THE EFFECT OF ISOMETRIC EXERCISE ON INTENSITY AND DURATION OF PAIN AMONG PHYSICALLY INACTIVE YOUNG FEMALES WITH PRIMARY DYSMENORRHEA

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by

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Dissertation submitted in partial fulfilment
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CERTIFICATE

This is to certify that the dissertation entitled “THE EFFECT OF ISOMETRIC EXERCISE ON INTENSITY AND DURATION OF PAIN AMONG PHYSICALLY INACTIVE YOUNG FEMALES WITH PRIMARY DYSMENORRHEA” is the bona fide record of research work done by Ms. NIK SITI NURAMIZA AISYAH BINTI NIK MOHD ZAID” during the period from September 2020 to Jun 2021 under my supervision. I have read this dissertation and that in my opinion it conforms to acceptable standards of scholarly presentation and is fully adequate, in scope and quality, as a dissertation to be submitted in partial fulfilment for the degree of Bachelor of Health Science (Honours) (Exercise and Sports Science).

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DECLARATION

I hereby declare that this dissertation is the result of my own investigations, except where otherwise stated and duly acknowledged. I also declare that it has not been previously or concurrently submitted as a whole for any other degrees at Universiti Sains Malaysia or other institutions. I grant Universiti Sains Malaysia the right to use the dissertation for teaching, research and promotional purposes.

Nik Siti Nurāmiza Aisyah Binti Nik Mohd Zaid

Date: 23 June 2021

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LIST OF ABBREVIATIONS

PD	– Primary Dysmenorrhea
PMS	– Premenstrual Syndrome
WHO	– World Health Organisation
PG	– Prostaglandin
OCP	– Oral Contraceptives Pills
NSAIDs	– Non-Steroidal Anti-Inflammatory Drugs
TENS	– Transcutaneous Electrical Nerve Stimulation
PA	– Physical Activity
NHS	− National Health Service
RCT	– Randomised Control Trial
TCAM	– Traditional Complementary and Alternative Medicine
VRS	– Verbal Rating Scale
WaLIDD	– Working Ability, Location, Intensity, Days of Pain, Dysmenorrhea
ACSM	– American College of Sport Medicine
PAR-Q	– Physical Activity Readiness Questionnaire
GLTEQ	– Godin Leisure Time Exercise Questionnaire
LTPA	− Leisure-Time Physical Activity
VAPS	−Visual Analog Pain Scale
HRES	– Human Research Ethics Committee
USM	– Universiti Sains Malaysia

KESAN-KESAN SENAMAN ISOMETRIK TERHADAP INTENSITI DAN TEMPOH KESAKITAN DISMENOREA PRIMER DALAM KALANGAN WANITA MUDA YANG TIDAK AKTIF SECARA FIZIKAL

ABSTRAK

Pengenalan: Dismenorea Primer (PD) ditakrifkan sebagai kesakitan seperti kekejangan yang berulang dan berlaku semasa haid yang normal tanpa sebarang patologi pelvis. Senaman isometrik adalah sub-kumpulan senaman di mana kepanjangan otot dan sendi tidak berubah sepanjang penguncupan berlaku. Sehingga kini, keberkesanan senaman isometrik dalam mengurangkan intensiti dan tempoh kesakitan dismenorea masih belum dapat dipastikan. Diharapkan kajian ini akan dapat menambah pengetahuan mendalam tentang senaman isometrik dan kesannya ke atas PD dalam kalangan wanita muda yang tidak aktif secara fizikal untuk mengatasi kekurangan data mengenai pengurusan PD dan aktiviti fizikal.

Objektif: Tujuan utama kajian ini adalah untuk menyiasat kesan senaman isometrik terhadap intensiti dan tempoh kesakitan PD dalam kalangan wanita muda yang tidak aktif dari segi fizikal.

