS ($p > 0.05$) kecuali kekerapan pengambilan makanan yang ditapai menunjukkan hubungan yang signifikan terhadap skor keterukan IBS ($\beta = 0.313$, $p = 0.040$). **Kesimpulan:** Kekerapan pengambilan makanan yang ditapai adalah ramalan terhadap tahap keparahan IBS. Tahap aktiviti fizikal, masa duduk yang lebih panjang, pengambilan minuman semasa makan, kekurangan kadar kunyah, kehilangan gigi yang lebih banyak dan pengambilan makanan pedas dan goreng tidak berkaitan dengan peningkatan risiko IBS.

ASSOCIATIONS OF SELF-REPORTED PHYSICAL ACTIVITY LEVELS AND LIFESTYLE RISK FACTORS WITH IRRITABLE BOWEL SYNDROME SEVERITY SCORES

ABSTRACT

Objectives: The purpose of this study was to explore the relationship between various components of self-reported physical activity levels, lifestyle factors and irritable bowel severity scores in irritable bowel syndrome (IBS) patients. **Methods:** thirty-eight IBS patients who previously sought treatment from Hospital Universiti Sains Malaysia were recruited in this study. They were asked to complete the International Physical Activity Questionnaire (IPAQ), IBS Severity Scoring System (IBS-SSS) and, lifestyle and dietary questionnaires and fill the personal demographic data form. We used multiple regression analysis to investigate the influence of physical activity and lifestyle factors on IBS severity scores. **Result:** There is no significant difference in the self-reported physical activity levels among IBS patients ($p>0.05$). We were unable to find any significant relationship between self-reported physical activity levels on the IBS severity scores of IBS patients ($p>0.05$). There is also no significant relationship between lifestyle factors on the IBS severity scores of IBS patients ($p>0.05$) except the frequency of fermented food intake showed a significant relationship on the IBS severity score ($\beta = 0.313$, $p=0.040$). **Conclusion:** The frequency of fermented food intake is a predictor of IBS severity level. Physical activity levels, longer sitting time, intra-meal fluid intake, chewing insufficiency, higher tooth loss and the consumption of spicy and fried food were not associated with increased severity of IBS.

CHAPTER 1

INTRODUCTION

1.1 Background of study

Irritable bowel syndrome (IBS) is a gastrointestinal disorder. IBS can also refer to spastic colitis, mucous colitis, and nervous colon as it is a group of intestinal symptoms that typically occur together (Brazier, 2019). It is a chronic condition as the patients' symptoms could last at least three days per month for a total of at least three months. Even though IBS does not increase the risk of gastrointestinal cancers, it can reduce a person's quality of life (QoL) significantly, as it causes persistent discomfort due to cramping, abdominal pain, bloating, constipation, and diarrhoea (Brazier, 2019; Herdon, 2019). IBS comes in multiple forms; hence, patients may experience different symptoms that require individualised treatments.

The causes of IBS are still unclear, however, many of the scientists believe that microbial factors may play a key role, but they do not exclude other factors such as the diet intake, inability of the central nervous system (CNS) to control the digestive system, sensitive colon or immune system, and environmental or lifestyle factors (Herdon, 2019; Brazier, 2019). According to Lovell and Ford's (2012) meta-analysis, IBS symptoms decline modestly with increasing age. Hence, IBS frequently occurs in adolescents. The prevalence in students aged 15 years showed an increment from 14.6% in 2004 to 19% in 2009 (Endo *et al.*, 2011). Women are showing higher IBS prevalence than men that may be due to the symptoms associated with hormonal factors (Herndon, 2019). In Malaysia, IBS was diagnosed in 148 individuals from the state of Perak (Rajendra *et al.*, 2004; Rahman *et al.*, 2017). In west coast Malaysia, the prevalence is 14%, while in east coast Malaysia, the prevalence is 10.9%. (Rajendra *et al.*, 2004; Lee *et al.*, 2012).

Studies involving healthy adults have indicated that exercise can reduce the feelings and symptoms of fatigue, bloating and constipation (Villoria *et al.*, 2005; Tuteja *et al.*, 2005). Villoria *et al.* (2005) stated that mild physical activity would enhance intestinal gas clearance and reduce the abdominal bloating symptom that occur frequently in IBS patients. While regular physical activity may not change the constipation symptom significantly, it improves the QoL in people with constipation (Tuteja *et al.*, 2005). According to Johannesson *et al.* (2011), IBS patients who exercised 20 to 30 minutes with moderate to vigorous intensity between three to five times per week had significantly improved abdominal pain, stool problem, and QoL compared with control group. However, the effectiveness of physical activity in the improvement of IBS symptoms and QoL remains unclear. According to an observational study, QoL was unchanged after 12 weeks of exercise intervention (Daley *et al.*, 2008). Besides, some forms of physical activity can induce negative effects on gastrointestinal conditions such as nausea, heartburn, and diarrhoea especially when conducting the vigorous and prolonged exercise. (Nunez, 2020; Stewart *et al.*, 2016)

Based on the available studies, there are insufficient studies on physical activity as a significant modality in the reduction of IBS symptoms. We need evidence if physical activity can reduce IBS symptoms. Thus, the purpose of this study is to explore the relationship between self-reported physical activity levels, lifestyle factors and irritable bowel severity scores in IBS patients.

1.2 Problem statement

It is suggested that regular exercise can improve certain IBS symptoms (Kuttner *et al.*, 2006). Based on previous studies, exercise is effective in treating some IBS

symptoms but not QOL. Results have shown that 12 weeks of exercise can improve symptoms in IBS patients with constipation, not other IBS symptoms (Daley et al., 2008). There are limited data on the association of physical activity levels and lifestyle risk factors of IBS patients on the severity of IBS symptoms in Malaysia.

1.3 Objective

General Objective

To explore the relationship between various components of self-reported physical activity levels, lifestyle factors and irritable bowel severity scores in irritable bowel syndrome (IBS) patients.

Specific Objective:

- i. To determine the difference in physical activity levels among IBS patients.
- ii. To determine the risk factors (physical activity levels and lifestyle) for IBS severity scores.

1.4 Hypothesis

To address research question 1: Is there a difference in the physical activity levels among IBS patients?

H_{01} There is no significant difference in the self-reported physical activity levels among IBS patients.

H_{A1} There is a significant difference in the self-reported physical activity levels among the IBS patients.

To address research question 2: Are there any significant relationships between self-reported physical activity levels, lifestyle factors and IBS severity scores of IBS patients?

H_{02} There is no significant relationship between self-reported physical activity levels on the IBS severity scores of IBS patients.

H_{A2} There is a significant relationship between self-reported physical activity levels on the IBS severity scores of IBS patients.

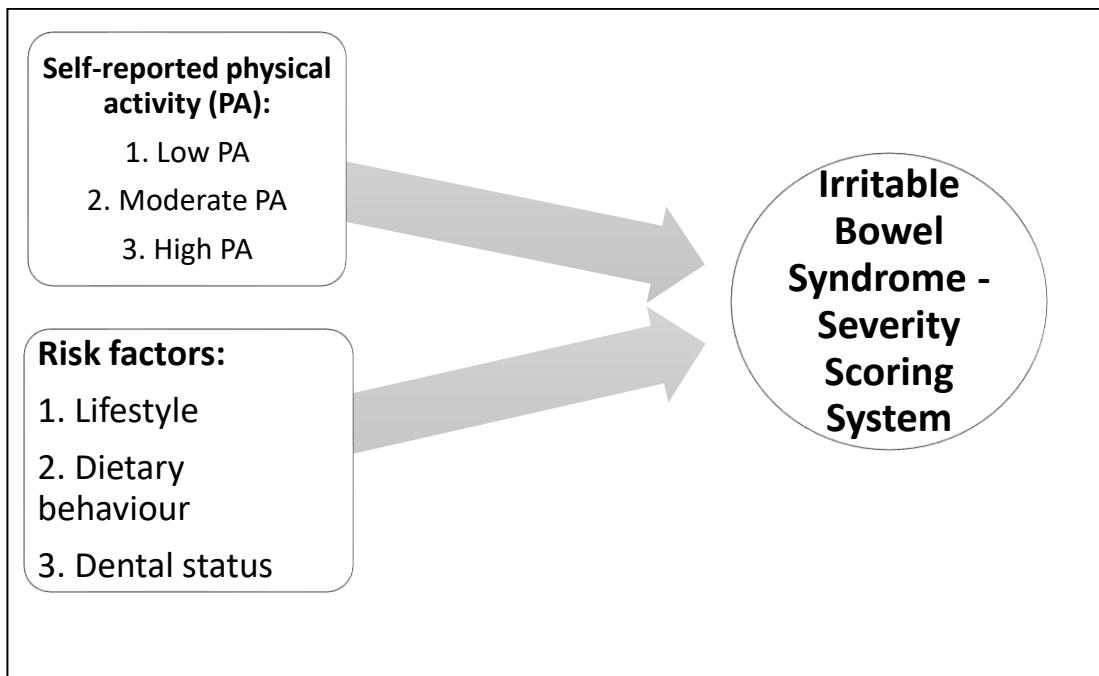
H_{03} There is no significant relationship between lifestyle factors on the IBS severity scores of IBS patients.

H_{A3} There is a significant relationship between lifestyle factors on the IBS severity scores of IBS patients.

1.5 Significance of study

The findings from this study will help inform on the possible components of physical activity related to IBS symptom severity. Knowing the associations of physical activity components will help inform on the possibility applications of future intervention studies to determine the effects of prescribed physical activity or exercise to alleviate IBS conditions. Findings on the possibly related lifestyle behaviours may further inform on prevention strategies that may aggravate the condition of IBS sufferers. Overall, this study is required to shed more light on what would be effective to study IBS and lifestyle behavior (including physical activity levels and components) that would contribute to a better quality of life for people with IBS.

1.6 Conceptual framework



CHAPTER 2

LITERATURE REVIEW

2.1 The risk factors and prevalence of irritable bowel syndrome (IBS)

Although the factors of developing IBS are still unclear, many experts believe that it is caused by a combination of physiological and psychological factors. The changes in gut microbes, muscle contraction in the intestine, abnormalities in the nervous system, severe infection and psychological distress have all been reported as factors in developing IBS (Herdon, 2019). Besides, bad habits are also risk factors to develop IBS. For instance, frequent consumption of alcohol and smoking are positively associated with IBS (Nam *et al.*, 2010). As the frequent consumption of alcohol and smoking have a strong positive association with psychological stress which could increase the risk to get IBS (Nam *et al.*, 2010). Furthermore, individuals with poor diet behavior such as low or absence of intra-meal fluid intake, insufficient chewing, high tooth loss, and frequent consumption of spicy and fried food have positive associations with increased risk of IBS (Khayyatzaeheh *et al.*, 2017). Guo *et al.* (2015) stated that individuals with irregular eating behavior have higher chance to get IBS. Moreover, people with sedentary lifestyle have greater risk of IBS (Sadeghian *et al.*, 2018). IBS patients were also reported to spend less time doing physical activity compared with healthy people (Lustyk *et al.*, 2001).

According to Lovell and Ford (2012), the global prevalence of IBS, is estimated at 11.2% and the rate did not change in the last 30 years. From the previous statistic, the prevalence is varied in different countries (Lovell & Ford, 2012; Endo *et al.*, 2015; Rahman *et al.*, 2017). Based on previous studies, the highest prevalence is in South America (21.0%), while the lowest in Southeast Asia (7.0%) (Endo *et al.*, 2015). The reported IBS prevalence in Malaysia varied between 11%-14% as the prevalence is

higher in urban than those diagnosed based on the Rome III criteria (Rahman *et al.*, 2017). The report of prevalence from Lovell and Ford (2012), Endo *et al.* (2015) and Rahman *et al.* (2017) seemed low as IBS is defined by category and subtypes to diagnose IBS.

Differences in IBS prevalence can be accounted by the different diagnostic criteria used. For example, using the Rome criteria, the prevalence of Rome III criteria IBS in Iranian adults is 21.5% (Keshteli *et al.*, 2015). Using the Rome II criteria, the prevalence in Iran was reported as 9.0% (Lovell & Ford, 2012). Besides the Rome criteria, the types of IBS also greatly influence prevalence estimates. For instance, in Japan, prevalence of IBS based on Rome III criteria was 13.1%. When classified into IBS subtypes, a majority reporting having mixed IBS (IBS-M) with 47% of cases, IBS with diarrhoea (IBS-D) the second highest subtype with 29% of cases and followed by the IBS with constipation (IBS-C) with 24% of cases (Miwa, 2008).

Overall, studies have reported that IBS prevalence in women is higher than men, and IBS is more prevalent in adulthood, which will decrease when the age increases (Lovell & Ford, 2012). Besides, IBS rates are higher in urban compared to rural areas. According to Tan *et al.* (2003), west coast Malaysia is a well-developed economic region in the Peninsula of Malaysia that results in a high prevalence of IBS (14%) compared to the east coast of Malaysia (10.9%). This east coast region of Malaysia is less developed than the west coast of Malaysia. (Rajendra *et al.*, 2004).

2.2 Types of IBS

Irritable bowel syndrome (IBS) is a type of gastrointestinal disorder categorised in multiple forms. People with IBS may experience symptoms such as pain or cramping, diarrhoea, constipation, changes in bowel movements, gas and bloating,

food intolerance, fatigue and difficulty sleeping. Abdominal pain or cramp is the most common symptom, the pain usually happens in the lower abdomen or the entire abdomen and is less likely to be in the upper abdomen alone. Besides, people with IBS will face changes in bowel movement such as slow-moving stool, watery or loose stool, mucus that accumulates in stool and even blood in stool (Thorpe, 2019).

The symptoms of IBS may vary based on their conditions, hence, understanding the exact type of IBS is important to determine the correct treatment. There are three common types of IBS, which are IBS-C, IBS-D and IBS-A (Cherney, 2020). IBS-C is constipation-predominant IBS. People with IBS-C will experience fewer bowel movements, abdominal pain, and bloating. IBS-D is known as IBS with diarrhoea; its condition is the opposite of IBS-C. IBS-D affects about one-third of patients with IBS. People with IBS-D will experience accelerated bowel transit that causes a sudden and immediate urge to have a bowel movement. Moreover, they tend to have a loose and watery stool and may contain mucus. While some people may have IBS with mixed bowel habits which called IBS with alternating constipation and diarrhoea (IBS-A), IBS-A is also called IBS-M (Cherney, 2020; Thorpe, 2019). People with IBS-A will experience hard or lumpy stools during at least 25% of bowel movements on symptomatic days, while another 25% will experience loose or mushy stools on symptomatic days. (Schmulson & Drossman, 2017). The stools changes may occur over periods of hours or days. Some people may also find that their predominant bowel problem alternates between weeks or months of constipation or diarrhoea. (Palsson *et al.*, 2012).

