

**DEVELOPMENT, VALIDATION AND THE
EFFECTS OF CULTURALLY SPECIFIC GUIDED
IMAGERY AND PROGRESSIVE MUSCLE
RELAXATION AUDIO FOR PATIENTS WITH
FUNCTIONAL ABDOMINAL BLOATING**

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UNIVERSITI SAINS MALAYSIA

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FUNCTIONAL ABDOMINAL BLOATING**

by

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LIST OF SYMBOLS

δ	Difference between parameters
χ^2	Chi square
F	F Statistics
N	Number of items
n	Frequency
λ	Factor loading
Σ	Summation of all values
η^2	Eta-squared
β	probability of Type II error/regression coefficient
p	Constant (for sample size calculation)
α	significance level/probability of a type I error
a	Constant (for regression formula)
p	p value

LIST OF ABBREVIATIONS

AB	Abdominal Bloating
AGFI	Adjusted Goodness Fit Indices
ANS	Autonomic Nervous System
BLQoL	Bloating Quality of Life
BMRI-2	Brunel Music Rating Inventory-2
BSQ	Bloating Severity Questionnaire
CFA	Confirmatory Factor Analysis
CFI	Comparative Fit Index
CI	Confidence Interval
DGBI	Disorder of Gut-brain Interaction
DSM	Diagnostic and Statistical Manual
EEG	Electroencephalogram
EFA	Exploratory Factor Analysis
ERP	Event-Related Potential
FAB	Functional Abdominal Bloating
FC	Functional Constipation
FD	Functional Dyspepsia
FDr	Functional Diarrhea
FGID	Functional Gastrointestinal Disorder
GBA	Gut-brain Axis
GFI	Goodness of Fit Index
GI	Guided Imagery
GIT	Gastrointestinal tract
HRV	Heart Rate Variability
HB-Bloat	Health Belief for Bloating Scale
HPB-Bloat	Health Promoting Behavior for Bloating Scale
HUSM	Hospital Universiti Sains Malaysia
IBS	Irritable Bowel Syndrome
IDI	In-depth Interview
JEPeM	Jawatankuasa Etika Penyelidikan Manusia (Human Research Ethics Committee)
MAUQ	mHealth App Usability Questionnaire

PHT	Persuasive Health Technology
RMSEA	Root Mean Square Error of Approximation
SCT	Social Cognitive Theory
SD	Standard Deviation
SDT	Social Determination Theory
SEM	Structural Equation Modeling
SPSS	Statistical Product and Service Solutions
SRMR	Standardized Root Mean Square Residual
SS-Bloat	Social Support for Bloating Scale

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**PEMBENTUKAN, KESAHAN DAN KESAN AUDIO TERAPI IMEJAN
BERPANDU DAN AUDIO RELAKSASI OTOT PROGRESIF BAGI
PESAKIT BERGEJALA KEMBUNG PERUT FUNGSIAN**

ABSTRAK

Pasukan Kerja Rome telah mengesyorkan terapi minda-badan, termasuk Imejan Berpanduan (Guided Imagery, GI) dan Kelonggaran Otot Progresif (Progresif Muscle Relaxation, PMR) telah lama digunakan sebagai modality terapeutik untuk pelbagai gejala. Bagaimanapun, kesesuaian dan keberkesanannya dalam merawat pesakit dengan DGBI di Malaysia masih tidak dikaji secara mendalam. Kajian ini boleh dibahagikan kepada tiga fasa utama. Fasa 1 melibatkan pembentukan dan pengesahan audio GI dan PMR khusus untuk pesakit. Pada permulaannya, skrip audio direka menurut sorotan literatur dan penemuan-penemuan melalui temuduga mendalam dengan pesakit yang mengalami kembung perut berdasarkan kriteria Rome IV. Skrip telah dibuat pengesahan menggunakan skala psikometrik (indeks kesahan kandungan dan permukaan) dan parameter fisiologi [(potensi berkaitan peristiwa otak (Evoked Resting Potential, ERP) & kebolehubahan kadar jantung (Heart Rate Variability, HRV)]. 35 daripada 63 peserta telah ditemuduga dalam temu ramah mendalam. Penemuan daripada temu ramah itu termasuklah kemunculan 'belon' sebagai penerangan imejan sinonim untuk kembung, di mana perut kembung itu dikaitkan dengan rasa sakit. Kemudian, skrip dinukilkan dan digabungkan dengan muzik latarbelakang yang telah disahkan. Secara keseluruhan, indeks kesahan kandungan dan permukaan untuk PMR dan GI adalah di antara 0.92 - 1.00. Untuk ERP dan HRV, 17/20 peserta telah dianalisis. Untuk ERP, terdapat perbezaan yang ketara antara GI dan PMR untuk gelombang alfa ($p = 0.029$), gelombang delta ($p = 0.029$) dan antara PMR dan kawalan untuk gelombang delta ($p = 0.014$). Untuk HRV, kedua-

dua GI dan PMR menunjukkan respon autonomik yang sama terhadap kawalan dengan perbezaan signifikan dalam kalangan nisbah Frekuensi Rendah/Frekuensi (keseluruhan $p < 0.05$). Fasa 2 bertujuan untuk menghasilkan dan mengesahkan aplikasi telefon khas yang membantu perjalanan audio untuk kajian ini. Hasil daripada soal selidik kami, Malay-version mHealth App Usability Questionnaire (MAUQ) menunjukkan skala yang memuaskan (5.45-5.85/7.00). Tambahan lagi, sebanyak 132 peserta telah dibahagikan secara rawak kepada 3 kumpulan (GI, PMR, kawalan). Penemuan daripada 96 hasil kajian telah dianalisis. Perubahan yang signifikan didapati dalam Keterukan Umum (Severity General), Keterukan dalam 24 jam (Severity in 24 hours), Kualiti Kehidupan (Quality of Life), Sikap yang Mendorong ke arah Kesihatan (Health-Promoting Behavior), dan pemboleh ubah kebimbangan (anxiety variables). Hanya pemboleh ubah kebimbangan menunjukkan perubahan signifikan antara kumpulan ($p = 0.027$) dan antara interaksi masa*kumpulan ($p < 0.001$).