Kaedah: Dalam kajian intervensi-percubaan kawalan rawak ini, 24 wanita muda dengan dismenorea primer telah dibahagikan secara rawak sama ada kepada kumpulan senaman atau kumpulan kawalan. Sementara peserta dalam kumpulan kawalan meneruskan gaya hidup mereka yang tidak aktif secara fizikal, perserta dalam kumpulan senaman melakukan senaman isometrik selama 8 minggu, 5 hari seminggu, 2 sesi sehari, 10 minit setiap sesi. Intensiti dan tempoh kesakitan semua peserta diukur pada pra-ujian, pertengahan ujian dan pasca-ujian. Intensiti kesakitan diukur dengan menggunakan skala

kesakitan analog visual (VAPS) dan tempoh kesakitan direkodkan dalam jam. Data telah dianalisis dengan menggunakan ’Mixed ANOVA’, SPSS vs 25.0.

Keputusan: Selepas 8 minggu intervensi senaman isometrik, purata skor intensiti kesakitan (VAPS) berkurang secara signifikan dalam kumpulan senaman (6.08 to 1.92) ($p<0.05$) dan kekal tidak berubah dalam kumpulan kawalan (6.25 to 6.58) ($p>0.05$). Purata tempoh kesakitan (jam) juga berkurang dengan signifikan dalam kumpulan senaman (10.00 to 2.00) ($p<0.05$) dan kekal tidak berubah dalam kumpulan kawalan (9.25 to 9.42) ($p>0.05$).

Kesimpulan: Purata intensiti dan tempoh kesakitan dismenorea primer berkurang secara signifikan dalam kumpulan senaman berbanding kumpulan kawalan selepas 8 minggu intervensi senaman isometrik. Oleh itu, senaman isometrik boleh dijadikan sebagai kaedah bukan farmakologi yang berkesan dalam menghasilkan kesan positif yang signifikan bagi mengurangkan intensiti dan tempoh kesakitan dismenorea primer.

THE EFFECT OF ISOMETRIC EXERCISE ON INTENSITY AND DURATION OF PAIN AMONG PHYSICALLY INACTIVE YOUNG FEMALES WITH PRIMARY DYSMENORRHEA

ABSTRACT

Introduction: Primary dysmenorrhea (PD) is defined as recurrent, cramp-like pain occurring with normal ovulatory menses in the absence of any pelvic pathology. Isometric exercise is a subgroup of exercises, during which the muscle length and joint remain constant during contraction. To date, effectiveness of isometric exercise in reducing intensity and duration of pain is not yet established. It is hoped this study will provide in-depth knowledge on isometric exercise and its effect on PD in sedentary young females to overcome the deficiency of data on the management of PD and physical activity.

Objectives: The primary aim of the study was to investigate the effect of isometric exercise on intensity and duration of PD among physically inactive young females.

Methods: In this randomised controlled trial, 24 young females with primary dysmenorrhea were randomly assigned to either exercise or control groups with 12 participants in each group. While participants in the control group continued with their physically inactive lifestyle, those in the exercise group were required to perform isometric exercise for 8 weeks with 5 days per week, 2 sessions per day, 10 min per session. Pain intensity and duration of all the participants were measured at pre, mid and post-test. The intensity of pain was measured by using the Visual Analog Pain Scale (VAPS) and duration of pain was recorded in hour. The data was analysed by Mixed ANOVA, SPSS vs. 25.0.

Results: After 8 weeks of isometric exercise intervention, the mean score of pain intensity (VAPS) was significantly reduced in exercise group (6.08 to 1.92) ($p<0.05$) and remained constant in control group (6.25 to 6.58) ($p>0.05$). The mean duration of pain (hours) was also significantly reduced in exercise group (10.00 to 2.00) ($p<0.05$) and remained constant in control group (9.25 to 9.42) ($p>0.05$).

Conclusion: The mean intensity and duration of menstrual pain significantly reduced in exercise group compared to control group after 8 weeks of isometric exercise intervention. Hence, it can be concluded that isometric exercise appears to be an effective non-pharmacological method and provide significant positive reduction for intensity and duration of pain for primary dysmenorrhea.