Apart from the three types of IBS, many experts have classified the IBS symptoms into Rome criteria. Doctors later used the Rome criteria to diagnose IBS (GI Society, 2006). The Rome criteria can be divided into Rome I, Rome II, Rome III

and Rome IV. Rome I is used to classify and understand functional gastrointestinal disorders (FGIDs) by using a symptom-based classification scheme and highlighting the patients' report symptoms. The Rome II required the same symptoms as Rome I and symptoms need to be present for at least 12 weeks out of the preceding 12 months but did not need to be consecutive week. Besides, the term of "discomfort" and a new criterion was added, noting that two of the three abdominal pain-related criteria had to be required for the diagnosis of IBS to ensure that altered bowel habits were present (Lacy & Patel, 2017)

The Rome III criteria is depending on the recurrent abdominal pain or discomfort at least three days per month and associated with two or more of the following: 1) improvement with defecation, 2) onset associated with a change in the frequency of stool, and 3) onset associated with a change in form of stool. The criteria need to be last at least three months with symptom onset at least six months prior to diagnosis. The Rome IV criteria is the recurrent abdominal pain on average at least one day per week in the last three months and associated with two or more of the following: 1) related to defecation, 2) associated with a change in frequency of stool and 3) associated with a change in form (appearance) of stool (Ghoshal, 2017). As there are no precise biomarkers for IBS, the Rome criteria can be an ideal test with sufficient sensitivity and specificity to help doctors diagnose of IBS (Lacy and Patel, 2017). Besides, the classification by using Rome criteria helps many researchers report prevalence easily because they do not need to conduct laboratory tests to diagnose IBS (GI Society, 2006). Even though the Rome IV criteria is claimed to be scientifically more valid, it just applied mainly in USA and may not apply in Asia. As bloating is very common in Asia IBS patients and Rome IV questionnaire only mentioned

bloating is a quite common symptom but not included bloating in the list of diagnostic criteria (Ghoshal, 2017).

2.3 Physical activity and IBS

Regular exercise not only helps to reduce stress due to the secretion of dopamine, but it also helps to improve the digestive system mainly for the IBS-C patient as exercise helps to improve constipation symptoms significantly (Rodriguez, 2015). Studies have been done to compare the decrement in the severity of IBS symptoms between sedentary and physically active IBS groups (Sadeghian *et al.*, 2018; Johannesson *et al.*, 2011). According to Bull *et al.* (2004), physical inactivity is defined as not doing or having very little physical activity at work, home, for transport or in discretionary time and insufficiently active was doing some physical activity but less than 150 minutes of moderate intensity physical activity or 60 minutes of vigorous intensity of physical activity per week accumulated across work, home, transport or discretionary domains. Physical activity can be defined as the bodily movement produced by skeletal muscle that results in energy expenditure (Caspersen *et al.*, 1985). According to Sadeghian *et al.* (2018), they found that physically active IBS people were able to decrease the severity of IBS symptoms, while the less physically active group was associated with more severe IBS symptoms. Even though exercise can improve IBS symptoms, there are insufficient research to inform on the exercise intensity and duration that will affect IBS symptoms (Nunez, 2020).

Additionally, researchers observed that the increment of physical activity may not change the symptoms of constipation, but it had improved their overall well-being as indicated by QoL assessments (Tuteja *et al.*, 2005). However, other researchers observed improved constipation symptoms in physically active people, while other

symptoms like diarrhoea did not improve (Daley *et al.*, 2008). In the recent past ten years, studies have focused on the effectiveness of physical activity on the improvement of IBS symptoms. Based on Johannesson *et al.* (2011), increased physical activity can reduce the gastrointestinal symptoms such as constipation and abdominal bloating in IBS. In 2015, researchers found that intervention to increase physical activity has positive long-term effects on IBS symptoms and psychological symptoms (Johannesson *et al.*, 2015). Sedentary behaviour (active less than 1 hour per week) had a significant positive association with IBS symptoms, particularly in women and normal weight individuals. This association was attenuated after adjusting for age, smoking habit and medical history of colitis and diabetes, indicating that an active lifestyle can reduce the risk to suffer from IBS (Sadeghian *et al.*, 2018).

2.4 Measurement of Physical Activity

One questionnaire used for measuring physical activity levels, the International Physical Activity Questionnaire (IPAQ) is a self-administered physical activity questionnaire suitable for individuals aged between 15 to 69 years old (Craig *et al.*, 2003). Patients will be asked about their current physical activities, including the frequency and duration that they had spent being physically active in the last seven-day. It comprises 27-item, which includes data in different domains (job-related, transport-related, domestic and leisure-time physical activity) and intensities (moderate, vigorous, walking) and includes sitting time. This IPAQ long format is a more detailed assessment compared to the short form. The long-form of IPAQ consists 27 items while the short-form IPAQ only compromises 7 items (Cleland *et al.*, 2018).

IPAQ can provide researchers an estimation of physical activity and sedentary behaviour across the range of socio-economic settings. (Craig *et al.*, 2003). Based on Cleland *et al.* (2018) study, IPAQ had moderate and acceptable levels of validity for moderate-to-vigorous physical activity, while for sedentary behaviour, had a substantial level of validity on weekdays and fair levels of validity on weekends. Although IPAQ has been used widely and globally, its measurements in IBS studies is limited (Miller, 2014; Basandra & Bajaj, 2014)

2.5 Severity levels of IBS

It is important to understand the severity of IBS, especially when evaluating the improvement of IBS symptoms in a study. Thus, it is important to have questionnaires to assist diagnosis and to assess the severity of the disease. Irritable Bowel Syndrome – Severity Scoring System (IBS-SSS) is one of the questionnaires that is valid and has a high sensitivity to assess changes in symptoms severity, especially in moderate symptoms of IBS patients. The IBS-SSS has five items that ask about 1) the severity of abdominal pain, 2) frequency of abdominal pain, 3) severity of abdominal distension, 4) dissatisfaction with bowel habits, and 5) interference with quality of life over the past 10 days. The total ranges from 0 to 500. Participant with scores of 75-175 are classified as mild, 176-300 as moderate, and more than 300 as severe (Francis *et al.*, 1997).

The association of IBS severity related to physical function is also essential to understand the progression of IBS. A multi-centre study by Drossman *et al.* (2007) demonstrated that IBS severity is correlated with low physical functioning. The work ability decreased less than 5% in mild group, decreased about 6 to 10% in moderate

group and more than 10% in severe group. Johannesson *et al.* (2015) found that by increasing the physical activity such as walking, aerobics and cycling can reduce the severity of IBS symptoms. Besides, increased physical activity can improve quality of life by reducing fatigue, depression, and anxiety.

CHAPTER 3

METHODOLOGY

3.1 Study population

Participants were recruited among IBS patients from the Hospital Universiti Sains Malaysia, Kubang Kerian, Kelantan (HUSM) after approval from the Human Ethical Committee of Universiti Sains Malaysia. Patients' contact numbers were obtained from the HUSM Internal Medicine Department records after permission (OBB form was completed) is acquired.

3.1.1 Subject criteria

Inclusion criteria

- a. Age 18 to 70 years old
- b. IBS diagnose with Rome III criteria on the initial visit, regardless of subtypes
- c. Follow-up IBS patients

Exclusion criteria

1. Diagnosed as organic gastrointestinal disorder – Ulceration colitis, Crohn's or celiac disease
2. Taking painkillers, intestinal relaxants, antibiotics, antidepressants, anticholinergic or anti-diarrheal medications in the past three months
3. Diagnosed with cardiopulmonary disease
4. Currently pregnant
5. Diagnosed with type 1 and 2 diabetic Mellitus
6. Had bowel surgery
7. Have acute musculoskeletal injuries that limit physical activity

3.1.2 Recruitment of subject

A total of 102 IBS patients were received from the pathology report. Thirty-five patients were excluded as seven patients did not provide contact numbers and 28 patients did not meet the requirement. The 62 patients left were contacted through WhatsApp messaging and 19 patients were contacted through phone calls. Among the 62 patients, 30 patients replied to the message and complete the questionnaires, while 32 patients were excluded as 12 patients declined to participate in the study, 10 patients did not meet the requirement, one patient had a wrong number and nine patients did not provide any response. While, from the 19 patients contacted via phone call, eight patients agreed and complete the questionnaire, and 11 patients were excluded because two patients provided the wrong contact number and nine of them with invalid number. Finally, a total of 38 patients had completed the questionnaires.

3.1.3 Information of subject

Table 3.1 shows the characteristic and educational background of the 38 IBS patients. The age of the patients was divided into five age ranges. Most of the patients were in the 60 to 69 years with 29% and followed by 26 % of patients stated in 50 to 59 years. According to the BMI of the patient, majority of the patients (45%) had normal BMI range while there were two patients (5%) categorised as underweight BMI range. In this sample of patients, the number of women is higher than men, which are 23 and 15 respectively. The majority of the patients were university degree holders (37%) and followed by certificate or Diploma holders (26%).

Table 3.1: Characteristic and educational background of IBS patients (n=38)

Characteristic		n	%
Age (years)	20-29	3	8
	30-39	4	11
	40-49	8	21
	50-59	10	26
	60-69	11	29
	70	2	5
BMI (kg/m²)	Underweight (< 18.5)	2	5
	Normal (18.5-24.9)	17	45
	Overweight (25-29.9)	13	34
	Obese (> 30)	6	16
Gender	Male	15	39
	Female	23	61
Educational background	Primary-school	4	11
	High school	7	18
	Diploma/ certificate	10	26
	University Degree	14	37
	Others	3	8

3.2 Sample size calculation

The sample size of the present study was calculated by G*Power software (version 3.1.9.7). The prevalence of IBS in the east coast of Malaysia is 10.9% according to a previously reported sample (Lee *et al.*, 2012). From Raja Abdul Wafy (2020) unpublished study, the list of available patients with IBS by ROME-III are 48 individuals. From there, we will sample everyone and from an initial post-hoc calculation with total of 48 sample size, we are still able to achieve a power of 95% and a type 1 error of 5%.

Sample size calculation is as follows:

χ^2 tests - Variance: Difference from constant (one sample case)

Analysis: Post hoc: Compute achieved power

Input:	Tail(s)	= One
	Ratio var1/var0	= 2
	α err prob	= 0.05
	Total sample size	= 48
Output:	Lower critical χ^2	= 64.0011120
	Upper critical χ^2	= 64.0011120
	Df	= 47
	Power (1- β err prob)	= 0.9535651

3.3 Data collection

The study was conducted via phone interview through both verbally and text messaging methods. Therefore, participants can provide responses at their convenience and without the need to travel to meet researchers face-to-face.

3.4 Study design

The study is a cross-sectional study. The participants were given the International Physical Activity Questionnaire (IPAQ), Irritable Bowel Syndrome – Severity Scoring System (IBS-SSS) and questionnaire of lifestyle, dietary and dental status.

3.5 Procedure

IBS patients, who previously sought treatment from the Hospital Universiti Sains Malaysia, were contacted via a text message (short messaging service; SMS) and WhatsApp to invite them to be part of this study. Interested patients were briefed of the procedures and the study objective. After the participants have agreed to

volunteer in this study, the consent forms were provided to them via an online survey form. Patients were interviewed over the phone by a trained research assistant to complete the IPAQ, IBS-SSS, educational background, lifestyle and dietary questionnaires and the personal demographic data form. Participant's data was treated with full confidentiality and will not be released to another outside of this study unless required by law.

Assessment of self-reported physical activity levels

The IBS patient's physical activity levels were assessed using the International Physical Activity Questionnaire (IPAQ). IPAQ is a self-reported questionnaire used to measure the physical activity in a population (Craig *et al.*, 2003). Patients were asked about their current physical activities, including the frequency and duration that they had spent being physically active in the last seven-day. It comprises 27-item, which includes data in different domains (job-related, transport-related, domestic and leisure-time physical activity) and intensities (moderate, vigorous, walking) and includes sitting time. This IPAQ long format is a more detailed assessment compared to the short-form and has been validated in English (Wanner *et al.*, 2016) and Malay versions (Hin & Foong, 2015). The participants took about 10 15-20 minutes to complete the long-form IPAQ.

The responses from the IPAQ were presented as categorical data on low, moderate, and high physical activity levels. The calculation of categorical data was based on the Guidelines for Data Processing and Analysis of the IPAQ (IPAQ Scoring Protocol, 2005)

The categorical score is defined as:

1. Low

No activity is reported OR

- a. Some activity is reported but not enough to meet Categories 2 or 3.

2. Moderate

Either of the following 3 criteria:

- a. 3 or more days of vigorous-intensity activity of at least 20 minutes per day OR
- b. 5 or more days of moderate-intensity activity and/or walking of at least 30 minutes per day OR
- c. 5 or more days of any combination of walking, moderate-intensity or vigorous intensity activities achieving a minimum of at least 600 MET-min/week.

3. High

Any one of the following 2 criteria:

- Vigorous-intensity activity on at least 3 days and accumulating at least 1500 MET-minutes/week OR
- 7 or more days of any combination of walking, moderate- or vigorous- intensity activities accumulating at least 3000 MET-minutes/week.

In calculating ‘moderately active’, the primary requirement was used to identify those individuals who undertake activity on at least ‘5 days’/week. Participants who meet this criterion should be coded in a new variable called “at least five days” and this variable should be used to identify participants meeting criterion b) at least 30 minutes

of moderate-intensity activity and/or walking; and those meeting criterion c) any combination of walking, moderate-intensity or vigorous-intensity activities achieving a minimum of 600 MET-minutes/week. The same approach was used to calculate total days for computing the ‘high’ category. The primary requirement according to the stated criteria is to identify participants who undertake a combination of walking, moderate-intensity and or vigorous-intensity activity on at least 7 days/week. Participants who meet this criterion should be coded as a value in a new variable to reflect “at least 7 days”.

The algorithm for calculating Total Physical Activity MET-minutes/week is Total MET-minutes/week (at Work + for Transport + in Chores + in Leisure)

Assessment using the Irritable Bowel Syndrome – severity scoring system (IBS-SSS)

IBS-SSS was used to determine the severity of the IBS symptoms. It has five items that ask about the severity of abdominal pain, frequency of abdominal pain, the severity of abdominal distension, dissatisfaction with bowel habits and interference with quality of life over the past ten days. It consists of a 100-point visual analogue scales. The score ranges from 0 to 500, the participant with scores of 75-175 can be classified as mild, while moderate group scores in the range of 176-300, and for the severe group scores are more than 300. (Francis *et al.*, 1997). 10 to 15 minutes were needed to complete IBS-SSS questionnaire.