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ABDOMINAL BLOATING**

ABSTRACT

The Rome Working Team had recommended the use of brain-gut behaviour therapies in treating Disorders of Gut-brain Interaction (DGBI). Mind-body techniques, including Guided Imagery (GI) and Progressive Muscle Relaxation (PMR) has been long used as therapeutic modalities for various disorders. However, its relevance and efficacy in treating patients with DGBI in Malaysia is still unexplored. The study herein aimed to develop, validate, and explore the effects of audio-based GI and PMR techniques on patients with functional abdominal bloating. The study can be divided into three main phases. Phase 1 involves the development and validation of culturally specific GI and PMR audios. Initially, the audio scripts were drafted according to literature reviews and findings from in-depth interviews with participants diagnosed with bloating based on the Rome IV criteria. Scripts were validated using psychometric (content and face validity index) and physiological parameters [(brain event-related potentials (ERP) & heart rate variability (HRV)]. 35/63 participants completed the in-depth interview. The findings include the frequent usage of ‘balloon’ as a synonymous imagery description for bloating, of which the sensation of bloatedness is association with pain. Eventually, the scripts were narrated and compiled with a validated musical backgrounds. Overall, the content and face validity index for PMR and GI ranged from 0.92 - 1.00. For ERP and HRV, 17/20 participants were analysed. For ERP, there were significant difference between GI and PMR for alpha waves ($p=0.029$), delta waves ($p=0.029$) and between PMR and control for delta

waves ($p=0.014$). For HRV, both GI and PMR exhibited similar autonomic responses over controls with significant difference among Low Frequency/High Frequency ratio, Total Power, Low Frequency, and Respiratory Rate (overall $p<0.05$). Phase 2 involves the development and validation of a mobile application that helps to facilitate the delivery of the audios. The validation process involves inviting expert panels, volunteers, and participants with bloating to rate and navigate the application. Feedbacks and comments were noted. Revision was made accordingly. The findings from the Malay-version mHealth App Usability Questionnaire (MAUQ) indicate satisfactory levels (5.45-5.85/7.00). Furthermore, 132 participants were randomly assigned into three groups (GI, PMR, control), each receiving different audios. Findings from 96 participants were analysed. Significant differences were observed in terms of time effect among the Severity General, Severity in 24 hours, Quality of Life, Health-Promoting Behaviour, and anxiety variables. Only anxiety showed significant changes among the group ($p=0.027$) and time*group interaction ($p<0.001$).

CHAPTER 1

INTRODUCTION

1.1 Overview

Abdominal bloating (AB), a typically observed gastrointestinal symptom that affects many, regardless of their gender and age. Often, AB is associated with feeling of excessive gas, abdominal rumbling, and frequent burping (Foley et al., 2014). Asians commonly depicts this type of feeling as a sensation of “having a lot of gases” (Seo et al., 2013). Meanwhile, in Malaysia, terms like “kembung” (bloated), “angin”, and “sengkak” (tightness) were used.

In conjunction, abdominal distention (AD) is described as a measurable physical increment of abdominal circumference/girth. AD often co-exist with AB, although they may occur independently (Lacy et al., 2021; Lacy et al., 2016). Distinguishing of both symptoms may prove to be a challenge due to the nature of its overlapping occurrence.

To date, there are multiple disorders and illnesses associated with AB and AD. The possible causal relationship of both symptoms could not be distinguished due to its complexity. The differential diagnosis of both symptoms includes both functional and organic disorders, further contributing to its diagnostic dilemma among clinicians. Having said that however, our present study only focuses on symptoms originating from the Functional Gastrointestinal Symptoms (FGID) or better known as Disorders of Gut-brain Interactions (DGBIs) spectrums.

1.1.2 Definition

The vague description of AB may prove to be a challenge for clinicians to differentiate the nature of the disease. To better distinguish the symptoms, the ROME Foundation has established a diagnostic algorithm to classify symptoms based on their presentations (Lacy et al., 2016). Our current study centrals around the definition according to the ROME IV criteria for FAB (Figure 1.1). The current studies only cover AB that are “functional” and arises from the DGBI spectrums.

ROME IV Diagnostic Criteria

Diagnostic Criteria for Functional Abdominal Bloating/Distention

Must include both/one of the following:

1. Recurrent feeling of bloating or visible distention for at least 1 days per week, on average, at least day per week; abdominal bloating and/or distention predominates over other symptoms.
2. There are **insufficient criteria for a diagnosis** of irritable bowel syndrome, functional constipation, functional diarrhea, or postprandial distress syndrome.
 - The onset of symptoms for at least 6 months prior to diagnosis, presence of symptoms for at least 3 months.
 - Mild pain related to bloating may be present as well as minor bowel movement abnormalities.

Figure 1.1 ROME IV Diagnostic Criteria for FAB, adapted from Lacy et al., 2016

1.1.3 Epidemiology

A large-scale multinational study shows that more than 40% of the global population are affected by Functional Gastrointestinal Disorders (Sperber et al., 2021). FAB is a common symptom affecting up to 76% of patients with FGIDs (Ryu et al., 2016). Interestingly, only 40-60% of them visited the outpatient Gastroenterology clinic (Lackner et al., 2014).

Among Asian populations, the prevalence rate of AB varies from 15%-23% (Lacy et al., 2011). Malaysia, a nation in South-East Asia has an estimated population of 32.7 million in 2020 (Department of Statistics Malaysia, 2020) has a total of 19.7%

prevalence rates of its population affected with FGIDs (Sperber et al., 2021). Among them, 0.9% are having functional bloating/distention.

1.2 Problem Statement

Although bloating is deemed as a less urgent from a clinicians' view of point perspective, it still impacts one's ability to work, participate in social or recreational activities, and their quality of life (Lacy et al., 2016). A survey from the United States had reported that at least 65% of patients with bloating rated as moderate to severe for the symptoms and the complaints of decreased in physical activity due to bloating increased up to 54%; where 43% of them took medication for bloating or needed medication (Sandler et al., 2000). Bloating could be disturbing to the patients and causes frustration to the physician because there is still a lack of effective treatments recommended (Lacy et al., 2011). This is because the symptom has no known aetiology, and their symptoms oftentimes mimic those of 'organic' diseases with underlying physical pathology. Hence, FGIDs are often a source of frustration for physicians and of despair for patients, their families, and friends. Moreover, the costs - direct and indirect - associated with FGIDs impose a significant burden on our health care systems (Lackner et al., 2014).