CHAPTER 1

INTRODUCTION

1.1 Background of The Study

The adolescence phase experienced by a girl is a period of physical and psychological transformation for motherhood. The onset of menarche is one of the main physiological changes that takes place in adolescent girls. Following that, many girls have to cope with menstrual problems such as irregular menstruation, excessive bleeding and dysmenorrhea. Dysmenorrhea is derived from the Greek words 'dys' which means difficult, painful or abnormal, while 'meno' means month, and 'rrhea' means flow (Chauhan & Kala, 2012). It is the most common periodical pelvic pain suffered by most women (Latthe, Champaneria & Khan, 2011) and appears up to 6–12 months after menarche, affecting primarily young women, often those in university or occupational activity (Teherán *et al.*, 2018). Even though it is one of the frequent problems endured by most girls from adolescence onwards, yet it is hardly taken into consideration when assessing adolescents' health (Kumbhar *et al.*, 2011).

Dysmenorrhea can be partitioned into comprehensive categories of primary and secondary. Primary dysmenorrhea (PD) is described as recurrent, cramp-like pain occurring with normal ovulatory menses in the absence of any pelvic pathology (Lefebvre *et al.*, 2005). Meanwhile, secondary dysmenorrhea is menstrual pain associated with underlying pelvic pathology such as pelvic inflammatory disease, endometriosis, adenomyosis, intra-uterine devices, infertility problems, ovarian cysts, uterine myomas or polyps, intra-uterine adhesions or cervical stenosis (Unsal *et al.*, 2010).

PD is not life-threatening and does not cause disabilities, but it precedes to absenteeism and substantially affects the life productivity (Ju, Jones & Mishra, 2013). It is characteristically described as colicky pain associated with menstruation that begins on

the first day of bleeding and normally becomes most severe on day two to three of menstrual cycle before gradually tapering off towards the end of the menstrual flow. Furthermore, the pain may be intermittent and may range from mild to severe. However, PD becomes less as women's age advances and it is more common in women under the age of 30 (Ju, Jones & Mishra, 2013). After the third decade of woman's life, the symptoms tend to stabilize, as well as after childbirth (Brito *et al.,* 2012). During menstrual bleeding, at least one out of three young women had to be absent due to the pain intensity that limit their abilities to do daily pursuits (De Sanctis *et al.,* 2015).

In addition, the high prevalence of PD among adolescents appears in the early years of their reproductive life which affects their daily activities including school absenteeism and thus it makes PD as a public health problem (Santina *et al.,* 2012). Approximately, 20-90% of women suffer from this problem during their reproductive age (French, 2008). Worldwide, the prevalence of dysmenorrhea was estimated to be between 16% and 91% and it is approximated that around 25-95% women whom suffer from dysmenorrhea had significant psychological, behavioural, social and physical stress (Gagua *et al.,* 2012). In fact, a cross-sectional study conducted in a public secondary school in Selangor involving 300 female students (12 to 17 years old) found a 62.3% prevalence of dysmenorrhea and noted to be significantly higher in the middle adolescence (15 to 17 years old) age group with an overall 38% school absence (Wijesiri & Suresh *et al.,* 2013).

Isometric exercises are a subgroup of exercises, during which the muscle length and joint angle remain constant during contraction (Kubo, Kanehisa & Fukunaga, 2005). Isometric exercises stimulate the constant muscles which are of a δ-type and C fibres which in turn reduce the pain via pain inhibitory effects (Umeda *et al.,* 2010). The potential mechanism of the effect of isometric exercises is strengthening pelvic muscles,

facilitating bleeding, and excretion of wastes containing prostaglandin which causes the excessive contraction (Shavandi, Taghian & Soltani, 2010). Regular exercise reduces stress and, as a result, decreasing the activity of sympathetic system causing contraction and pain in uterine muscles (Noorbakhsh *et al.,* 2012). Moreover, increasing proprioception and control of pelvic motions and muscular balance, lead to reduction of backache especially during pregnancy (Shavandi, Taghian & Soltani, 2010).