Assessment of risk factors

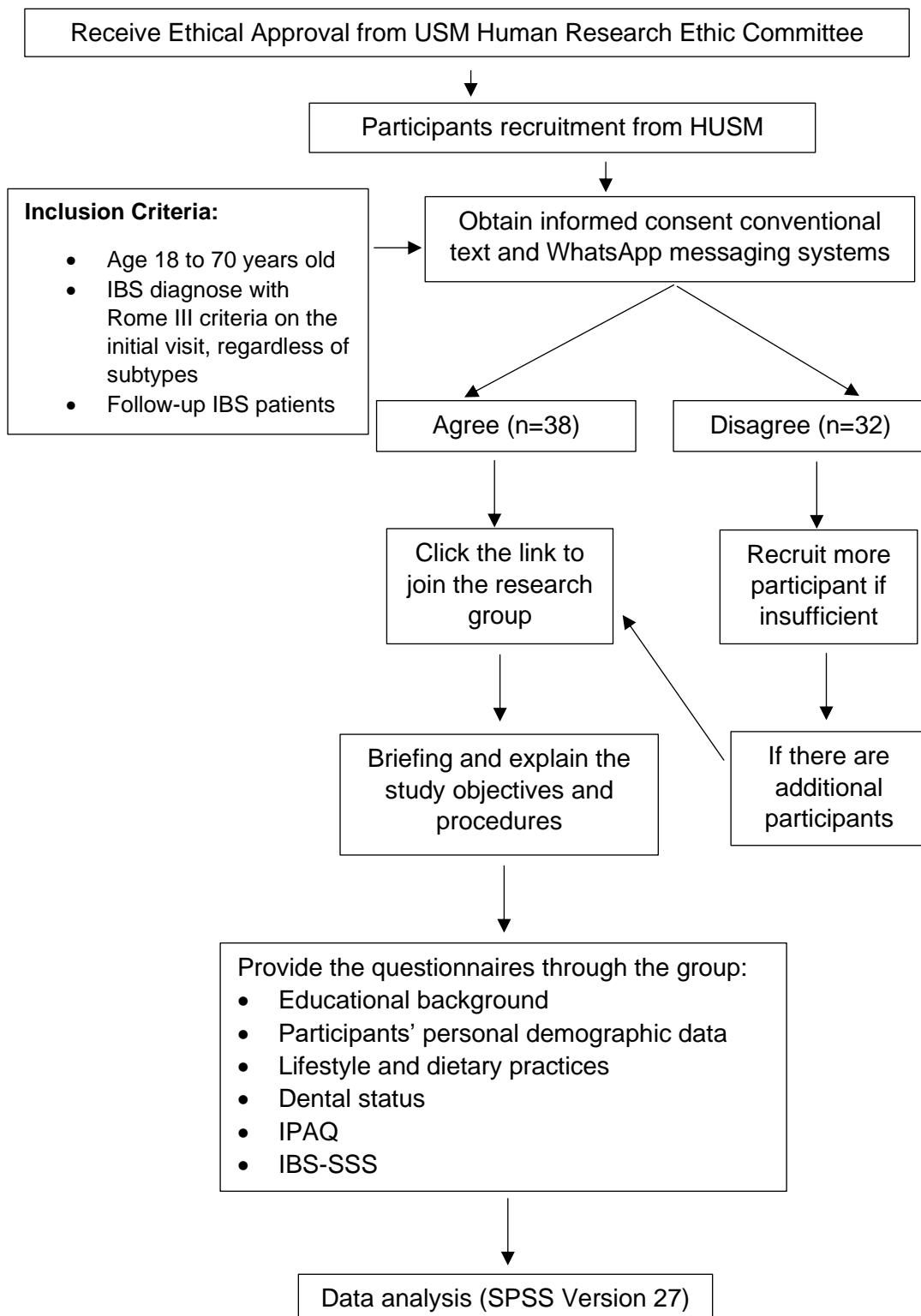
Assessment of risk factors such as educational background, smoking status and dietary habits were obtained based on a modified questionnaire (Sadeghian *et al.*, 2018). Regarding their dietary habits, the questions included meal regularity, chewing

sufficiency, eating rate, intra-meal fluid intake as well as the frequency of skipping breakfast meals, spicy food intake, the quantity of consumed spices, fried and fermented (i.e. *budu*) food consumption (Sadeghian *et al.*, 2018). Participants were also classified into 3 categories of dental health status: “fully dentate”, “loss of 1–5 teeth” and “loss of more than 5 teeth” (Sadeghian *et al.*, 2018). Poor dental health status (losing 1 to 5 teeth) might be associated with higher prevalence of IBS (Esmaillzadeh *et al.*, 2013). This questionnaire needed 10 minutes to complete.

3.6 Statistical analysis

All data was analysed using the IBM SPSS version 27. For categorical variables, Chi-square test was used to examine association between physical activity levels and symptom severity categories in IBS patients. To address the predictive factors of physical activity levels, age, gender and body weight affect the degree of IBS severity scores, a multiple regression model was conducted. The obtained variables (IBS severity scores of mild, moderate and severe) were entered as dependent variables, with highly active, moderately active, inactive, age, gender, BMI tested, lifestyle, dietary behaviour and dental status as predictors. Statistical significance level is set at $p<0.05$.

3.7 Flow Chart of Cross-sectional Study



CHAPTER 4

RESULTS AND DISCUSSION

4.1 Result

Table 4.1 shows the lifestyle, dietary and dental status of all IBS patients. Majority of the IBS patients (n=31, 82%) were non-smokers. Smoking frequency in those who were current smokers (n=3, 8%) and ex-smokers (n=4, 11%), one patient smoked more than 10 cigarette sticks per day. Majority of patients (n=36, 95%) do not consume alcohol at all and most of them (n=16, 42%) always consume fluid during mealtime (intra-meal fluid). Majority of the patients chewed moderately per meal (n=20, 53%) and spent more than 10 minutes to eat per meal (n=24, 63%). Most of the patients never skip breakfast (n=26, 68%) and majority of them had indicated that they had lost one to five teeth (n=18, 47%). Table 4.2 shows the regular meal pattern of all IBS patients whereas Table 4.3 shows the type of food intake of IBS patients. Most of the patients had practiced regular meal patterns by always taking the breakfast on 6.00 a.m. to 10.00 a.m. (n=22, 58%), always taking their lunch on 12.00 p.m. to 2.00 p.m. (n=17, 45%), always having their dinner on 6.00 p.m. to 9.00 p.m. (n=18, 47%) and rarely to take supper (n=14, 37%). There were 19 patients (50%) who consumed some dessert or bread during teatime sometimes. Majority of the patients were less likely to take spicy food (n=21, 55%) and fermented food (n=24, 63%) with one to three times per week. However, most of the patients were preferable to take fried food (n=18, 47%) with four to six times per week.

Table 4.1: Lifestyle, dietary and dental status of IBS patients (n=38)

Lifestyle, dietary and dental status		n	%
Smoking status	Current smoker	3	8
	Non-smoker	31	82
	Ex-smoker	4	11
Smoking frequency	Less than 5	3	8
(cigarette stick)/day	5 to 10	3	8
	More than 10	1	3
Alcohol consumption	Not at all	36	95
	Seldom	2	5
Intra-meal fluid consumption	Never	4	11
	Sometimes	10	26
	Often	8	21
	Always	16	42
Chewing sufficiency	A lot	15	39
	Moderate	20	53
	Little	3	8
Eating rate per meal	More than 10 minutes	24	63
	Less than 10 minutes	14	37
Skipping breakfast (per week)	Never	26	68
	1 day	8	21
	2-4 days	4	11
	5-6 days	0	0
	Everyday	0	0
Dental status	Fully dentate	13	34
	Loss 1-5 teeth	18	47
	Loss more than 5 teeth	7	18

Table 4.2: Regular meal pattern of IBS patients.

Regular meal pattern	Never		Rarely		Sometimes		Often		Always	
	N	%	N	%	N	%	N	%	N	%
Breakfast on 6.00 - 10.00 a.m.	0	0	1	3	4	11	11	29	22	58
Lunch on 12.00 – 2.00 p.m.	0	0	0	0	8	21	13	34	17	45
Dinner on 6.00 – 9.00 p.m.	0	0	1	3	5	13	14	37	18	47
Teatime	1	3	7	18	19	50	8	21	3	8
Supper	8	21	14	37	10	26	3	8	3	8

Table 4.3: Types of food intake of IBS patients

Types of food intake (per week)	Never		1-3 times		4-6 times		More than 10 times	
	N	%	N	%	N	%	N	%
Spicy food	10	26	21	55	3	8	4	11
Fried food	1	3	15	39	18	47	4	11
Fermented food	10	26	24	63	1	3	3	8

Stratification of IBS patients by categories of physical activity and their characteristics, lifestyle, food intake and IBS-SSS are described in Table 4.4. Most of the patients (n=23) were categorised as having performed high physical activity in the last 7 days. Although there were more highly active patients with normal BMI (n=11, 28.9%), there were highly active IBS patients who were underweight (n=2, 5.3%), overweight (n=8, 21.1%) and obese (n=2, 5.3%). Majority of the vigorous or high physical activity patients always consume intra-meal fluid (n=8, 21.1%), chewed a lot (n=11, 28.9%), had an eating rate per meal of more than 10 minutes (n=16, 42.1%), had never skipped breakfast per week (n=18, 47.4%), and was reported to have a loss 1 to 5 teeth (n=11, 28.9%). The majority of the vigorous/highly active patients (n=12, 31.6%) were also found to be taking spicy food and fried food one to three times per week. However, it was observed that the majority of the vigorous/highly active patients (n=14, 36.8%) took fermented food one to three times per week. There was only one patient who took fermented food of 4-6 times per week and more than 10 times per week respectively. Most of the highly active patients were categorised with mild level of IBS (n=10, 26.3%), followed by patients in remission status (n=6, 15.7%) while there were two patients (5.3%) categorised as having severe level of IBS.

Table 4.4: Prevalence of characteristic, lifestyle, food intake and IBS-SSS of IBS patients (n=38) by categories of physical activity

Characteristics		Inactive/ low physical activity, n (%)	Moderate physical activity, n (%)	Vigorous/ high physical activity, n (%)
Gender	Male	3 (7.9)	3 (7.9)	9 (23.7)
n= 38	Female	1 (2.6)	8 (21.1)	14 (36.8)
BMI (Kg/m2)	Underweight (< 18.5)	0	0	2 (5.3)
n= 38	Normal	3 (7.9)	3 (7.9)	11 (28.9)
	Overweight	0	5 (13.1)	8 (21.1)
	Obese	1 (2.6)	3 (7.9)	2 (5.3)
Lifestyle, dietary and dental status				
Smoking frequency	Less than 5	1 (14.3)	0	2 (28.6)
(cigarette stick)	5 to 10	1 (14.3)	0	2 (28.6)
n= 7	More than 10	0	1 (14.3)	0
Alcohol consumption	Not at all	4 (10.5)	10 (26.3)	22 (58)
n=38	Seldom	0	1 (2.6)	1 (2.6)
Intra-meal fluid consumption	Never	0	2 (5.3)	2 (5.3)
n= 38	Sometimes	1 (2.6)	3 (7.9)	6 (15.8)
	Often	0	1 (2.6)	7 (18.4)
Chewing sufficiency	Always	3 (7.9)	5 (13.1)	8 (21.1)
n= 38	A lot	1 (2.6)	3 (7.9)	11 (28.9)
	Moderate	3 (7.9)	7 (18.4)	10 (26.3)
n= 38	Little	0	1 (2.6)	2 (5.3)
Eating rate per meal	<10 minutes	2 (5.3)	5 (13.1)	7 (18.4)
n= 38	>10 minutes	2 (5.3)	6 (15.8)	16 (42.1)
Skipping breakfast (per week)	Never	3 (7.9)	5 (13.2)	18 (47.4)
n= 38	1 day	0	4 (10.5)	4 (10.5)
	2-4 days	1 (2.6)	2 (5.3)	1 (2.6)
	5-6 days	0	0	0
	Everyday	0	0	0
Dental status	Fully dentate	1 (2.6)	5 (13.2)	7 (18.4)
n= 38	Loss 1-5	2 (5.3)	5 (13.2)	11 (28.9)
	Loss more than 5	1 (2.6)	1 (2.6)	5 (13.2)
Types of food intake (per week)				
Spicy food (time/week)	Never	1 (2.6)	1 (2.6)	8 (21.1)
n= 38	1-3	2 (5.3)	7 (18.4)	12 (31.6)
	4-6	0	2 (5.3)	1 (2.6)
	>10	1 (2.6)	1 (2.6)	2 (5.3)
Fried food	Never	0	0	1 (2.6)
n= 38	1-3	1 (2.6)	2 (5.3)	12 (31.5)

	4-6	2 (5.3)	8 (21.1)	8 (21.1)
	>10	1 (2.6)	1 (2.6)	2 (5.3)
Fermented food	Never	1 (2.6)	2 (5.3)	7 (18.4)
n= 38	1-3	3(7.9)	7 (18.4)	14 (36.8)
	4-6	0	0	1 (2.6)
	>10	0	2 (5.3)	1 (2.6)
IBS-SSS				
	< 75 (remission)	0	3 (7.9)	6 (15.7)
n= 9				
	Mild	4 (10.5)	5 (13.2)	10 (26.3)
n= 19				
	Moderate	0	3 (7.9)	5 (13.2)
n= 8				
	Severe	0	0	2 (5.3)
n= 2				

Table 4.5 shows the comparison of physical activity categories among the IBS patients. There was no statistically significant difference between low physically active and moderately active patients ($p=0.954$). There was also no statistically significant difference between low physically active and vigorously active patients ($p=0.905$). similarly, there was no significant difference between moderately active and vigorously active patients ($p=0.985$).

Table 4.5: Comparison of physical activity categories among IBS patients

Categories of physical activity	N	MET per week		Categories of physical activity		
		Mean	SD	Low	Moderate	Vigorous
Low	4	78.38	90.75	-	0.954	0.905
Moderate	11	1461.5	620.23	0.954	-	0.985
Vigorous	23	6106.22	3179.08	0.905	0.985	-

Table 4.6 shows the regression analysis of predictors of IBS severity scores. The regression analysis shows that the frequency of fermented food intake is a predictor of IBS severity level ($\beta = 0.313$, $p=0.040$). The surveyed physical activities, demographics and lifestyle variables were not significant predictors of IBS severity in this sample of IBS patients.