1.3 Rationale of Study

The pathophysiology of bloating is complicated and poorly understood by clinicians and researchers. Intestinal gas production and transit, gut microflora, and visceral hypersensitivity of the patient's gut are suggested as the causes of symptom generations (Lacy et al., 2011). The possible factors are still inconclusive, yet various complications are explained (Seo et al., 2013). Although no treatment is universally regarded as an effective treatment for bloating, several new interventions have

developed during the past half-decade (Lacy et al., 2011). However, as it is still affecting individuals' quality of life, it becomes a concern to be addressed by many clinicians and the health care provider. In more severe patients, psychological and social factors exert a particularly strong influence on the expression of GI symptoms and related distress (Lackner et al., 2014). The concept of the biopsychosocial model was introduced as appropriate. It is important to emphasise that although psychological stresses and disorders do not exhibit causal relationship with FGIDs, they do play a role in worsening the GI symptoms. Regardless of its relationship with FGIDs, psychological issues should be addressed as necessary (Wilkinson et al., 2019).

1.3.1 The Biopsychosocial model

The biopsychosocial model of FGIDs holds that individual biology (e.g. genetic predisposition, GI physiology), behavior, and higher-order cognitive processes (e.g. coping, illness beliefs, abnormal central processing of gut stimuli) influence FGIDs through their interaction with each other, with early-life factors (e.g. trauma, negative learning experiences), and with the individual's social and physical environments (e.g. reinforcement contingencies, interpersonal stress) (Van Oudenhove et al., 2016). At its core, the model acknowledged that FGIDs involve a dysregulation in interactions among the cognitive and emotional centers of the central nervous system (CNS), the immune system, the neuroendocrine system, and the enteric nervous system. Although alterations at any level of the neuroenteric axis may result in hallmark features of symptoms of FGIDs, a string of literatures had undermined the role of CNS activity in modulating symptoms, specifically among severely affected patients referred to tertiary healthcare facilities (Lackner et al., 2014).

Notwithstanding, psychological factors may play a major part in one's physiological responses (Dickhaus et al., 2003; Murray et al., 2004), illness behaviors

(Levy et al., 2000; Turner & Aaron, 2001), patients' beliefs (Galloway, 2003; Jones et al., 2015), and psychological vulnerability factors (Chitkara et al., 2008; Drossman, 2011; Levy et al., 2004; Videlock et al., 2009). More research is needed to understand, modulate, and enhance patients' health beliefs, intentions, and behaviour toward abdominal bloating and the relationship with their quality of life. Cultural-specific aspects should be considered as well in improving the treatment of patients with FGIDs in conjunction with the ROME IV Multidimensional Clinical Profile (MDCP) developed and introduced by the ROME Foundation (Drossman, 2017; Ghoshal, 2020; Hou et al., 2018).

1.3.2 Psychological Interventions

Owing to its somewhat unique nature of the disease, patients with FGIDs are treated with behavioural and psychological therapies (Foley et al., 2014; Palsson & Whitehead, 2013). Techniques such as hypnosis, cognitive behavioural therapy (CBT), and mindful breathing were generally preferred and even recommended by gastroenterologists from the American Gastroenterological Association and the American College of Gastroenterology (Palsson, 2015). Various evidence from various reviews has positive outcomes and are supportive towards the implementation of such techniques (Black et al., 2020; Palsson & Whitehead, 2013; Whitehead, 2006).

Guided Imagery (GI) therapy, a common mind-body relaxation therapy utilizes the projection of a pleasant image in facilitating relaxation among individuals (Dukic et al., 2021; Nguyen & Brymer, 2018). By using themes such as relaxation places, serene and tranquil sceneries, participants are guided to create an ambient safe zone that shelter them from untoward and negative thoughts. The therapy is further enhanced by involving different sensory receptors (sound, light, taste, sight, and touch). These stimuli will eventually be used to transform the pain and tension into other forms of

comfort and relaxation (Coelho, 2018; Draucker et al., 2015). Alternatively, Progressive Muscle Relaxation (PMR) is well renowned in the clinical and rehabilitative field as an alternative means for reducing stress, anxiety, pain, and discomfort in chronically ill patients. PMR focuses on tightening and relaxing specific muscle groups of the body to achieve a state of relaxation (Toussaint et al., 2021). The goal of PMR is to achieve a state of relaxation by tensing and relaxing specific muscles of the body (Hashim & Hanafi Ahmad Yusof, 2011; Rizal, Hajar, Kuan, et al., 2019).

1.3.3 Mobile Applications

According to Sperber et al., the prevalence of FGIDs is increased in the younger populations and in women (Sperber et al., 2021). As such, it is of utmost importance to design a therapeutic mode of delivery that suits the culture and social aspect. In bridging the gap and removing various health-seeking barriers, efforts had been made in accordance with the Sustainable Development Goals (SDG) 3: Good Health and Well-being (Schwan, 2019).

Malaysia has a mobile penetration rate of 144.8% as of the year 2019, with a 63.6% of its population reportedly owning at least a smartphone (Lee et al., 2019). Instinctively, the gradually increasing trend indicates that more and more Malaysians are having a mobile phone at their disposal. Looking from the perspective of exposure time, an average Malaysian spends around 8 hours and 5 minutes using the internet via any device (Digital Influence Lab, 2020). This further solidify the fact that mobile applications may be a pertinent component in delivering healthcare information and facilitating disease management.

Furthermore, a mobile application that caters functions such as reminder, symptoms tracker, dietary diary feature, educational content, communications with therapists are important to detect possible triggers and long-term lifestyle modifications.