1.2 Problems Statement

Though PD is not life threatening, these conditions can seriously decrease the productivity of life in many women which affect their mental health (Lakshmi *et al.,* 2011). PD is known to affect physical and social disability resulting in school or class absence, hinder sports participation and school activities. Identification of modifiable risk factors for PD is crucial as this condition could affect a large fraction of women in their reproductive age which further contributes to school absenteeism, lost work time, and reduced physical activity. Treatment of PD should be directed at providing pain and associated symptoms relief in which non-steroidal anti-inflammatory drugs (NSAIDs) and oral contraceptives pills (OCP) are reported as being the most efficient treatment (Wang *et al.,* 2004).

However, these days, broad studies are being conducted on complementary and alternative methods due to high costs, complications, and contraindications of some drug therapies as well as accessibility and public desire for using complementary treatments (Lee, 2011). One of the complementary methods is doing exercises. Isometric exercises are easy and safe for sedentary population as the protocol is non-invasive and implemented at low intensity, and it is widely used in rehabilitation settings (Schafer, 2017). In addition, it is inexpensive as special facilities or equipment is not required, and

not time-consuming, hence they seem to be an appropriate non-pharmacological method for reducing the pain intensity of PD. However, up to now, contradictory, and inconsistent findings have been obtained about the effects of exercises on PD. Positive effect of isometric exercises on PD has been observed in some, but not all studies which contribute to mixed and conflicting evidence. Due to the undesirable symptoms and complications of some common treatments and the contradictory results of the studies conducted on the effects of doing exercises on primary dysmenorrhea, hence, clarification is necessary for more reliable studies in this regard.

1.3 Objectives of The Study

1.3.1 Main Objective

I. To investigate the effect of isometric exercise on the intensity and duration of pain among young females with primary dysmenorrhea.

1.3.2 Specific Objectives

I. To investigate the effect of isometric exercises on intensity of pain among young females with primary dysmenorrhea.

II. To investigate the effect of isometric exercises on duration of pain among young females with primary dysmenorrhea.

1.4 Study Hypotheses

H_{O1}: There is no significant difference in intensity of pain between young females with primary dysmenorrhea in the exercise and control groups.

H_{A1}: There is a significant difference in intensity of pain between young females with primary dysmenorrhea in the exercise and control groups.

H_{O2}: There is no significant difference in duration of pain between young females with primary dysmenorrhea in the exercise and control groups.

H_{A2}: There is a significant difference in duration of pain between young females with primary dysmenorrhea in the exercise and control groups.

1.5 Significance of The Study

It is hope that this study will provide in-depth knowledge on isometric exercise and its effect on PD. This will provide a major contribution to overcome the deficiency of data on the management of Primary Dysmenorrhea (PD) and physical-related activity. Most of local studies in Malaysia only focus on exploring the prevalence of primary dysmenorrhea with its risk factors rather than evaluating the effectiveness of other alternative management such as isometric exercise.

In addition, it is still uncertain whether the effect of isometric exercise on reducing the intensity and duration of pain in PD observed in exercise group is identical to control group. This randomised control study may identify the possible differences between the respective groups as it focuses on physically inactive young females which would identify the gaps between previous research and add in current knowledge. Most of the previous research does not focus on sedentary population and view the young female with PD as a

whole. This would also be interesting to see whether this minor act of exercise would benefit the students suffering from dysmenorrhea.

Lastly, this could contribute towards building a proper and effective systematic menstrual health education program for female adolescents and PD would not be a barrier anymore for young female to engage in physical activity. In addition, this study can greatly benefit university students who are already under considerable academic related stress, to have a proper management of PD by practicing the most preferable alternative methods. Hence, contributing more achievements in the university context.