Table 4.6: Predictors of IBS severity scores

Predictors		Mean (SD)	Standardised coefficients β	Adjusted R square	t	p- value
Physical activity	Total minutes of work domain	136.97 (83.489)	-0.255	0.214	- 0.586	0.227
	Total minutes of transportation	164.21 (315.872)	-0.229		- 0.956	0.344
	Total minute of housework	659.87 (713.691)	-1.007		- 1.465	0.060
	Total minute of leisure time	169.34 (251.214)	-0.025		- 0.098	0.295
	Total minutes of weekday sitting time	181.32 (151.357)	-0.067		- 0.278	0.271
	Total minutes of weekend sitting time	228.68 (193.756)	0.323		1.342	0.072
	Total MET (per week)	4127.18 (3526.090)	1.018		1.145	0.286
Demographics	Gender	0.61 (0.495)	-0.088	-0.017	0.511	0.287
	BMI	2.61 (0.823)	0.87		0.509	0.289
	Dental status	1.84 (0.718)	0.003		0.019	0.430
Lifestyle	Smoker	2.03 (0.434)	0.101	-0.043	0.604	0.271
	Alcohol consumption	0.05 (0.226)	-0.051		0.306	0.376
Dietary habits and food intake	Intra-meal fluid consumption	1.95 (1.064)	-0.162	-0.078	- 0.858	0.194
	Chewing sufficiency	1.68 (0.620)	0.036		0.196	0.415
	Eating rate	1.63 (0.489)	0.070		0.345	0.305

Frequency of skipping breakfast	0.42 (0.683)	-0.036	-	0.398
Frequency of spicy food intake	1.03 (0.885)	-0.125	-	0.380
Frequency of fried food intake	1.66 (0.708)	0.082	0.416	0.251
Frequency of fermented food intake	0.92 (0.784)	0.313	1.576	0.040*

*Denotes significant predictors of IBS-SSS. MET=Metabolic equivalent of task;
 SD=standard deviation, t=test statistics

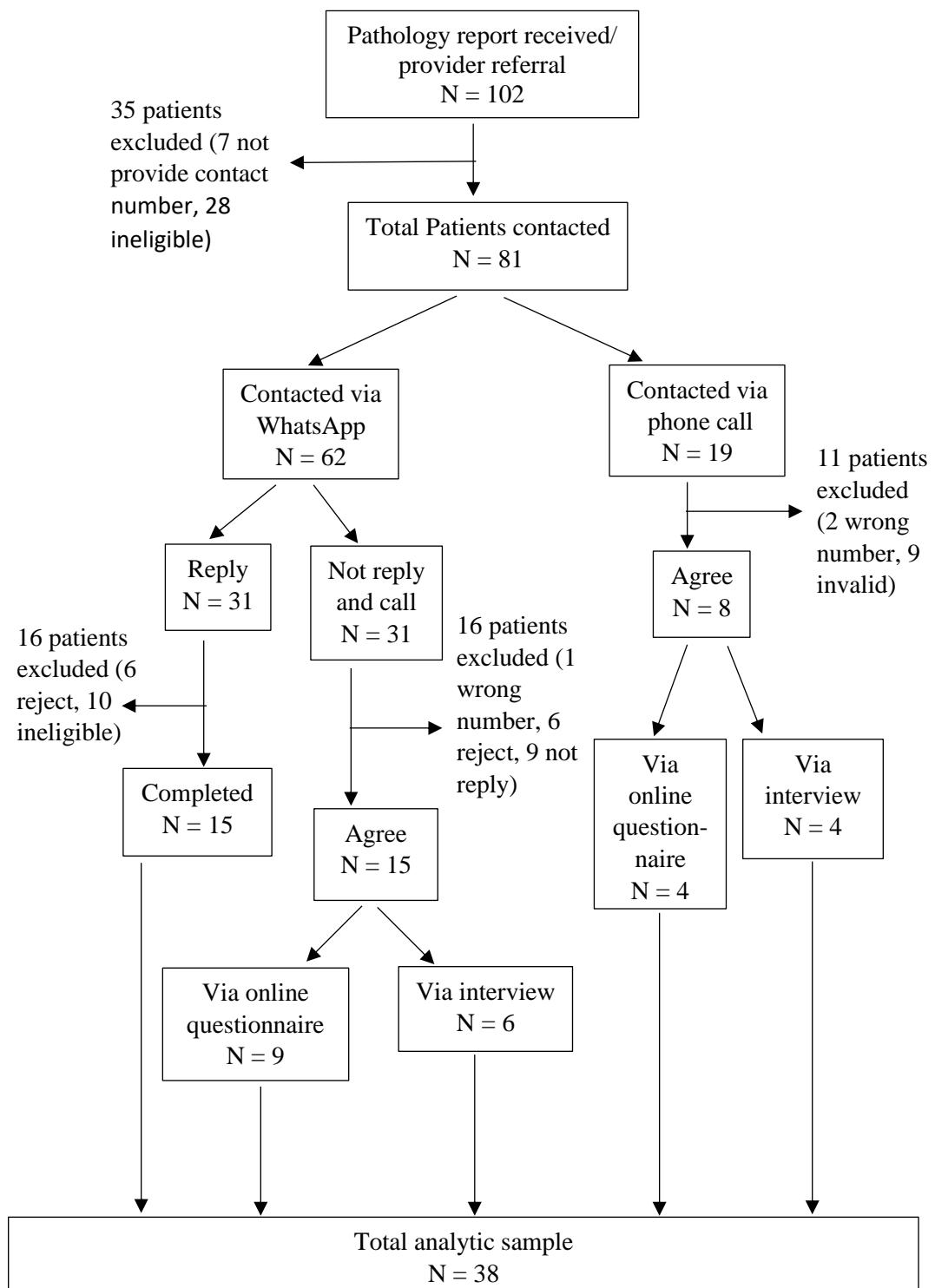


Figure 4.1. Flow chart of recruitment and screening for the study

CHAPTER 5

DISCUSSION

In this current study, we assessed the prevalence of IBS among a sample of IBS patients who previously sought treatment from the Hospital Universiti Sains Malaysia (HUSM) as well as their IBS severity level associations with lifestyle and nutritional habit. The main finding from this study showed that there was no significant difference between the physical activity categories on the IBS severity levels among the IBS patients. Based on this sample of IBS patients, the surveyed physical activity, demographics, dietary habits and lifestyle variables were not significant predictors of IBS severity levels except the frequency of fermented food intake was a significant predictor of the IBS severity levels.

There were more women (61%) with IBS from our sample size, about two times more than men (39%). It has been said the higher prevalence of IBS in women was due to the hormone estrogen, a hormone responsible for the development and regulation of the female reproductive system (Lovell & Ford, 2012). In IBS, estrogen receptor alpha ($E\alpha$) and beta ($E\beta$), and G protein-coupled estrogen receptor (GPER) were found upregulated, indicating a role of the hormone in IBS pathophysiology (Jacenik *et al.*, 2018). The estrogen receptors located throughout the brain, such as the amygdala, hypothalamus, pituitary, hippocampus, cerebral cortex, midbrain, and brain stem to support the target sites of estrogen actins on neurocognitive processes (Ter Horst *et al.*, 2009). According to Naliboff *et al.* (2003), the results of brain imaging studies stated that the greater responsiveness of emotional arousal circuits in relation to visceral pain had been implicated as the central mechanism that induces pain amplification in IBS. During menses, the decline of ovarian hormone levels in women may contribute to the exacerbation of gastrointestinal (GI) symptoms, including

abdominal pain or discomfort, altered bowel habits and bloating (Mulak *et al.*, 2014). There was an observed higher percentage of IBS patients with an educational background of university level in the current study. Mentally stress such as anxiety may be more common in individuals with higher educational levels as psychological distress has been reported as a factor in developing IBS (Gulewitsch *et al.*, 2013). The “brain-gut axis” can be defined as the interconnection between the central and enteric nervous systems. There is a relationship between altered cognitive processes, including strain and hypervigilance. Thus, the increased arousal of the autonomic nervous system will increase the visceral sensitivity and other IBS symptoms (Levy *et al.*, 1997).

Based on our findings on the dietary factors, the frequency of fermented food intake was found as the only predictor for IBS severity scores. Most of the patients (63.1%) consumed fermented food at least one to three times per week. Study shows that fermented food has beneficial effects on GI symptoms (Rezac *et al.*, 2018). Fermented foods are the foods or beverages produced via controlled microbial growth, and the conversion of food components through enzymatic action (Dimidi *et al.*, 2019). According to Marco *et al.* (2017), the consumption of fermented food containing live microorganisms (beneficial yeast or bacteria) has emerged as an important dietary strategy for improving human health. Fermented food such as soybeans may reduce phytic acid concentrations, a substance found mainly in plant food that may impair absorption in the body. Other carbohydrate fermentations, such as sourdough bread fermentation, can reduce the content of fermentable carbohydrates, particularly the fermentable oligosaccharides, disaccharides, monosaccharides, and polyols (FODMAPs). The reduction of FODMAPs may increase the tolerance of these

products in IBS patients (Dimidi *et al.*, 2019). Intolerance to poorly absorbed carbohydrates or food allergy has been a significant problem in IBS.

We did not find other dietary factors that are linked with IBS severity. We believed that the participants had practised healthy dietary habits. We found 52.6% of patients had a ‘moderate’ chewing sufficiency and followed by 39.4% of the patients who indicated they chewed ‘a lot’ in every meal. Moreover, most of the patients (63.2%) had slower eating rate (more than 10 minutes) per meal. Thus, in our group of patients, dietary habits are not a risk factor for IBS severity. Even though we observed the highest percentage of participants (47.4%) who had lost one to five teeth, most of them had a slower eating rate and ‘moderate’ to ‘a lot’ chewing sufficiency. Some studies reported that chewing insufficiency and losing at least 1 to 5 teeth were associated with a higher prevalence of IBS (Khayyatzadeh *et al.*, 2017; Esmaillzadeh *et al.*, 2015). Rathee and Hooda (2009), stated that inadequate masticatory and chewing have a significantly increased risk of GI disorders. Insufficiency of chewing will decrease the breakdown of food and reduce the exposure to saliva that might be related to inadequate gastric secretion, impaired bolus formation and consequent digestive disorders (Malocclusion, 2010). Hence, our patients were able to digest the food well. Besides, most of the patients in the three categories of physical activity groups had consumed intra-meal fluid. As drinking water or other liquids during or after meal helps digestion by breaking down food and absorbing nutrients. Fluid intake increases hydration, thus softens stool that helps prevent constipation (Picco, 2020).

In this study, more than half of the patients have a low intake of spicy food with one to three times per week, which showing very low frequency of consumption per week. According to Esmaillzadeh *et al.* (2013), the consumption of spicy foods was associated with an increased prevalence of IBS, particularly in women. However,

there was about half of the patients ingested fried food frequently (4 to 6 times per week). Fried food was not a factor for IBS severity scores in our patients from HUSM. During the individual phone call interview sessions, we found that frying food is a very commonly preferred method of cooking, and most of the patients prefer the pan-frying style instead of the deep-frying style. Pan-frying is considered healthier than deep-frying as a smaller amount of oil is used. Fatty and fried food can intensify IBS symptoms by increasing gas retention, GI sensitivity and exaggerating gastro-colonic response (Khayyatzaeh *et al.*, 2017). The mechanism responsible for GI sensitivity after a meal in IBS patients may be due to lipid-induced hypersensitivity (Simrén *et al.*, 2007). A study stated that the intraluminal lipids can induce intestinal gas retention which predominantly acting on the proximal small bowel (Hernando-Harder *et al.*, 2004).

There were also a higher number of IBS patients categorised as vigorously or highly active (n=23, 60.5%). Johannesson *et al.*, (2015) stated that a moderate increase in physical activity could alleviate IBS symptoms and enhance some aspects of disease-specific quality of life. A study by Dishman *et al.* (2006) shows that physical activity can counteract the effects of stress and cause positive influence on brain plasticity. Therefore, physical activity has a protective effect on depression symptoms and prevent IBS symptoms deterioration (Herring *et al.*, 2012). This study showed there was no significant association between physical activity levels and severity scores of IBS. However, in vigorous/high physically active patients, we observed the prevalence of mild level of IBS was the highest and followed by patients in remission and moderate severity, while the prevalence of the severe level of IBS was the lowest. Therefore, in our group of patients, IBS symptoms still exist mildly at high physical activity levels. However, upon assessing for different predictors in the physical activity

domains (job-related physical activity, transportation physical activity, housework-related physical activity, recreation, sports and leisure-time physical activity, and time spent for sitting), we found that all the domains of physical activity were not the risk factor of IBS. The longer time spent sitting during weekday and weekend was also not the risk factor to cause IBS. This finding was inconsistent with Sadeghian *et al.* (2108) study which reported that sedentary or physically inactive individuals have a greater risk of IBS. Furthermore, a case-control study found that physically active individuals were 3.6 times less likely to suffer from IBS than individuals with physically inactive lifestyle (Guo *et al.*, 2015). Our insignificant findings for the association of physical activity and IBS severity levels were not consistent with some studies that reported that increased physical activity would improve the IBS symptoms. Physically active IBS patients have less symptom deterioration than physically inactive patients (Johannesson *et al.*, 2011). Based on Villoria *et al.* (2006), moderate physical activity can improve intestinal gas clearance and reduce symptoms in patients who complain of abdominal bloating. A 12-week exercise therapy has significantly enhanced only constipation, not other IBS symptoms, in a randomised controlled trial of 56 IBS patients (Daley *et al.*, 2008).

This study has several limitations. Due to the small sample, there may lower statistical power to detect associations of physical activity levels with IBS severity scores. There were also more women patients in our sample group. Increasing the number of patients recruitments is necessary to study different age ranges and BMI categories, including age and gender-matched. This study was also conducted through the online administered questionnaires, assisted by phone call. The physical activity was self-reported, and the patients may have overestimated the frequency and levels of physical activity they were achieving for the past seven days. Future studies may

include other known factors associated with IBS that were not addressed in this current study, such as depression and anxiety.

CHAPTER 6

CONCLUSION

In conclusion, the result of this current study showed there are no significant differences in the self-reported physical activity levels among IBS patients. We were unable to find any significant relationship between self-reported physical activity levels on the IBS severity scores of IBS patients. There is also no significant relationship between lifestyle factors on the IBS severity scores of IBS patients except the frequency of fermented food intake. We found that the frequency of fermented food intake is a predictor of IBS severity level. Further research is needed to examine the association between physical activity levels, age, gender, BMI, lifestyle, dietary behaviour and dental status with the IBS severity levels. The stress levels of the patients should be tested as a risk factor in future study. Based on the limitations stated in the Chapter 5, increasing the sample of the participant and conducting face to face interview sessions are recommended.

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APPENDICES

APPENDIX A HUMAN ETHICAL APPROVAL



4th April 2021

Miss Chang Zhuang Yu
Undergraduate Student (Exercise and Sport Science)
School of Health Sciences
Universiti Sains Malaysia
16150 Kubang Kerian, Kelantan.

Jawatankuasa Etika
Penyelidikan Manusia USM (JEPeM)
Human Research Ethics Committee USM (HREC)

Universiti Sains Malaysia
Kampus Kesihatan
16150 Kubang Kerian, Kelantan, Malaysia.
Tel. : +609 - 767 3000/2354/2362
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JEPeM Code : USM/JEPeM/21010021
Protocol Title : Associations of Self-Reported Physical Activity Levels and Lifestyle Risk Factors with Irritable Bowel Syndrome Severity Scores.