Additionally, a session with the therapists is time consuming and expensive. Patients will need to undergo multiple sessions to complete a course. A mobile application that allows patients to listen to the therapeutic audio at their discrete and on demand is crucial in removing various health seeking barriers. This is extremely relevant during the global pandemic period. Hence, paradigm shift had to be implemented to facilitate the delivery health-related management,

1.4 Significance of Study

Our study focuses on developing a suitable treatment modality that tackles the problems faced by patients suffering from FAB in a multidimensional angle. Health education plays an important role in reducing clinical symptoms and improving overall health condition (Rota et al., 2011). We would like to include educational content related to gastrointestinal diseases, specifically on knowledge about FAB to educate patients. Moreover, treatment approaches among patients from the DGBI spectrums should encompass psychological and supportive aspects that caters not just the clinical symptoms but also the mental wellbeing, quality of life, health promoting behaviour, and health beliefs dimension.

To this end, psychological therapeutic interventions have been increasingly developed and employed as either a stand-alone treatment or adjunct therapy for patients with FGIDs. Despite its abundance usage, a robust methodology on its development is seldom addressed in recent literatures. Herein, we would like to introduce a novel approach in providing supportive therapy to patients with abdominal bloating symptoms through a gut-directed guided imagery (GI) and progressive muscle relaxation (PMR) technique.

We would highlight the methodology employed throughout the development and validation process of the audio. Furthermore, a preliminary finding in terms of the physiological changes (evoked resting potential and heart rate variability) elicited during the hearing sessions would also be reported. Also, we would delineate the development and validation of a mobile application, specifically designed for users facing FAB symptoms. Lastly, we would explore the effects of the relaxation audios (GI and PMR) on patients with FAB symptoms.

1.5 Research Objectives

To examine the effects of guided imagery vs progressive muscle relaxation on symptom severity, health beliefs, intention, health promoting behaviour, social support, quality of life, anxiety and depression, brain wave changes, and heart rate variability among patients with FAB.

1.5.1 Phase 1

1. To develop and validate cultural-specific guided imagery and progressive muscle relaxation audios for patients with FAB symptoms.
2. To examine the mean difference between intervention and control groups in terms of their physiological changes: heart rate variability and brainwave changes among patients with FAB symptoms.

1.5.2 Phase 2

1. To develop and validate a mobile application specifically designed for patients with FAB symptoms

1.5.3 Phase 3

1. To examine the mean difference between intervention and control groups in terms of their clinical features: symptom severity and quality of life among patients with FAB symptoms.
2. To examine the time effects between intervention and control groups in terms of their symptom severity, health beliefs, intention, health promoting behaviour, social support, anxiety, and depression among patients with FAB symptoms.
3. To examine the group effects in terms of symptom severity, health beliefs, intention, health promoting behaviour, quality of life, social support, anxiety, and depression among patients with FAB symptoms.
4. To examine the interaction effects (time*groups) in terms of symptom severity, health beliefs, intention, health promoting behaviour, quality of life, social support, anxiety, and depression among patients with FAB symptoms.

1.6 Research Hypotheses

1.6.1 Phase 1

1. There are significant mean differences between intervention and control groups in terms of their physiological changes: heart rate variability and brainwave changes among patients with FAB symptoms.

1.6.2 Phase 2

Not applicable

1.6.3 Phase 3

1. There are significant mean differences between intervention and control groups in terms of their clinical features: symptom severity and quality of life among patients with FAB symptoms.
2. There are significant time effects between intervention and control groups in terms of their symptom severity, health beliefs, intention, health promoting behaviour, social support, anxiety, and depression among patients with FAB symptoms.
3. There are significant group effects in terms of symptom severity, health beliefs, intention, health promoting behavior, quality of life, social support, anxiety, and depression among patients with FAB symptoms.
4. There are significant interaction effects (time*groups) in terms of symptom severity, health beliefs, intention, health promoting behaviour, quality of life, social support, anxiety, and depression among patients with FAB symptoms.

1.7 Organisation of the thesis

The thesis is organised into 10 chapters. Chapter 1 provides a brief introduction on the study. Chapter 2 describes the relevant literature reviews that gives an insight on published studies related to FAB. Then, Chapter 3 talks about the methodology used in Phase 1 of the study while Chapter 4 describes its results. This is followed by Chapter 5 that describes the research methods and Chapter 6 describes the results of Phase 2 study respectively. Chapter 7 and Chapter 8 elaborate on the methods and results for Phase 3 respectively. Meanwhile, Chapter 9 discuss about the findings based on specific research objectives in this study. The last chapter, Chapter 10 delineates the conclusions, limitations, and recommendations for future study.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

This chapter provided the state of art on scientific information related to AB. This review focused on the research questions and objectives as stated in the previous chapter. This chapter was organised into 10 sections: database and search results, ROME IV Diagnostic Criteria, relevant theories, psychological theories, relevance of mobile applications in healthcare, gaps in literatures, variables, and measurement tools. This chapter ends with the conceptual framework of the present study.

2.2 Database and Search Terms

The search engines that were used include Scopus, Google Scholar, Pubmed, and EBSCOhost using keywords listed in the table below (Table 2.1). Eventually, the information used in this study was revised and selected based on the suitability to the present study.

Publication date was set at 2010 to 2021. Article types are limited to systematic review, meta-analysis, clinical trials, review articles, and observational study. Conference proceedings and pre-prints were excluded. Only English language and human studies are selected. Next, the information to be used in the study was revised and chosen based on the suitability to the present study.