1.6 Operational Definitions

- Dysmenorrhea — Menstrual cramps which cause menstrual pain due to uterine contraction (Chauhan & Kala, 2012).
- Primary Dysmenorrhea — Menstrual pain resulting from cramping in the lower abdomen in the absence of other diseases such as endometriosis (Lefebvre *et al.*, 2005).
- Secondary Dysmenorrhea — Painful menses resulting from pelvic pathology such as endometriosis (Unsal *et al.*, 2010).
- Isometric Exercise — Exercise involving muscular contraction without the movement of the involved parts of the body (Kubo, Kanehisa & Fukunaga, 2005).
- Young Females — Female who is in the range of late adolescence to young adult (Ju, Jones & Mishra, 2013).
- Physically inactive — People who do not meet the recommended level of regular physical activity by WHO (WHO, 2010).
- Premenstrual Syndrome (PMS) — A complex of symptoms including weight gain, bloating, irritability and fatigue that often starts one to two weeks before menstruation (Andrew, 1999).
- Irregular Menstrual Cycle — The menstrual cycle that continually falls outside of regular cycle length which is more than 35 days (Lea *et al.*, 2005).
- Duration of Pain — The average hour of pain per day during menstrual pain (Azima et al., 2015).

1.7 Conceptual Framework

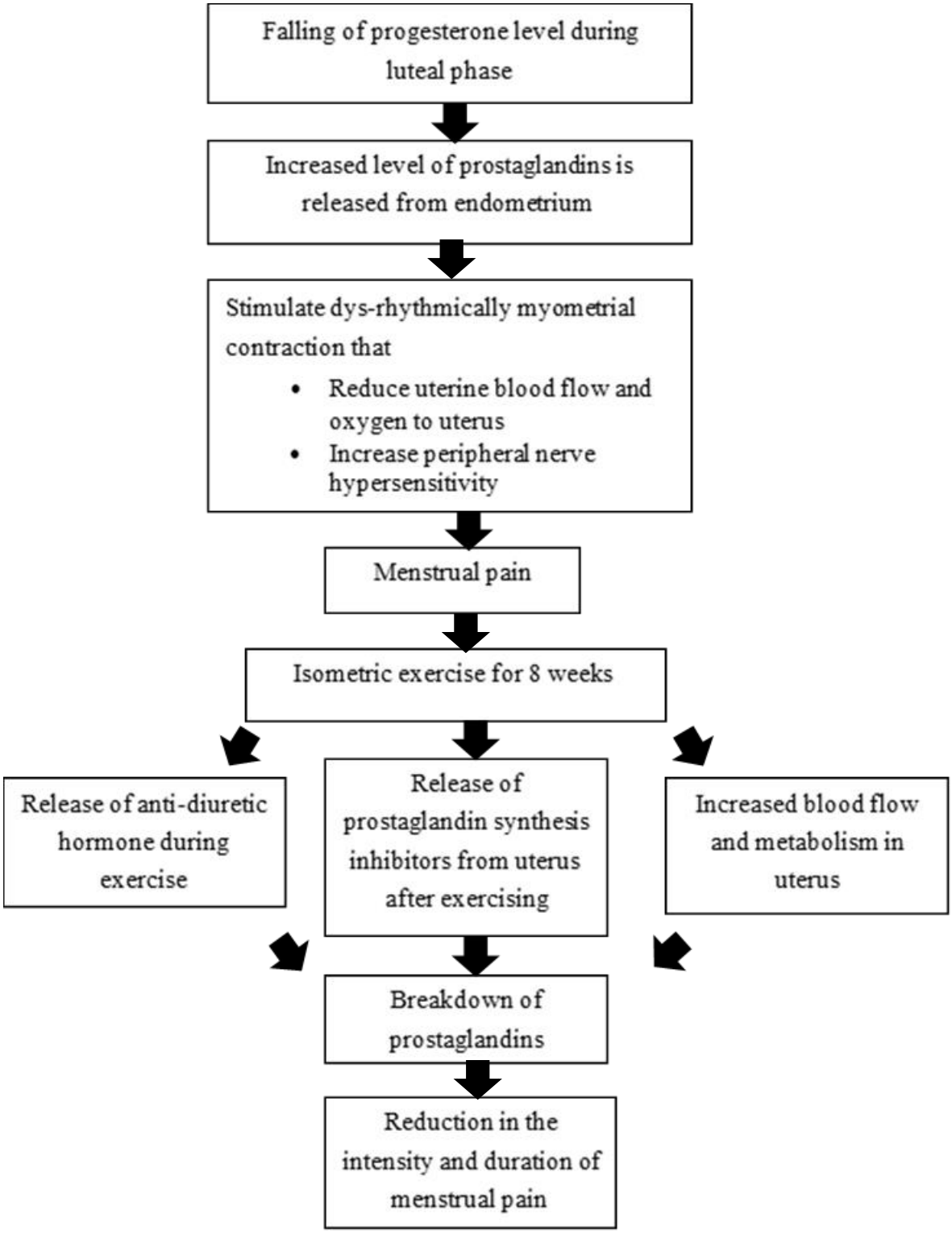

Figure 1.1: Conceptual framework of the study

CHAPTER 2

LITERATURE REVIEW

2.1 Primary Dysmenorrhea and Its Physiological Factor

Primary Dysmenorrhea (PD) has its onset when ovulatory cycles begin, generally starting three years after menarche and peaks during the late teenage years and early twenties, and gradually declines with age (Armour *et al.*, 2019). The largest contributing physiological factor in PD is the excessive or imbalanced amount of prostaglandins (PG), particularly $PGF_{2\alpha}$ that is released from endometrium during menstruation. These prostaglandins stimulate myometrial contractions, which reduce uterine blood flow and causing uterine hypoxia. This hypoxia is responsible for the painful cramping characterises PD (Armour *et al.*, 2019). Female with PD have higher PG levels in the endometrium and menstrual blood (Ju, Jones & Mishra, 2013).