Dear Miss.,

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the Jawatankuasa Etika Penyelidikan Manusia Universiti Sains Malaysia (JEPeM-USM). Your study has been assigned study protocol code **USM/JEPeM/21010021**, which should be used for all communications to JEPeM-USM in relation to this study. This ethical approval is valid from **4th April 2021** until **3rd April 2022**.

Study Site: Hospital Universiti Sains Malaysia.

The following researchers are also involved in this study:

1. Dr. Marilyn Ong Li Yin
2. Dr. Vina Tan Phei Sean

The following documents have been approved for use in the study.

1. Research Proposal

In addition to the above mentioned document, the following technical documents were included in the review on which this approval was based:

1. Patient Information Sheet and Consent Form (English version)
2. Patient Information Sheet and Consent Form (Malay version)
3. IBS Questionnaire
4. International Physical Activity Questionnaire
5. Educational Background, Lifestyles, Dietary Habits and Dental Status Questionnaire

While the study is in progress, we request you to submit to us the following documents:

1. Application for renewal of ethical approval 60 days before the expiration date of this approval through submission of **JEPeM-USM FORM 3(B) 2019: Continuing Review Application Form**.
2. Any changes in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, must be submitted or reported using **JEPeM-USM FORM 3(A) 2019: Study Protocol Amendment Submission Form**.
3. Revisions in the informed consent form using the **JEPeM-USM FORM 3(A) 2019: Study Protocol Amendment Submission Form**.
4. Reports of adverse events including from other study sites (national, international) using the **JEPeM-USM FORM 3(G) 2019: Adverse Events Report**.



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5. Notice of early termination of the study and reasons for such using **JEPeM-USM FORM 3(E) 2019**.
 6. Any event which may have ethical significance.
 7. Any information which is needed by the JEPeM-USM to do ongoing review.
 8. Notice of time of completion of the study using **JEPeM-USM FORM 3(C) 2019: Final Report Form**.

Please note that forms may be downloaded from the JEPeM-USM website: www.jepem.kk.usm.my

JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

Thank you.

Sincerely,



PROF. DR. HANS AMIN VAN ROSTENBERGHE
Chairperson
Jawatankuasa Etika Penyelidikan (Manusia) JEPeM
Universiti Sains Malaysia

APPENDIX B INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE (IPAQ) (MALAY VERSION)

SOAL SELIDIK AKTIVITI FIZIKAL ANTARABANGSA

Kami berminat untuk mengetahui aktiviti fizikal yang dilakukan oleh masyarakat umum dalam kehidupan harian mereka. Soalan-soalan berikut akan menycaal anda tentang jumlah masa yang anda gunakan untuk berada dalam keadaan aktif secara fizikal dalam tempoh **7 hari yang lepas ini**. Sila jawab soalan-soalan ini walaupun anda berpendapat bahawa anda bukanlah seorang yang aktif. Sila fikirkan tentang aktiviti-aktiviti yang anda lakukan di tempat kerja, di rumah dan kawasan halaman, untuk bergerak dari satu tempat ke tempat yang lain, dan pada waktu luang untuk rekreasi, senaman atau bersukan.

Fikirkan tentang semua aktiviti fizikal **berat** dan **sederhana** yang anda telah lakukan dalam tempoh **7 hari yang lepas ini**. Aktiviti fizikal **berat** adalah aktiviti yang menggunakan daya tenaga fizikal yang kuat dan membuat anda bernaafas jauh lebih kuat daripada biasa. Aktiviti fizikal **sederhana** adalah aktiviti yang menggunakan daya tenaga fizikal yang sederhana dan membuatkan anda bernaafas agak lebih kuat daripada biasa.

BAHAGIAN 1: AKTIVITI FIZIKAL BERKAITAN DENGAN PEKERJAAN

Bahagian ini adalah berkenaan dengan pekerjaan anda. Ini termasuk kerja bergaji, bertani, kerja sukarela, kerja kursus dan lain-lain kerja tidak bergaji yang dilakukan di luar rumah. Kerja tidak bergaji yang dilakukan di sekitar rumah seperti kerja rumah, kerja laman, kerja pengurusan am dan menjaga keluarga tidak termasuk dalam bahagian ini kerana ia akan ditanya di bahagian 3.

1. Adakah anda kini mempunyai pekerjaan atau bekerja tanpa gaji di luar rumah?

Ya

Tiada → **Jawab BAHAGIAN 2: PENGANGKUTAN**

Soalan seterusnya berkenaan dengan semua aktiviti fizikal yang menjadi sebahagian daripada kerja bergaji atau kerja tanpa gaji anda yang telah dilakukan dalam tempoh **7 hari yang lepas ini**. Ini tidak termasuk bergerak ke kerja.

2. Dalam tempoh **7 hari yang lepas ini**, berapa harakah anda melakukan aktiviti fizikal **berat** seperti mengangkat barang berat, mencangkul, pembinaan berat atau menaiki tangga **sebahagian daripada pekerjaan anda**? Sila mempertimbangkan hanya aktiviti fizikal yang anda telah lakukan sekurang-kurangnya 10 minit pada satu masa.

_____ hari seminggu

Tiada aktiviti fizikal berat → **Jawab soalan 4**

3. Berapakah masa yang anda biasa gunakan untuk melakukan aktiviti fizikal **berat** pada salah satu daripada hari berkenaan **sebahagian daripada pekerjaan anda**?

_____ jam sehari
_____ minit sehari

4. Sekali lagi, fikirkan hanya tentang aktiviti-aktiviti fizikal yang anda telah lakukan selama sekurang-kurangnya 10 minit pada satu masa.
Dalam tempoh **7 hari yang lepas ini**, berapa harakah anda melakukan aktiviti fizikal **sederhana** seperti mengangkat beban ringan **sebahagian daripada pekerjaan anda?**
Ini tidak termasuk berjalan kaki.

_____ hari seminggu

Tiada aktiviti fizikal sederhana → **Jawab soalan 6**

5. Berapakah jangka masa yang anda biasanya luangkan untuk melakukan aktiviti fizikal **sederhana** pada salah satu daripada hari berkenaan **sebahagian daripada pekerjaan anda?**

_____ jam sehari
_____ minit sehari

6. Dalam tempoh **7 hari yang lepas ini**, berapa harakah yang anda telah luangkan untuk **berjalan** sekurang-kurangnya 10 minit pada satu masa **sebahagian daripada pekerjaan anda?** Ini tidak termasuk aktiviti berjalan anda untuk bergerak ke atau dari tempat kerja.

_____ hari seminggu

Tiada → **Jawab BAHAGIAN 2: PENGANGKUTAN**

7. Berapakah jangka masa anda luangkan untuk **berjalan** pada salah satu daripada hari berkenaan sebahagian perkerjaan anda?

_____ jam sehari
_____ minit sehari

BAHAGIAN 2: AKTIVITI FIZIKAL BERKAITAN DENGAN PENGANGKUTAN

Bahagian ini adalah mengenai cara anda bergerak dari satu tempat ke tempat lain termasuk tempat kerja, pasar raya, panggung wayang dan sebagainya.

8. Dalam tempoh **7 hari yang lepas ini**, berapa harikah anda telah menggunakan kenderaan bermotor seperti motosikal, kereta, bas, KTM (Keretapi Tanah Melayu), LRT (Light Rail Transit), KL Monorail atau kenderaan bermotor lain untuk bergerak?

_____ hari seminggu

Tiada → **Jawab soalan 10**

9. Berapakah jangka masa yang anda luangkan untuk manaiki motosikal, kereta, bas, KTM (Keretapi Tanah Melayu), LRT (Light Rail Transit), KL Monorail atau kenderaan bermotor yang lain pada salah satu daripada hari berkenaan?

_____ jam sehari

_____ minit sehari

Tumpukan pada waktu yang anda gunakan untuk **berbasikal** atau **berjalan** untuk pergi ke tempat kerja atau bergerak dari satu tempat ke tempat lain.

10. Dalam tempoh **7 hari yang lepas ini**, berapa harikah anda telah luangkan untuk **menunggang basikal** sekurang-kurangnya 10 minit pada satu masa untuk bergerak **dari satu tempat ke tempat yang lain**?

_____ hari seminggu

Tiada berbasikal → **Jawab soalan 12**

11. Berapakah jangka masa yang anda luangkan **menunggang basikal** untuk bergerak dari satu tempat ke tempat yang lain pada salah satu daripada hari berkenaan?

_____ jam sehari

_____ minit sehari

12. Dalam tempoh **7 hari yang lepas ini**, berapa harikah anda luangkan untuk **berjalan kaki** sekurang-kurangnya 10 minit pada satu masa untuk bergerak **dari satu tempat ke tempat yang lain**?

_____ hari seminggu

Tiada → **Jawab BAHAGIAN 3: KERJA RUMAH, PENGURUSAN RUMAH TANGGA, DAN PENJAGAAN KELUARGA**

13. Berapakah jangka masa biasanya anda **berjalan kaki** untuk bergerak dari satu tempat ke tempat yang lain pada salah satu daripada hari berkenaan?

_____ jam sehari

_____ minit sehari

BAHAGIAN 3: KERJA RUMAH, PENGURUSAN RUMAH TANGGA, DAN PENJAGAAN KELUARGA

Seksyen ini adalah berkenaan dengan aktiviti fizikal yang anda mungkin telah melakukan dalam tempoh **7 hari yang lepas ini** di sekitar rumah dan kawasan halaman, contohnya pekerjaan rumah tangga, berkebun, kerja laman, kerja pengurusan am, dan menjaga keluarga anda.

14. Sila rujuk pada aktiviti fizikal yang telah anda lakukan sekurang-kurangnya 10 minit pada sesuatu masa untuk menjawab soalan ini. Dalam tempoh **7 hari yang lepas ini**, berapa harikah anda telah melakukan aktiviti fizikal **berat**, contohnya mengangkat barang berat, memindah perabot, mencangkul **di taman atau halaman rumah**?

_____ hari seminggu

Tiada aktiviti fizikal di kawasan halaman → **Jawab soalan 16**

15. Berapakah masa yang anda biasanya gunakan untuk melakukan aktiviti fizikal **berat** pada salah satu daripada hari berkenaan **di taman atau halaman rumah**?

_____ jam sehari

_____ minit sehari

16. Sekali lagi, sila rujuk pada aktiviti fizikal yang telah anda lakukan sekurang-kurangnya 10 minit pada sesuatu masa untuk menjawab soalan ini. Dalam tempoh **7 hari yang lepas ini**, berapa harikah anda telah luangkan untuk melakukan aktiviti fizikal **sederhana**, contohnya mengangkat benda yang ringan, memotong rumput, menyapu laman, mencuci tingkap, mengecat dan membersihkan longkang di **taman atau halaman rumah**?

_____ hari seminggu

Tiada aktiviti fizikal di kawasan halaman → **Jawab soalan 18**

17. Berapakah jangka masa yang anda biasanya gunakan untuk melakukan aktiviti fizikal **sederhana** pada salah satu daripada hari berkenaan **di taman atau halaman rumah**?

_____ jam sehari

_____ minit sehari

18. Sekali lagi, sila rujuk pada aktiviti fizikal yang telah anda lakukan sekurang-kurangnya 10 minit pada sesuatu masa. Dalam tempoh **7 hari yang lepas ini**, berapa harikah anda telah melakukan aktiviti fizikal **sederhana**, contohnya mengangkat barang ringan, mengelap lantai, mencuci tingkap, vakum, menyapu, mencuci pakaian dengan tangan, memindah perabot dan memperbaiki alatan rumah tangga **dalam rumah**?

_____ hari seminggu

Tiada aktiviti fizikal di rumah → **Jawab BAHAGIAN 4: REKREASI, SUKAN DAN AKTIVITI FIZIKAL MASA LAPANG**

19. Berapakah jangka masa yang anda biasa luangkan untuk melakukan aktiviti fizikal **sederhana** pada salah satu daripada hari berkenaan di rumah?

_____ jam sehari

_____ minit sehari

BAHAGIAN 4: REKREASI, SENAMAN DAN AKTIVITI FIZIKAL MASA LAPANG

Seksyen ini adalah berkenaan dengan aktiviti fizikal yang anda telah melakukan dalam tempoh **7 hari yang lepas ini** pada waktu lapang untuk rekreasi, senaman atau bersukan. Harap anda tidak mengambil kira aktiviti-aktiviti yang telah anda sertakan di atas.

20. Dalam tempoh **7 hari yang lepas ini**, berapa harikah telah anda luangkan **berjalan kaki** selama sekurang-kurangnya 10 minit pada satu masa **pada waktu lapang?** Ini tidak termasuk segala maklumat berjalan yang telah anda sertakan sebelum ini.

_____ hari seminggu

Tiada berjalan kaki pada waktu lapang → **Jawab soalan 22**

21. Berapakah jangka masa yang anda biasanya gunakan untuk **berjalan kaki** pada salah satu daripada hari berkenaan pada waktu lapang?

_____ jam sehari
_____ minit sehari

22. Sila rujuk pada aktiviti fizikal yang anda telah lakukan selama sekurang-kurangnya 10 minit pada sesuatu masa. Dalam tempoh **7 hari yang lepas ini**, berapa harikah anda telah luangkan melakukan aktiviti fizikal **berat**, contohnya berjogging, badminton, bola keranjang, bola sepak, bola tampar, squash, senaman aerobik, berbasikal atau berenang cepat **pada waktu lapang?**

_____ hari seminggu

Tiada aktiviti fizikal berat pada waktu lapang → **Jawab soalan 24**

23. Berapakah jangka masa yang anda biasa luangkan untuk melakukan aktiviti fizikal **berat** pada salah satu daripada hari berkenaan pada waktu lapang?

_____ jam sehari
_____ minit sehari

24. Sekali lagi, sila rujuk pada aktiviti fizikal yang anda telah lakukan selama sekurang-kurangnya 10 minit pada sesuatu masa. Dalam tempoh **7 hari yang lepas ini**, berapa harikah anda telah melakukan aktiviti fizikal **sederhana** seperti berbasikal/berenang pada kelajuan biasa, bermain tenis beregu, bowling, golf, atau tenis meja **pada waktu lapang?**

_____ hari seminggu

Tiada aktiviti fizikal sederhana pada waktu lapang → **Jawab BAHAGIAN 5:
MASA DIGUNAKAN
UNTUK DUDUK**

25. Berapakah jangka masa yang anda biasa gunakan untuk melakukan aktiviti fizikal **sederhana** pada salah satu daripada hari berkenaan **pada waktu lapang?**

_____ jam sehari
_____ minit sehari

BAHAGIAN 5: MASA DIGUNAKAN UNTUK DUDUK

Bahagian terakhir ini adalah berkaitan dengan masa yang anda telah gunakan untuk **duduk** di tempat kerja, di rumah, sewaktu belajar dan pada masa lapang. Masa ini juga merangkumi waktu yang dihabiskan duduk di meja, menziarahi kawan-kawan, membaca, menduduk atau baring sambil menonton televisyen. Sila mengecualikan masa yang anda gunakan semasa menunggang motosikal atau di dalam kenderaan.