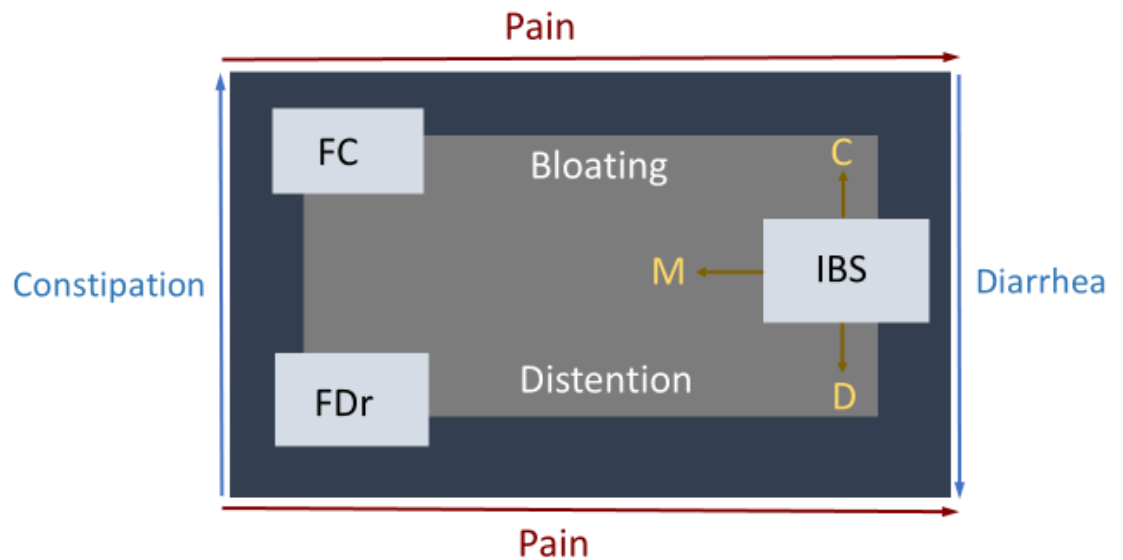
Table 2.1 Summary of literature search for the present study

	Search engine			
	Google Scholar	PubMed	Scopus	EBSCOhost
Using Boolean operators and keywords (example)				
“Abdominal bloating” AND “Theory of Planned Behavior”	15	1	1	2
“Health belief” AND “abdominal bloating”	34	1	1	13
“Intention” AND “abdominal bloating”	1140	7	10	378
“Health promoting behaviour” AND “abdominal bloating”	3	1	1	0
“Abdominal bloating” AND “severity”	6140	68	106	1904
“Abdominal bloating” AND “quality of life”	5840	75	88	1693
“Abdominal bloating” AND “social support”	383	1	1	101
“Abdominal bloating” AND “brainwave”	8	0	0	2
“Abdominal bloating” AND “heart rate”	1330	3	7	291

2.3 ROME IV Criteria

The ROME diagnostic criteria was formed through expert consensus. The first meeting, held in Rome, was tasked in forming a shared consensus in diagnosing Irritable Bowel Syndrome (IBS). Since its inception in 1990, the ROME foundation has established symptom-based criterias periodically in aiding gastroenterologist with their diagnosis and deepening the understanding on FGID. The latest edition of the ROME Diagnostic Criteria, Rome IV, released in May of 2016 has been used as the benchmark of the current study (Lacy et al., 2016). Having said so however, ROME IV considers functional bowel disorders exist as a continuum rather than as an isolated diagnosis. Notwithstanding, bloating and/or distension are common symptoms that are frequently

observed and reported by patients under the functional bowel disorder spectrum, as shown below (Figure 2.1).



- FC: Functional Constipation
- FDr: Functional Diarrhea
- IBS-C: Irritable Bowel Syndrome with Predominant Constipation
- IBS-D: Irritable Bowel Syndrome with Predominant Diarrhea
- IBS-M: Irritable Bowel Syndrome with Predominant Irregular Bowel Habits (mixed D/C)

Figure 2.1 Conceptual framework on functional bloating/distention (FBD) symptoms, adapted from Lacy et al., 2016.

The FBDs are classified into 5 distinct categories: IBS, FC, FD, and unspecified FBD. Although often thought of as existing as separate and discrete disorders, it is important to acknowledge that significant overlap exists between these disorders. This figure illustrates that a patient with IBS (right) will have symptoms of abdominal pain, in contrast to a patient with FC or FDr, who does not have abdominal pain. Bloating and distention are common symptoms frequently reported by patients with any FBD.

2.4 Related Theories

2.4.1 Multidimensional Clinical Profile (MDCP)

Since the inception of the ROME IV Criteria, the ROME Foundation has increased its emphasis on ethnocentric focus to bridge the multi-cultural gaps in addressing the global perspective of the FGIDs (Drossman, 2017). In the “Multi-cultural Aspects in Functional Gastrointestinal Disorders (FGIDs) chapter, the interaction between culture and FGIDs are explained (Francisconi et al., 2016; Schmulson & Drossman, 2017). Focuses were brought to the physicians and patients’ perspective, dietary habit, culture, and local-beliefs in interpreting the symptoms (Francisconi et al., 2016). Culture defined as the values, beliefs, norms, and practices of a particular group that are learned and shared may guide, thinking, decisions, and actions (Ballard, 2002). The explanatory models of the FGIDs in the “health-seeking intentions” context encompasses patients’ beliefs. It may influence their concerns, anxieties, and expectations of the health care process (Casiday et al., 2008; Zhang et al., 2020). Thus, imposing an effect on their clinical symptoms. Hence, it is important to understand and treat the patients through a “multi-dimensional clinical profile” (shown in Figure 2) kaleidoscope (Schmulson & Drossman, 2017).

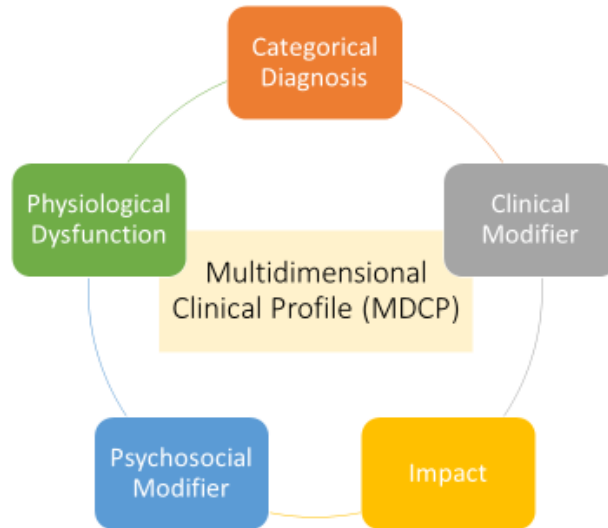


Figure 2.2 The multidimensional clinical profile of FGIDs explores 5 aspects that needs to be targeted in patients’ management.