26. Dalam tempoh **7 hari yang lepas** ini, berapakah jangka masa yang anda telah gunakan untuk **duduk** pada **sesuatu hari bekerja**?

jam sehari
 minit sehari

27. Dalam tempoh **7 hari yang lepas** ini, berapakah jangka masa yang anda telah gunakan untuk **duduk** pada **hujung minggu**?

jam sehari
 minit sehari

Soal selidik tamat. Terima kasih atas penyertaan anda.

Translated and validated by Chu, A. H. Y., & Moy, F. M. (2012). Reliability and Validity of the Malay International Physical Activity Questionnaire (IPAQ-M) Among a Malay Population in Malaysia. Asia Pac J Public Health. [Epub ahead of print].

APPENDIX C IRRITABLE BOWEL SYNDROME- SEVERITY SCORING SYSTEM (IBS-SSS) (MALAY VERSION)

7/9/2021

Soal Selidik Tahap Sindrom Iritasi Usus (IBS-SSS)

Soal Selidik Tahap Sindrom Iritasi Usus (IBS-SSS)

ARAHAN

Borang ini direka bentuk untuk membolehkan kami memantau tahap Sindrom Gangguan Usus anda. Sindrom Gangguan Usus juga lebih dikenali dengan singkatan IBS yang mewakili Irritable Bowel Syndrome. Adalah dijangkakan bahawa gejala-gejala anda mungkin berbeza dari masa ke masa. Sila cuba menjawab soalan-soalan berdasarkan bagaimana anda rasa pada masa kini (iaitu dalam tempoh 10 hari yang lalu). Semua maklumat akan dirahsiakan. Soal selidik ini akan mengambil masa selama 10 minit. Kajian ini hanya bertujuan untuk pendidikan, dan bukan untuk tujuan komersial. Respon anda akan dirahsiakan. Terima kasih atas kerjasama anda.

Sekiranya anda mempunyai pertanyaan lanjut mengenai soal selidik ini, sila hubungi saya, Chang Zhuang Yu (011-28651233) atau Dr. Marilyn Ong Li Yin (010-5355200) (penyelia).

* Required

- Nombor Telefon *

Bahagian 1: Masalah Sakit Perut

016. Adakah anda kini sakit abdomen (perut)? *

Mark only one oval.

Ya

Tidak Skip to question 5

Bahagian 1: Masalah Sakit Perut

3. 017. Jika ya, berapa teruk sakit abdomen (perut) anda? *

Mark only one oval.

- Tidak sakit
- Tidak teruk
- Agak teruk
- Teruk
- Sangat teruk

4. 018. Sila masukkan jumlah hari anda sakit dalam masa 10 hari yang lalu. (contoh: Jika anda masukkan 4 maknanya anda sakit 4 hari dalam masa 10 hari. Jika sakit setiap hari masukkan angka 10) *
-

Bahagian 2: Masalah Kembung Perut

5. 019. Adakah anda menghadapi masalah kembung perut ? *

Mark only one oval.

- Ya
- Tidak *Skip to question 7*

Bahagian 2: Masalah Kembung Perut

6. 020. Jika ya, berapa teruk masalah kembung perut anda? *

Mark only one oval.

- Tiada
- Tidak teruk
- Agak teruk
- Teruk
- Sangat teruk

Bahagian 3: Tabiat Buang Air Besar

7. 021. Sejauh manakah anda puas hati dengan tabiat buang air besar anda? *

Mark only one oval.

- Sangat gembira
- agak gembira
- Tidak gembira
- Sangat tidak gembira

8. 022. Sila nyatakan sejauh mana Sindrom Gangguan Usus (IBS) memberi kesan atau mengganggu hidup anda secara umum? *

Mark only one oval.

- Tidak sama sekali
- Tidak banyak
- Agak banyak
- Sepenuhnya

9. 023. Berapakah jumlah paling banyak anda buang air besar setiap hari/minggu/bulan? (contoh: 1 kali sehari, 3 kali seminggu, 20 hari sebulan) *
-

10. 024. Berapakah jumlah paling sedikit anda buang air besar setiap hari/minggu/bulan? (contoh: 1 kali sehari, 3 kali seminggu, 20 hari sebulan) *
-

Pada soalan seterusnya, anda boleh tanda pada petak jawapan yang berkaitan dalam tempoh 10 hari yang lalu.

11. 9. Adakah najis anda: *

Mark only one oval per row.

	Kerap	Kadang-kadang	Tidak pernah
025. Normal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
026. Keras	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
027. Sangat nipis (seperti tali)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
028. Dalam kepingan kecil (seperti tahi arnab)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
029. Lembik (seperti bubur)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
030. Berair	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

12. 10. Pernahkah anda: *

Mark only one oval per row.

	Ya	Tidak
031. Meneran untuk membuang air besar	<input type="radio"/>	<input type="radio"/>
032. Buang mucus (lender atau jeli) dengan najis	<input type="radio"/>	<input type="radio"/>
033. Keluar darah dengan najis anda	<input type="radio"/>	<input type="radio"/>
034. Perlu bergegas / tergesa-gesa untuk ketandas	<input type="radio"/>	<input type="radio"/>
035. Rasa tidak buang air besar sepenuhnya selepas anda buang air besar	<input type="radio"/>	<input type="radio"/>
036. Sedar najis anda lebih kerap atau cair apabila anda mengalami kesakitan	<input type="radio"/>	<input type="radio"/>
037. Sedar bahawa kesakitan itu beransur pulih dengan membuang air besar	<input type="radio"/>	<input type="radio"/>

Bahagian 4: Kesan Sindrom Gangguan Usus (IBS) Terhadap Kehidupan

Sila menjawab semua soalan.

13. 039. Dalam tempoh 12 bulan yang lepas, berapa hari anda tidak hadir bekerja kerana Sindrom Gangguan Usus (IBS)? (contoh: 52 hari) *
-

14. 040. Dalam tempoh 12 bulan yang lepas, berapa hari anda mengalami Sindrom Gangguan Usus (IBS) di tempat kerja? (contoh: 52 hari) *
-
-

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<https://docs.google.com/forms/d/1HS5iji7ggRATMcHwtXu8I-0bzcVzTwN-CSm5qFlBaus/edit>

5/6

APPENDIX D EDUCATIONAL BACKGROUND, LIFESTYLE, DIETARY HABITS AND DENTAL STATUS QUESTIONNAIRE (MALAY VERSION)

7/9/2021

Hubungan Antara Tahap Aktiviti Fizikal yang Dilaporkan Sendiri dan Faktor-faktor Risiko Gaya Hidup dengan Skor Kekerapan Sindrom Irit...

Hubungan Antara Tahap Aktiviti Fizikal yang Dilaporkan Sendiri dan Faktor-faktor Risiko Gaya Hidup dengan Skor Kekerapan Sindrom Iritasi Usus (IBS) (Kod Etika: USM/JEPeM/21010021)

Kajian ini dilakukan oleh pensyarah dan pelajar Universiti Sains Malaysia sebagai sebahagian daripada kajian penyelidikan mengenai hubungan tahap aktiviti yang dilaporkan sendiri dan faktor risiko dengan skor keparahan sindrom iritasi usus (IBS). Soal selidik ini mengandungi soalan-soalan berkaitan latar belakang pendidikan, gaya hidup, tabiat pemakanan dan status perggian. Soal selidik ini akan mengambil masa selama 5 minit. Kajian ini hanya bertujuan untuk pendidikan, dan bukan untuk tujuan komersial. Respon anda akan dirahsiakan. Terima kasih atas kerjasama anda.

Sekiranya anda mempunyai pertanyaan lanjut mengenai soal selidik ini, sila hubungi saya, Chang Zhuang Yu (011-28651233) atau Dr. Marilyn Ong Li Yin (010-5355200) (penyelia).

Terima kasih atas kerjasama anda.

* Required

1. Adakah anda bersetuju untuk menyertai kajian ini? *

Mark only one oval.

Ya

Tidak

SOAL SELIDIK LATAR BELAKANG PENDIDIKAN, GAYA HIDUP,
GAYA PERMAKANAN DAN STATUS GIGI

ARAHAH

Sila menjawab semua soalan.

2. 1. Nama Peserta (nama penuh) *

3. 2. Numbor telefon (cth. 011-1234567) *

4. 3. Berapakah umur anda? *

5. 4. Jantina *

Mark only one oval.

Lelaki

Perempuan

6. 5. Berapakah berat badan (Kilogram) anda? *

7. 6. Berapakah tinggi (Meter) anda? *

8. 7. Apakah latar belakang pendidikan anda? *

Mark only one oval.

Sekolah rendah

Sekolah menengah

Diploma

Ijazah Universiti

Other: _____

9. 8. Adakah anda seorang perokok? *

Mark only one oval.

- Ya, saya seorang perokok *Skip to question 10*
- Tidak, saya tidak merokok *Skip to question 11*
- Saya pernah merokok dan telah berhenti merokok *Skip to question 10*

SOAL SELIDIK LATAR BELAKANG PENDIDIKAN, GAYA HIDUP,
GAYA PERMAKANAN DAN STATUS GIGI

ARAHAH

Sila menjawab
semua soalan.

10. 9. Jika anda seorang perokok, berapa kerap anda merokok? *

Mark only one oval.

- Kurang daripada 5 rokok sehari
- 5-10 rokok sehari
- Lebih daripada 10 rokok sehari

SOAL SELIDIK LATAR BELAKANG PENDIDIKAN, GAYA HIDUP,
GAYA PERMAKANAN DAN STATUS GIGI

ARAHAH

Sila menjawab
semua soalan.

11. 10. Adakah anda minum minuman beralkohol? *

Mark only one oval.

- Tidak, saya tidak minum minuman beralkohol
- Saya minum, tetapi sangat jarang
- Ya, saya selalu minum minuman beralkohol
- Ya, saya minum minuman beralkohol setiap hari

12. 11. Bagaimanakah cara makanan biasa anda? *

Mark only one oval per row.

	Tidak pernah	Sangat jarang	Kadang- kadang	Selalu	Setiap hari
Saya mengambil sarapan pagi pukul 6.00 pagi - 10.00 pagi	<input type="radio"/>				
Saya makan tengah hari saya pukul 12.00 tengah hari - 2.00 petang	<input type="radio"/>				
Saya makan malam saya pukul 6.00 petang - 9.00 malam	<input type="radio"/>				
Saya akan minum petang	<input type="radio"/>				
Saya mengambil santapan terakhir sebelum tidur	<input type="radio"/>				

13. 12. Pengambilan minuman semasa makan *

Mark only one oval.

- Tidak pernah
- Jarang
- Kadang-kala
- Selalu

14. 13. Kadar mengunyah makanan *

Mark only one oval.

- Banyak
- Serderhana
- Sedikit

15. 14. Jangkamasa makan *

Mark only one oval.

- Kurang daripada 10 minit
- Lebih daripada 10 minit

16. 15. Kekerapan tidak mengambil sarapan anda? *

Mark only one oval.

- Tidak pernah
- 1 hari seminggu
- 2-4 hari seminggu
- 5-6 hari seminggu
- Setiap hari

17. 16. Kekerapan pengambilan makanan pedas. *

Mark only one oval.

- Tidak pernah
- 1-3 kali seminggu
- 4-6 kali seminggu
- Lebih daripada 10 kali seminggu

18. 17. Kekerapan pengambilan makanan goreng.*

Mark only one oval.

- Tidak pernah
- 1-3 kali seminggu
- 4-6 kali seminggu
- Lebih daripada 10 kali seminggu

19. 18. Kekerapan pengambilan makanan ditapai. (cth., cili yang ditapai, budu, tempe dan lain-lain) *

Mark only one oval.

- Tidak pernah
- 1-3 kali seminggu
- 4-6 kali seminggu
- Lebih daripada 10 kali seminggu

20. 19. Status kesihatan gigi *

Mark only one oval.

- Tidak kehilangan gigi dan semua gigi adalah sihat
- Kehilangan 1-5 gigi
- Kehilangan lebih daripada 5 gigi

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Google Forms

APPENDIX E JEPeM- USM



JAWATANKUASA ETIKA PENYELIDIKAN (MANUSIA) – JEPeM USM UNIVERSITI SAINS MALAYSIA

TEMPLATE BORANG MAKLUMAT DAN KEIZINAN PESERTA TEMPLATE OF PARTICIPANT INFORMATION SHEET AND CONSENT FORM

(PROJEK PENYELIDIKAN) (RESEARCH PROJECT)

Borang Maklumat dan Keizinan Peserta yang digunakan dalam Projek Penyelidikan mestilah mengikuti format maklumat berikut. Namun begitu pernyataan dan ayat yang digunakan hanyalah sebagai panduan sahaja.

The Participant Infomation and Consent Form used in the Research Project must be according to these information formats. However, statements and phrases used only as a guide.

- Tajuk Kajian / Topic of the Research
- Pengenalan / Introduction
- Tujuan Kajian / Purpose of the Study
- Kelayakan Penyertaan / Participants Criteria
- Prosedur-prosedur Kajian / Study Procedures
- Risiko / Risks
- Melaporkan Pengalaman Kesihatan / Reporting Health Experiences
- Penyertaan dalam Kajian / Participation in the Study
- Manfaat yang Mungkin Diperolehi / Possible Benefits
- Soalan / Questions
- Kerahsiaan / Confidentiality
- Tandatangan / Signatures

Sebagai **CONTOH**, sila rujuk Borang Maklumat dan Keizinan Peserta yang dilampirkan.

As an **EXAMPLE**, please refer to the attached Participant Infomation Sheet and Consent Form.

(Versi Bahasa Malaysia) / (Bahasa Malaysia Version)

1. **LAMPIRAN A**
HUBUNGAN ANTARA TAHAP AKTIVITI FIZIKAL YANG DILAPORKAN SENDIRI DAN FAKTOR-FAKTOR RISIKO GAYA HIDUP DENGAN SKOR KEPARAHAAN SINDROM IRITASI USUS (IBS)
2. **LAMPIRAN S** (Borang Keizinan Peserta)
3. **LAMPIRAN G** (Borang Keizinan Peserta – Sampel Genetik)
4. **LAMPIRAN P** (Borang Keizinan Penerbitan Bahan yang Berkaitan dengan Peserta)

(Versi Bahasa Inggeris) / (English Version)

1. **ATTACHMENT B**
ASSOCIATIONS OF SELF-REPORTED PHYSICAL ACTIVITY LEVELS AND LIFESTYLE AND RISK FACTOR WITH IRRITABLE BOWEL SYNDROME SEVERITY SCORES

2. **ATTACHMENT S** (Participant Information and Consent Form)
3. **ATTACHMENT G** (Participant Information and Consent Form – *Genetic Sample*)
4. **ATTACHMENT P** (Participant's Material Publication Consent Form)

Information for researchers: This template serves only as an example for you to build your own Informed Consent form that suits the need and specificity of your research. **Yellow parts** in this template should be replaced with specific information related to your studies, or serve as an explanation to you. Before submitting to the JEPM-USM Secretariat, please make sure all the **yellow parts** are replaced with specific information of your research.