The Categorical Diagnosis delineates the importance of a symptom-based diagnostic criteria, which may include physiological criteria. Clinical Modifier explores the innate characteristics of the FGIDs (e.g., IBS-C, D, M; post-infection aetiology; FODMAP sensitivity). The impact illustrates the severity of the disease in their life and how it affects their daily activities. It can be classified as mild, moderate, and severe. Psychosocial Modifier can be traced back to early childhood abuse history or a correlation with the Diagnostic and Statistical Manual of Menal Disorders (DSM) 5 diagnosis spectrum (Tandon, 2014). Lastly, the physiological dysfunction and biomarkers may give clue to the types and severity of the FGIDs patient are facing.

2.4.2 The Biopsychosocial Model

It is well established that the etiology and treatment modalities of FGIDs should be multicentric and comprehensive. The Biopsychosocial model (Figure 2.3) further elaborate the inclusion of dietitians and psychologists in the treatment modalities of patients with FGIDs (Van Oudenhove et al., 2016). Several studies have recommended

the application of antibiotic, hypnosis, and dietary intervention in relieving the occurrence of bloating in daily life (Azpiroz & Malagelada, 2005; Pimentel et al., 2006; Zar et al., 2002). Physicians should be prepared and open minded to work in a multicultural milieu in addressing patients' clinical symptoms. Awareness should be emphasised on how religion and culture could affect treatment modalities in the Complementary and Alternative Medicine aspect (Francisconi et al., 2016).

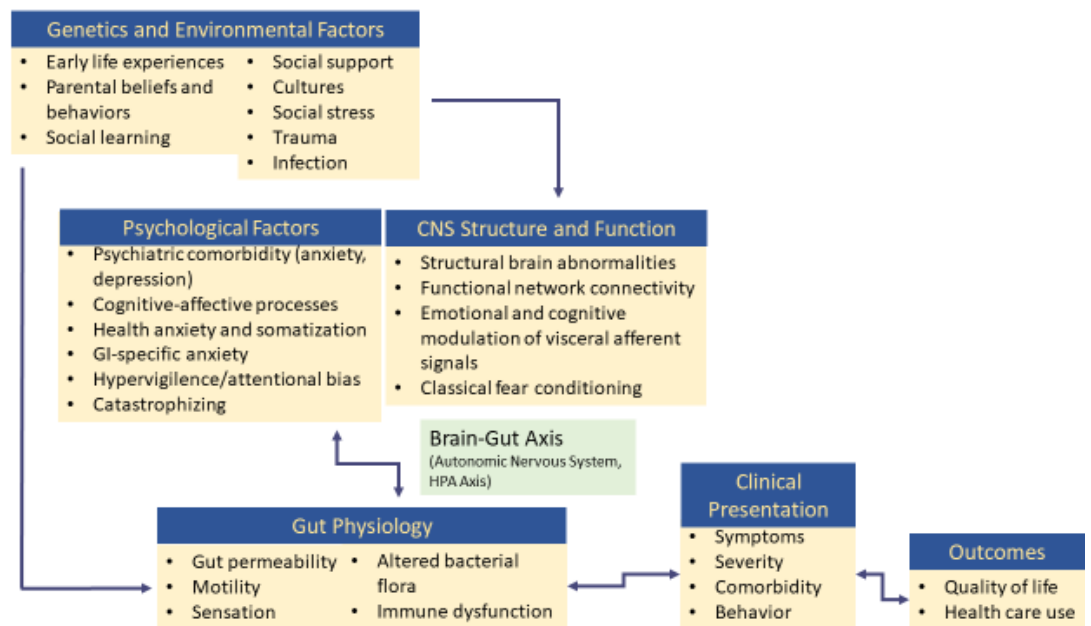


Figure 2.3 Biopsychosocial Model of IBS adapted from Drossman et al., 2002

Genetic and environmental factors, such as early life experiences, trauma, and social learning, influence both the brain and the gut, which in turn interact bidirectionally via the autonomic nervous system and the HPA axis. The integrated effects of altered physiology and the person's psychosocial status will determine the illness experience and ultimately the clinical outcome. Furthermore, the outcomes will in turn affect the severity of the disorder. The implication is that psychosocial factors are essential to the understanding of IBS pathophysiology and the formulation of an effective treatment plan (Drossman et al., 2002).

Psychological treatments were reported to be able to improve the outcomes of patients with functional gastrointestinal disorder (Palsson & Whitehead, 2013). Psychological factors such as stressful life, anxiety, and depression have been identified as associated with poor outcomes in FGID patients (Levy et al., 2006; Van Oudenhove et al., 2011; Whitehead et al., 2002). Palsson and Whitehead (2013) reported that some studies using certain psychological intervention could markedly improve the symptoms of several FGIDs, include abdominal bloating. These psychological treatments would indirectly or directly enhance emotional well-being and quality of life of people with FGID and sometimes reduce the needs of getting health care attention (Palsson & Whitehead, 2013).

2.4.3 The Polyvagal Theory

The Polyvagal Theory reiterates the triadic relationship between the neurophysiological mechanisms, bio-behavioural process, and the psychophysiology variable (Porges, 2007). The theory emphasises on the activation of the autonomic nervous system and the vagal pathways in regulating the bodily physiology, intertwining with our primary emotions during a fight and flight situation or a social engagement. The theory further depicts why a soothing voice may dramatically change our perception; why stepping out of our social circle and meeting new people leads to anxiety; why our body response with rage when we are being bluntly accused. Most importantly, it helps to introduce mind-body relaxation techniques in adjusting to phobias, anxieties, and regulating to arousals. Hence, we presumed that this theory is relevant in our current study as it introduces a relaxation technique in counteracting a functional disorder.

2.4.4 The Gut-brain Axis

The Polyvagal Theory further helps to solidify the complex interaction between the “gut-brain axis” (GBA). The pertinent role of the brain in controlling emotional changes and cognitive functions may allusively influences the homeostasis, peristalsis activity, and motility of the gastrointestinal tract (Carabotti et al., 2015). The autonomic nervous system (ANS) serves as the communicating bridge that connects the brain (central nervous system) to the enteric nervous system (ENS), forming a bidirectional communication network.

In essence, information like traumatic memories or emotional derailments of thoughts detected by the limbic system in the brain would transmit neural and hormonal triggers, influencing the hypothalamic pituitary adrenal (HPA) axis. A constellation of hormonal changes will be secreted from the hypothalamus and eventually triggers the release of cortisol from the adrenal glands. Subsequently, the intestinal functional effector cells in the ENS would be affected, impacting the gut microbiome habitual environment (Mayer et al., 2014). This alteration, termed dysbiosis were often linked with psychological comorbid among patients with DGBI (Simrén et al., 2001; Simrén et al., 2013).

Furthermore, the dysbiosis of the microbiota will cause an altered expression of the neurotransmitters, disrupting the normal regulation of the GBA (Barbara et al., 2005; Berrill et al., 2013). In conjunction, the affected nervous system will in turn dysregulate the gut sensory-motor functions, causing delayed gastric emptying and intestinal transit (Abrams & Bishop, 1967; Diaz Heijtz et al., 2011).

2.4.5 Theory of Planned Behavior

Most of the healthcare conditions cases are preventable through early recognition and modification of healthy lifestyle choices (Rota et al., 2011). Thus,

lifestyle could be facilitated through a combination of efforts to increase awareness, change behaviour and to create an environment that supports good health practices (Viner & Macfarlane, 2005). Health behaviour had been linked to various variables that would enhance the overall beliefs that lead behaviour change. The determinants of health behaviour often operate simultaneously for health behaviour change. Due to the multifactorial influences on the outcome behaviour change, various psychological theories such as Health Beliefs Model (HBM) (Jones et al., 2015), Theory of Planned Behaviour (TPB) (Ajzen, 1991), Theory Reasoned Action (TRA) (Ajzen, 1991), and Pender's Health Promotion Model (PHP) (Pender et al., 2006) had been developed to predict health behaviours. The theory centralized on the three essential concepts to prompt action or intention including attitude (favour of behaviour), subjective norm (social pressure to act in a certain way) and perceived behavioural control (power that controls action). Behaviour, the central core in the TPB model, acts on the principle of compatibility instead of general behaviour.

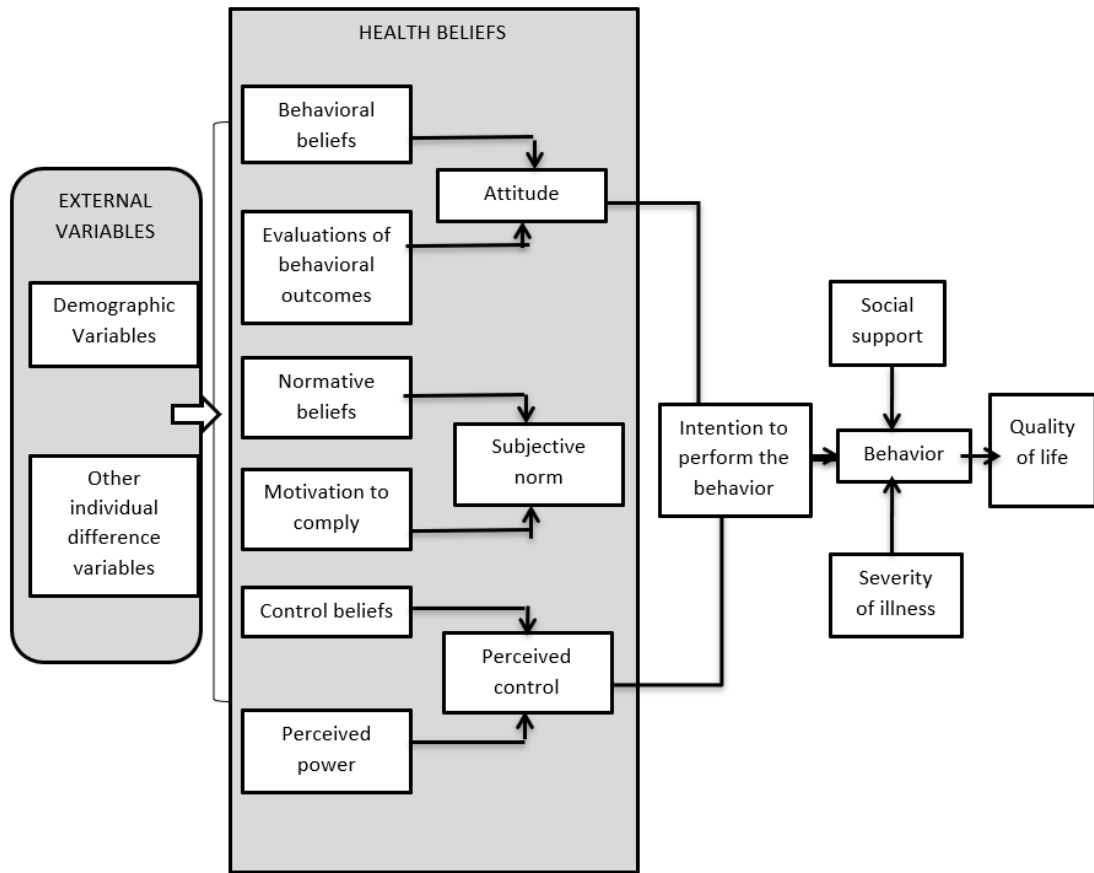


Figure 2.4 Conceptual framework of the relationship between health beliefs, health-seeking intention, severity of illness and quality of life

2.5 Psychological Interventions

2.5.1 Guided Imagery

The content of GI usually includes scenery, places or any image projected to the mind (Toussaint et al., 2021). By using information obtained, participants are guided to create a place in their mind using their senses of touch, sound, smell, sight, and taste. These stimuli will eventually be used to transform the pain and tension into other forms of objects or creative energy (Coelho, 2018). Subsequently, increasing their sense of control over their somatic responses. Guided Imagery may reduce autonomic nervous

system response. It blocks the transmission of painful stimuli through higher brain centres and has been widely used in managing patients with chronic pain such as recurrent fatigues, cancer, chronic headaches, and fibromyalgia (Coelho, 2018; Draucker et al., 2015; Elias et al., 2015; Menzies & Jallo, 2011). The 20-minute imagery therapy may exert beneficial effects by diverting patients' attention from the discomfort sensation of abdominal bloating as well as relieving abdominal muscle tension. Previous studies have demonstrated that these types of attentional diversion strategies are effective in reducing physical and psychological symptoms of distress and in improving symptoms control (Kwekkeboom et al., 2010; Kwekkeboom et al., 2008).