LAMPIRAN A

MAKLUMAT KAJIAN

Tajuk Kajian : HUBUNGAN ANTARA TAHAP AKTIVITI FIZIKAL YANG DILAPORKAN SENDIRI DAN FAKTOR-FAKTOR RISIKO GAYA HIDUP DENGAN SKOR KEPARAHAAN SINDROM IRITASI USUS (IBS)

Nama Penyelidik dan penyelidik bersama [sila sertakan no. Pendaftaran badan profesional (contoh MMC) sekiranya berkaitan] : Miss Chang Zhuang Yu
Dr. Marilyn Ong Li Yin
Dr. Vina Tan Phei Sean

PENGENALAN

Anda adalah dipelawa untuk menyertai satu kajian penyelidikan secara sukarela tentang hubungan antara tahap aktiviti fizikal yang dilaporkan sendiri dan faktor-faktor risiko gaya hidup dengan skor keparahan sindrom iritasi usus (IBS). Kajian ini melibatkan penggumpulan data melalui tiga set soalselidik iaitu Soal selidik Aktiviti Fizikal Antarabangsa (IPAQ), soalselidik tahap Sindrom Irritasi Usus (IBS-SSS) dan soal selidik gaya hidup, kebiasaan diet dan status kesihatan gigi. Kajian ini akan menentukan sama ada tahap aktiviti fizikal dan faktor-faktor tersebut akan mempengaruhi tahap keparahan IBS. Adalah penting bagi anda membaca dan memahami maklumat kajian sebelum anda bersetuju untuk menyertai kajian penyelidikan ini. Sekiranya anda menyertai kajian ini, anda akan menerima satu salinan borang ini untuk simpanan anda. Penyertaan anda di dalam kajian ini dijangka mengambil masa 30 minit secara keseluruhan. Seramai 48 orang dijangka akan menyertai kajian ini.

TUJUAN KAJIAN

Objektif Umum

Kajian ini bertujuan untuk meninjau hubungan antara tahap-tahap aktiviti fizikal yang dilaporkan sendiri, faktor-faktor gaya hidup dan skor keparahan sindrom iritasi usus (IBS).

Objektif Khusus

- i. Untuk menentukan perbezaan tahap aktiviti fizikal di kalangan pesakit IBS.
- ii. Untuk menentukan faktor-faktor risiko (tahap aktiviti fizikal dan gaya hidup) untuk skor keparahan IBS.

KELAYAKAN PENYERTAAN

Salah seorang kakitangan kajian akan membincangkan kelayakan untuk menyertai kajian ini. Kajian ini akan melibatkan individu yang:

1. Berumur 18 hingga 70 tahun
2. IBS didiagnosi dengan kriteria Rome III pada lawatan awal ke hospital, tanpa mengira subjenis.
3. Anda seorang pesakit IBS susulan.

Kajian ini tidak akan melibatkan individu yang:

1. Anda didiagnosi dengan gangguan gastrointestinal organik - Ulserasi kolitis, penyakit Crohn atau celiac.
2. Mengambil ubat penahan sakit, ubat penenang usus, antibiotik, antidepresan, ubat antikolinergik atau anti-cirit-birit dalam tiga bulan terakhir.
3. Anda didiagnosis dengan penyakit kardiopulmonari.
4. Mengandung (bagi wanita)
5. Anda didiagnosi dengan diabetes mellitus jenis 1 dan 2
6. Pernah menjalani pembedahan usus
7. Mengalami kecederaan muskuloskeletal akut yang mengehadkan aktiviti fizikal

PROSEDUR-PROSEDUR KAJIAN

Sebagai langkah pertama, pesakit IBS yang telah mendapatkan rawatan dari Hospital Universiti Sains Malaysia akan dihubungi melalui pesanan teks (khidmat pesanan ringkas; SMS) atau WhatsApp untuk menjemput mereka untuk menjadi peserta kajian ini. Sekiranya anda berminat dengan kajian ini, anda akan diberi penerangan tentang prosedur dan objektif kajian. Sekiranya anda bersetuju untuk menyertai kajian ini, anda akan memberikan persetujuan melalui borang tinjauan dalam talian. Kemudian, anda akan ditemuramah melalui telefon oleh seorang penyelidik yang telah dilatih untuk menerangkan cara-cara melengkapkan soal selidik IPAQ, IBS-SSS, gaya hidup dan kebiasaan diet serta borang data demografi peribadi di atas talian. Data anda akan disimpan dengan penuh kerahsiaan dan tidak akan disebarluaskan kepada orang lain yang tidak berkaitan dengan kajian ini melainkan jika dikehendaki perlindungan daripada undang-undang.

Masa keseluruhan untuk melengkapkan tiga set borang soalselidik adalah 30 minit iaitu IPAQ, (10 minit) IBS-SSS (10 minit) dan gaya hidup, kebiasaan diet serta borang data demografi peribadi (10 minit).

Anda akan melaporkan tahap aktiviti fizikal anda pada borang soal selidik IPAQ (versi panjang) yang mempunyai 27 bahagian yang merangkumi pelbagai domain, intensiti dan tempoh aktiviti fizikal. Maklum balas dari anda akan dianalisa dalam tiga kategori tahap aktiviti fizikal iaitu rendah, sederhana dan tinggi.

IBS-SSS digunakan untuk menentukan keparahan gejala IBS. Soal selidik tersebut mempunyai lima bahagian pertanyaan tentang keparahan sakit perut, kekerapan sakit perut, keparahan distensi perut, ketidakpuasan terhadap tabiat usus dan gangguan terhadap kualiti hidup selama sepuluh hari kebelakangan ini. Soal selidik ini terdiri daripada skala analog visual 100 mata. Skornya berkisar antara 0 hingga 500, peserta dengan skor 75-175 diklasifikasikan sebagai ringan, sementara skor kumpulan sederhana dalam julat 176-300, dan untuk skor kumpulan yang teruk adalah lebih dari 300 mata.

Soal selidik ketiga mempunyai pertanyaan tentang status merokok, tabiat pemakanan seperti keteraturan makan, kecukupan mengunyah, kadar makan, pengambilan minuman semasa

makan serta kekerapan kelewatan makan sarapan, pengambilan makanan pedas, makanan yang ditapai dan makanan yang digoreng. Anda juga akan ditanya mengenai status kesihatan gigi anda.

RISIKO

Bagi mengelakkan risiko penularan virus Covid-19 pada masa kini, adalah penting untuk anda mengikuti prosedur operasi standard Kementerian Kesihatan Malaysia. Oleh itu, untuk melindungi keselamatan anda, anda tidak perlu melawat ke Universiti Sains Malaysia. Penyelidik akan berhubung dengan anda melalui telefon dan menggunakan soal selidik atas talian untuk menjalankan kajian ini untuk mengelakkan pertemuan secara fizikal.

Sila maklumkan kepada kakitangan kajian sekiranya anda menghadapi sebarang masalah atau mempunyai sebarang maklumat penting yang mungkin mengubah persetujuan anda untuk terus menyertai kajian ini.

MELAPORKAN PENGALAMAN KESIHATAN (Jika Kajian Melibatkan Kesihatan SAHAJA)

Sila hubungi **Chang Zhuang Yu** di **011-28651233** pada bila-bila masa sekiranya anda mengalami sebarang masalah kesihatan, samada berkaitan atau tidak berkaitan dengan kajian dengan secepat mungkin.

PENYERTAAN DALAM KAJIAN

Penyertaan anda dalam kajian ini adalah secara sukarela. Anda berhak menolak penyertaan kajian ini atau menamatkan penyertaan anda pada bila-bila masa, tanpa sebarang kehilangan manfaat yang sepatutnya anda perolehi.

Penyertaan anda juga mungkin boleh diberhentikan oleh penyelidik tanpa persetujuan anda sekiranya anda didapati tidak sesuai untuk meneruskan kajian ini berdasarkan protokol kajian. Penyelidik akan memaklumkan anda sekiranya anda perlu diberhentikan dari menyertai kajian ini.

MANFAAT YANG MUNGKIN [Manfaat terhadap Individu, Masyarakat, Universiti]

Prosedur kajian ini akan diberikan kepada anda tanpa kos. Anda boleh menerima maklum balas mengenai tahap aktiviti fizikal anda, IBS-SSS, gaya hidup, pengambilan makanan dan status perggian. Dengan menjawab soalselidik ini, anda dapat menyumbangkan kepada projek penyelidikan dengan membantu para penyelidik memahami faktor-faktor yang mempengaruhi syndrom iritasi usus. Maklumat ini dapat membantu penyelidik melaporkan strategi pencegahan yang dapat meringankan keadaan penghidap IBS.

Anda tidak akan menerima sebarang pampasan kerana menyertai kajian ini.

PERSOALAN

Sekiranya anda mempunyai sebarang soalan mengenai prosedur kajian ini atau hak-hak anda, sila hubungi;

Dr. Marilyn Ong Li Yin
Pensyarah Program Sains Sukan
Universiti Sains Malaysia Kampus Kesihatan
16150 Kubang Kerian, Kelantan
Tel no.: 09-7677579/09-7677830

Chang zhuang yu
Pelajar Tahun (3) Sains Sukan
Univeriti Sains Malaysia Kampus Kesihatan
16150 Kubang Kerian, Kelantan
Tel no.: 011-28651233

Sekiranya anda mempunyai sebarang soalan berkaitan kelulusan Etika atau sebarang pertanyaan dan masalah berkaitan kajian ini, sila hubungi;

En. Mohd Bazlan Hafidz Mukrim
Setiausaha Jawatankuasa Etika Penyelidikan (Manusia) USM
Bahagian Penyelidikan dan Inovasi (P&I)
USM Kampus Kesihatan.
No. Tel: 09-767 2354 / 09-767 2362
Email : bazlan@usm.my

ATAU

Cik Nor Amira Khurshid Ahmed
Sekretariat Jawatankuasa Etika Penyelidikan (Manusia) USM
Pejabat Pengurusan dan Kreativiti Penyelidikan (RCMO)
USM Kampus Induk, Pulau Pinang.
No. Tel: 04-6536537
Email: noramira@usm.my

KERAHSIAAN

Maklumat yang anda berikan akan dirahsiakan oleh kakitangan kajian. Ianya tidak akan dedahkan secara umum melainkan jika ia dikehendaki oleh undang-undang.

Data yang diperolehi dari kajian ini tidak akan mengenalpasti anda secara perseorangan. Hasil kajian mungkin akan diterbitkan untuk tujuan perkongsian ilmu.

Semua borang kajian dan data yang anda berikan termasuk rekod perubatan anda yang asal mungkin akan disemak oleh pihak penyelidik, Lembaga Etika kajian ini dan pihak berkuasa regulatori bagi tujuan mengesahkan prosedur dan/atau data kajian klinikal. Maklumat anda akan disimpan dalam komputer dan hanya kakitangan kajian yang dibolehkan sahaja dibenarkan untuk mendapatkan dan memproses data tersebut.

Dengan menandatangani borang persetujuan ini, anda membenarkan penelitian rekod, penyimpanan maklumat dan pemprosesan data seperti yang dihuraikan di atas.

TANDATANGAN

Untuk dimasukkan ke dalam kajian ini, anda atau wakil sah anda mesti menandatangani serta mencatatkan tarikh halaman tandatangan (Lihat contoh Borang Keizinan Peserta di **LAMPIRAN S atau LAMPIRAN G (untuk sampel genetik) atau LAMPIRAN P**).

LAMPIRAN S

Borang Keizinan Peserta (Halaman Tandatangan)

Tajuk Kajian: HUBUNGAN ANTARA TAHAP AKTIVITI FIZIKAL YANG DILAPORKAN SENDIRI DAN FAKTOR-FAKTOR RISIKO GAYA HIDUP DENGAN SKOR KEPARAHAN
SINDROM IRITASI USUS (IBS)

Nama Penyelidik: Cik Chang Zhuang Yu
Dr. Marilyn Ong Li Yin
Dr. Vina Tan Phei Sean

Untuk menyertai kajian ini, anda atau wakil sah anda mesti menandatangani mukasurat ini. Dengan menandatangani mukasurat ini, saya mengesahkan yang berikut:

- Saya telah membaca semua maklumat dalam Borang Maklumat dan Keizinan Pesakit ini **termasuk apa-apa maklumat berkaitan risiko yang ada dalam kajian** dan saya telah pun diberi masa yang mencukupi untuk mempertimbangkan maklumat tersebut.
- Semua soalan-soalan saya telah dijawab dengan memuaskan.
- Saya, secara sukarela, bersetuju menyertai kajian penyelidikan ini, mematuhi segala prosedur kajian dan memberi maklumat yang diperlukan kepada doktor, para jururawat dan juga kakitangan lain yang berkaitan apabila diminta.
- Saya boleh menamatkan penyertaan saya dalam kajian ini pada bila-bila masa.
- Saya telah pun menerima satu salinan Borang Maklumat dan Keizinan Peserta untuk simpanan peribadi saya.

Nama Peserta

No. Kad Pengenalan Peserta

Tandatangan Peserta atau Wakil Sah

Tarikh (dd/MM/yy)
(Masa jika perlu)

Nama & Tandatangan Individu yang Mengendalikan
Perbincangan Keizinan

Tarikh (dd/MM/yy)

Nama Saksi dan Tandatangan

Nota: i) Semua peserta yang mengambil bahagian dalam projek penyelidikan ini tidak dilindungi insuran.

Tarikh (dd/MM/yy)

**Borang Keizinan Peserta untuk Pengambilan Sampel Genetik
(Halaman Tandatangan)**

Tajuk Kajian: HUBUNGAN ANTARA TAHAP AKTIVITI FIZIKAL YANG DILAPORKAN SENDIRI DAN FAKTOR-FAKTOR RISIKO GAYA HIDUP DENGAN SKOR KEPARAHAN SINDROM IRITASI USUS (IBS)

Nama Penyelidik: Cik Chang Zhuang Yu
Dr. Marilyn Ong Li Yin
Dr. Vina Tan Phei Sean

Untuk menyertai kajian ini, anda atau wakil sah anda mesti menandatangani mukasurat ini. Dengan menandatangani mukasurat ini, saya mengesahkan yang berikut:

- Saya telah membaca semua maklumat dalam Borang Maklumat dan Keizinan Pesakit ini **termasuk apa-apa maklumat berkaitan risiko yang ada dalam kajian** dan saya telah pun diberi masa yang mencukupi untuk mempertimbangkan maklumat tersebut.
- Semua soalan-soalan saya telah dijawab dengan memuaskan.
- Saya, secara sukarela, bersetuju menyertai kajian penyelidikan ini, mematuhi segala prosedur kajian dan memberi maklumat yang diperlukan kepada doktor, para jururawat dan juga kakitangan lain yang berkaitan apabila diminta.
- Saya boleh menamatkan penyertaan saya dalam kajian ini pada bila-bila masa.
- Saya telah pun menerima satu salinan Borang Maklumat dan Keizinan Peserta untuk simpanan peribadi saya.