A meta-analysis reported that systematic use of imagery treatment and rehearsing in the mind has been shown to produce actual physical movements without any direct engagement (Van Kuiken, 2004). Study showed significant performance enhancement in weightlifting and shooting performance by applying 12 sessions of imagery treatment with unfamiliar relaxing music (Rizal, Hajar, Savardelavar, et al., 2019). Imagery is powerful because of it "selection of bodily pathways, an image held in the mind can literally affect every cell in the body" (Haase et al., 2005). Clinical applications of imagery have been emerging. This started back by Siegel in 1986, who encourage his cancer patients to conduct pictorial imagery on a generic topic such as mountain, sea, dream place, etc., had showed promising results (Siegel, 1999). The patients felt less pain, less anxious, and less depressed. However, no statistical analysis was reported. Recently, guided imagery therapy is an emerging form of therapy with many successful case studies especially in the music therapy field, for example, in altering patients' states of consciousness, physical rehabilitation, cognitive and behavioural impairments, emotional adjustment and many more (Burns, 2001; Coelho, 2018; Draucker et al., 2015; Menzies & Jallo, 2011; Van Kuiken, 2004). However, the

mechanism facilitating the imagery still not well understood in patients with FGID that include patients with abdominal bloating illness. Thus, more research is needed to examine the effect of imagery in improving the psychological well-being of patients with abdominal bloating illness.

2.5.2 Progressive Muscle Relaxation

The Progressive Muscle Relaxation (PMR) is chosen to function as a control in this intervention. PMR is well renowned in the clinical and rehabilitative field as an alternative means for reducing stress, anxiety, pain and discomfort in chronically ill patients. The technique utilizes a neuronal principle of “top-down” and “bottom-up” processing (Toussaint et al., 2021). Firstly, an individual utilizes the cerebral cortex and cerebellum (high cortical function) to initiate the contraction of muscles through the activation of neurons at the peripheral limbs (lower motor neurons), forming a “top-down” processing. Whilst the momentarily holding and gradual releasing of muscle produces proprioceptive stimulation at the lower motor neurons. Stimulatory passages were activated, sending the stimulus from the muscles (bottom) to the brainstem (up) (Keptner et al., 2021).

PMR can also be used to improve general health as well as being used for patients suffering from disease like cancer, hypertension, and cardiovascular disease as well as other chronic illnesses (Lu et al., 2020; Meyer et al., 2016; Zamenjani et al., 2019, Sadeghi et al., 2018). The relaxation provided by PMR can reduce pain, stress and depression (Nasiri et al., 2018). PMR had be effective in reducing stress. A study found that PMR were able to reduce test anxiety among a group of nursing students (Zargarzadeh & Shirazi, 2014). Notwithstanding, PMR also exhibits positive effects on patients suffering from heart disease by reducing depression and anxiety (Chaudhuri et al., 2020). PMR focuses on tightening and relaxing specific muscle groups of the body

to achieve a state of relaxation (Rizal et al., 2019). The goal of PMR is to achieve a state of relaxation by tensing and relaxing specific muscles of the body (Torales et al., 2020). This process would allow participants to distinguish between a relaxed muscle and a tensed one, which would usually be accompanied by anxiety and stress (Charalambous et al., 2016).

2.6 Mobile Applications in Healthcare

2.6.1 Persuasive Health Technology

Persuasive Health Technology (PHT) denotes a purposive technology, specifically designed to encourage, mold, nurture, and enhance one's health promoting behavior (McLean, 2020). PHT advocates the use of modern technology in inculcating and persuade one in adhering to a behavioral change in improving one's health status. Looking from the kaleidoscope of implementing a healthcare-related mobile application, essential positive influences may be imparted into human behavior. For instance, an individual empowered with the knowledge on cancer-like symptoms may be able to recognize the need and urgency to visit a doctor at its early phase, hence rectifying the cause and further contributes to disease control at its early stage. Furthermore, with sufficient information, one could be aware of the importance of leading a healthy lifestyle and thus leading to a better healthcare.

2.6.2 Social Cognitive Theory

The Social Cognitive Theory (SCT) asserts that cognition, behavior, and environmental influences interact with and reinforce one another to impact health behavior (Frey, 2018). Observation on the behaviors of others may lead to a reciprocal mimicry of the behavior. The abundance usage of mobile application may elicit a trend in improving the healthcare quality of the others within the same social circle. Hence,

creating a movement of social networking that aspire for a better quality of healthcare pursuit.

2.6.3 Current Trend

Mobile application has successfully improved treatment adherence (Pérez-Jover et al., 2019). A national survey revealed that 36% of the sample population had a mobile health (mHealth) application downloaded. Furthermore, 60% of them mentioned that the apps help to achieve health behavior goals, while 35% of them revealed that the apps helped them in terms of medical care decision-making, 38% of them reiterated the convenience in enquiring medical-related questions from experts (Kim et al., 2019).

As of today, more than 325,000 health applications are readily available to be downloaded. These applications may facilitate a better continuum quality of care for patients while conserving the pre-existing resources (Grossman et al., 2018). They open doors in empowering patients and educating them to improve their quality of life through technology (Bert et al., 2014; Lorca-Cabrera et al., 2020). A great example would be the recent implementation of telemedicine in providing better patient care specifically during the pandemic (Papa et al., 2020). Patients are able to carry out their follow ups with their physicians even though they are far apart, albeit there are still certain limitations that one must consider.

2.7 Knowledge Gaps

While literature search support gut-directed psychological interventions including hypnotherapy (Palsson, 2006) and the Manchester approach (Gonsalkorale, 2006) but none exists with regards to the GI approach. The available scripts from these published studies were however useful, and parts of the scripts were modified to suit our intervention and adapted according to local culture and language context. In