Nama Peserta

No. Kad Pengenalan Peserta

Tandatangan Peserta atau Wakil Sah

Tarikh (dd/MM/yy)
Masa (jika perlu)

Nama & Tandatangan Individu yang Mengendalikan Perbincangan Keizinan

Tarikh (dd/MM/yy)

Nama Saksi dan Tandatangan

Nota:

- i) Lebihan sampel kajian ini akan dilupuskan dan tidak akan digunakan untuk tujuan lain kecuali setelah mendapat kebenaran daripada Jawatankuasa Etika Penyelidikan (Manusia), USM.
- ii) Semua peserta yang mengambil bahagian dalam projek penyelidikan ini tidak dilindungi insuran.

Borang Keizinan bagi Penerbitan Bahan yang berkaitan dengan Peserta Kajian (Halaman Tandatangan)

Tajuk Kajian: **HUBUNGAN ANTARA TAHAP AKTIVITI FIZIKAL YANG DILAPORKAN SENDIRI DAN FAKTOR-FAKTOR RISIKO GAYA HIDUP DENGAN SKOR KEPARAHAN SINDROM IRITASI USUS (IBS)**

Nama Penyelidik: **Cik Chang Zhuang Yu**
Dr. Marilyn Ong Li Yin
Dr. Vina Tan Phei Sean

Untuk menyertai kajian ini, anda atau wakil sah anda mesti menandatangani mukasurat ini.

Dengan menandatangani mukasurat ini, saya memahami yang berikut:

- Bahan yang akan diterbitkan tanpa dilampirkan dengan nama saya dan setiap percubaan yang akan dibuat untuk memastikan ketanpanamaan saya. Saya memahami, walaubagaimanapun, ketanpanamaan yang sempurna tidak dapat dijamin. Kemungkinan sesiapa yang menjaga saya di hospital atau saudara dapat mengenali saya.
- Bahan yang akan diterbitkan dalam penerbitan mingguan/bulanan/dwibulanan/suku tahunan/dwi tahunan merupakan satu penyebaran yang luas dan tersebar ke seluruh dunia. Kebanyakan penerbitan ini akan tersebar kepada doktor-doktor dan juga bukan doktor termasuk ahli sains dan ahli jurnal.
- Bahan tersebut juga akan dilampirkan pada laman web jurnal di seluruh dunia. Sesetengah laman web ini bebas dikunjungi oleh semua orang.
- Bahan tersebut juga akan digunakan sebagai penerbitan tempatan dan disampaikan oleh ramai doktor dan ahli sains di seluruh dunia.
- Bahan tersebut juga akan digunakan sebagai penerbitan buku oleh penerbit jurnal.
- Bahan tersebut tidak akan digunakan untuk pengiklanan ataupun bahan untuk membungkus.

Saya juga memberi keizinan bahawa bahan tersebut boleh digunakan sebagai penerbitan lain yang diminta oleh penerbit dengan kriteria berikut:

- Bahan tersebut tidak akan digunakan untuk pengiklanan atau bahan untuk membungkus.
- Bahan tersebut tidak akan digunakan di luar konteks – contohnya: Gambar tidak akan digunakan untuk menggambarkan sesuatu artikel yang tidak berkaitan dengan subjek dalam foto tersebut.

Nama Peserta

No. Kad Pengenalan Peserta

T/tangan Peserta

Tarikh (dd/MM/yy)

Nama & Tandatangan Individu yang Mengendalikan
Perbincangan Keizinan

Tarikh (dd/MM/yy)

Nota: i) Semua peserta yang mengambil bahagian dalam projek penyelidikan ini tidak dilindungi insuran.

ATTACHMENT B

RESEARCH INFORMATION

Research Title: ASSOCIATIONS OF SELF-REPORTED PHYSICAL ACTIVITY LEVELS AND LIFESTYLE RISK FACTORS WITH IRRITABLE BOWEL SYNDROME SEVERITY SCORES

Researcher's Name: Miss Chang zhuang yu
Dr. Marilyn Ong Li Yin
Dr. Vina Tan Phei Sean

INTRODUCTION

You are invited to take part voluntarily in a research study on the associations of self-reported physical activity levels and lifestyle risk factors with irritable bowel syndrome severity score. This study is conducted by collecting data through three sets of questionnaires which are the International Physical Activity Questionnaire (IPAQ), Irritable Bowel Syndrome Severity Scoring System (IBS-SSS) and assessment of risk factors questionnaire which includes lifestyle, dietary behaviour and dental health status. This study will determine the physical activity levels and the risk factors that will influence the severity of IBS. It is important that you read and understand this research information before agreeing to participate in this study. You will receive a copy of this form to keep for your records if you agree to participate. It also describes the alternative procedure that are available to you and your right to withdraw from this study at any time. Your participation in this study is expected to last up about 30 minutes in total. Total number of participants in this study is **48 people.**

PURPOSE OF THE STUDY

General Objective

To explore relationship between various components of self-reported physical activity levels, lifestyle factors and irritable bowel severity score in irritable bowel syndrome (IBS) patients.

Specific Objective

- i. To determine the difference in physical activity levels among IBS patients.
- ii. To determine the risk factors (physical activity levels and lifestyle) for IBS severity scores.

PARTICIPANTS CRITERIA

The research team members will discuss your eligibility to participate in this study.

This study will include individual who are:

1. Age 18 to 70 years old
2. IBS diagnose with Rome III criteria on the initial visit, regardless of subtypes
3. Follow-up IBS patients

This study will not include individual who are:

1. Diagnosed as organic gastrointestinal disorder – Ulceration colitis, Crohn's or celiac disease
2. Taking painkillers, intestinal relaxants, antibiotics, antidepressants, anticholinergic or anti-diarrheal medications in the past three months

3. Diagnosed with cardiopulmonary disease
4. Currently pregnant
5. Diagnosed with type 1 and 2 diabetic mellitus
6. Had bowel surgery
7. Have acute musculoskeletal injuries that limit physical activity

STUDY PROCEDURES

First, IBS patients, who previously sought treatment from the Hospital Universiti Sains Malaysia, will be contacted via a text message (short messaging service; SMS) or WhatsApp to invite them to be part of this study. If you are interested in this study, you will be briefed of the procedures and the study objective. If you agree to volunteer in this study, you will provide consent via online survey form. You will be interviewed over the phone by trained a researcher to complete the IPAQ, IBS-SSS, lifestyle and dietary questionnaires and the personal demographic data form. Your data will be treated with full confidentiality and will not be released to others outside of this study unless required by law.

You will spend about 30 minutes to completes the three sets of questionnaires. As you will spend about 10 minutes in IPAQ, 10 minutes in IBS-SSS questionnaire and 10 minutes in the lifestyle and dietary questionnaires and personal demographic data form.

You will report your physical activity levels on the long form of IPAQ questionnaire which compromises 27 items that includes data indifferent domains, physical activity intensities and duration. The responses from you will be presented as categorical data on low, moderate, and high physical activity levels.

IBS-SSS is used to determine the severity of the IBS symptoms. It has five items that ask about the severity of abdominal pain, frequency of abdominal pain, the severity of abdominal distension, dissatisfaction with bowel habits and interference with quality of life over the past ten days. It consists of a 100-point visual analogue scales. The score ranges from 0 to 500, the participant with scores of 75-175 can be classified as mild, while moderate group scores in the range of 176-300, and for the severe group scores are more than 300.

The third questionnaire will assess the smoking status, dietary habits such as meal regularity, chewing sufficiency, eating rate, intra-meal fluid intake as well as the frequency of skipping breakfast meals, spicy food intake, the quantity of

consumed spices, fried and fermented food consumption. You will also be asked about your dental health status.

RISKS

Due to the pandemic Covid-19, it is important to follow the Ministry of Health Malaysia's standard operational procedure to prevent the virus spreading. In order to protect your safety without travelling to Universiti Sains Malaysia, we use online questionnaires to conduct this study to prevent face-to-face meeting.

REPORTING HEALTH EXPERIENCES.

Please contact, at any time, the following researcher if you experience any health problem either directly or indirectly related to this study, make sure that you immediately report to the researcher **Chang Zhuang Yu** at **011-28651233**.

POSSIBLE BENEFITS [Benefit to Individual, Community, University]

By participating in this study, you will receive feedback on your current physical activity levels, IBS-SSS, lifestyle, food intake and dental status. You will be contributing your effort in a research project to obtain useful information to improve the prevention strategies that may alleviate the condition of IBS sufferers.

QUESTIONS

If you have any question about this study or your rights, please contact;

Dr. Marilyn Ong Li Yin
Pensyarah Program Sains Sukan
Universiti Sains Malaysia Kampus Kesihatan
16150 Kubang Kerian, Kelantan
Tel no.: 09-7677579/09-7677830

Sukan
Chang Zhuang Yu
Pelajar Tahun (3) Program Senaman dan Sains
Univeriti Sains Malaysia Kampus Kesihatan
16150 Kubang Kerian, Kelantan
Tel no.: 011-28651233

If you have any questions regarding the Ethical Approval or any issue / problem related to this study, please contact;

Mr. Mohd Bazlan Hafidz Mukrim
Secretary of Human Research Ethics Committee USM
Division of Research & Innovation (R&I)
USM Health Campus
Tel. No. : 09-767 2354 / 09-767 2362
Email : bazlan@usm.my

OR

Miss Nor Amira Khurshid Ahmed
Secretariat of Human Research Ethics Committee USM
Research Creativity & Management Office (RCMO)
USM Main Campus, Penang

Tel. No. : 04-6536537
Email : noramira@usm.my

CONFIDENTIALITY

Your information will be kept confidential by the researchers and will not be made publicly available unless disclosure is required by law.

Data obtained from this study that does not identify you individually will be published for knowledge purposes.

Your original records may be reviewed by the researcher, the Ethical Review Board for this study, and regulatory authorities for the purpose of verifying the study procedures and/or data. Your information may be held and processed on a computer. Only research team members are authorized to access your information.

By signing this consent form, you authorize the record review, information storage and data process described above.

SIGNATURES

To be entered into the study, you or a legal representative must sign and date the signature page **[ATTACHMENT S or ATTACHMENT G (for genetic sample only) or ATTACHMENT P]**

ATTACHMENT S

Subject Information and Consent Form (Signature Page)

Research Title: ASSOCIATIONS OD SELF-REPORTED PHYSICAL ACTIVITY ACTIVITY LEVELS AND LIFESTYLE RISK FACTORS WITH IRRITABLE BOWEL SYNDROME SEVERITY SCORES

Researcher's Name: Miss Chang Zhuang Yu
Dr. Marilyn Ong Li Yin
Dr. Vina Tan Phei Sean

To become a part this study, you or your legal representative must sign this page. By signing this page, I am confirming the following:

- I have read all of the information in this Patient Information and Consent Form **including any information regarding the risk in this study** and I have had time to think about it.
- All of my questions have been answered to my satisfaction.
- I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.
- I may freely choose to stop being a part of this study at anytime.
- I have received a copy of this Participant Information and Consent Form to keep for myself.

Participant Name

Participant I.C No

Signature of Participant or Legal Representative

Date (dd/MM/yy)

Name of Individual
Conducting Consent Discussion

Signature of Individual
(dd/MM/yy)
Conducting Consent Discussion

Date

Name & Signature of Witness

Date (dd/MM/yy)

Note: i) All participants who are involved in this study will not be covered by insurance.

ATTACHMENT G

**Subject Information and Consent Form
(Signature Page – Genetic Sample)**

Research Title: **ASSOCIATIONS OF SELF-REPORTED PHYSICAL ACTIVITY LEVELS AND LIFESTYLE RISK FACTORS WITH IRRITABLE BOWEL SYNDROME SEVERITY SCORES**

Researcher's Name: **Miss Chang Zhuang Yu**
Dr. Marilyn Ong Li Yin
Dr. Vina Tan Phei Sean

To become a part this study, you or your legal representative must sign this page. By signing this page, I am confirming the following:

- I have read all of the information in this Patient Information and Consent Form **including any information regarding the risk in this study** and I have had time to think about it.
- All of my questions have been answered to my satisfaction.
- I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.
- I may freely choose to stop being a part of this study at anytime.
- I have received a copy of this Participant Information and Consent Form to keep for myself.

Participant Name

Participant I.C No.

Signature of Participant or Legal Representative

Date (dd/MM/yy)

Name of Individual
conducting Consent Discussion

Signature of Individual
Conducting Consent Discussion

Date (dd/MM/yy)

Name & Signature of Witness
(dd/MM/yy)

Date

- Note:
- i) All participants who are involved in this study will not be covered by insurance.
 - ii) Excess samples from this research will not be used for other reasons and will be destroyed with the consent from the Human Research Ethics Committee, USM.

ATTACHMENT P

Participant's Material Publication Consent Form Signature Page

Research Title: **ASSOCIATIONS OF SELF-REPORTED PHYSICAL ACTIVITY LEVELS AND LIFESTYLE RISK FACTORS WITH IRRITABLE BOWEL SYNDROME SEVERITY SCORES**

Researcher's Name: **Miss Chang Zhuang Yu**
Dr. Marilyn Ong Li Yin
Dr. Vina Tan Phei Sean

To become a part this study, you or your legal representative must sign this page.

By signing this page, I am confirming the following:

- I understood that my name will not appear on the materials published and there have been efforts to make sure that the privacy of my name is kept confidential although the confidentiality is not completely guaranteed due to unexpected circumstances.
- I have read the materials or general description of what the material contains and reviewed all photographs and figures in which I am included that could be published.
- I have been offered the opportunity to read the manuscript and to see all materials in which I am included, but have waived my right to do so.
- All the published materials will be shared among the medical practitioners, scientists and journalist world wide.
- The materials will also be used in local publications, book publications and accessed by many local and international doctors world wide.
- I hereby agree and allow the materials to be used in other publications required by other publishers with these conditions:
- The materials will not be used as advertisement purposes nor as packaging materials.
- The materials will not be used out of context – i.e.: Sample pictures will not be used in an article which is unrelated subject to the picture.

Participant Name

Participant I.C No.

Participant's Signature

Date (dd/MM/yy)

Name and Signature of Individual
Conducting Consent Discussion

Date (dd/MM/yy)

Note: i) All participants who are involved in this study will not be covered by insurance.