In addition, uterine muscle is innervated by the sympathetic system that could enhance sympathetic activity during stressful condition which subsequently cause the uterus to contract frequently and dys-rhythmically, with increased basal tone and active pressure. This exacerbating uterine contraction reduced the uterine blood flow and increase the peripheral nerve hypersensitivity which eventually resulting in menstrual pain (Ju, Jones & Mishra, 2013). Similar to labour pains, these contractions can cause significant pain and discomfort (Smith & Kaunitz, 2019).

2.1.1 Symptoms and Diagnosis of Primary Dysmenorrhea

Typically, PD is represented by a crampy suprapubic pain that begins somewhere between several hours before and a few hours after the onset of the menstrual bleeding. Symptoms peak with maximum blood flow and usually last less than one day, but the

pain may persist up to two to three days of menstrual cycle. It is characterised by colicky **s**pasm and located in the midline of the lower abdomen but can also be described as dull and may extend to both lower quadrants, the lumbar area, and the thighs (Macaluso & McNamara, 2012).

The main associated systemic symptoms are pain, nausea, vomiting, cramps, diarrhoea, headache, dizziness, fatigue and syncope, which appear to be associated with menstruation with no any organic or pathological cause (French, 2008). Though not life threatening, these conditions can seriously decrease the quality of life of many women and affect their mental health and productivity (Lakshmi *et al.,* 2011). The pain is uneven in character and felt mainly in the lower abdomen but may radiate to the back and along the thigh.

Consensus Guideline of PD (Lea *et al.,* 2005) reported that the frequently associated symptoms include diarrhoea, nausea and vomiting, fatigue, light headedness, headache, dizziness and rarely syncope and fever. A focused history is usually sufficient to make the diagnosis of PD in participants with typical symptoms and no risk factors for secondary causes (Andrew, 1999). The history should focus on menstrual history, including age at menarche, length of cycle and duration of bleeding. In female with a typical mild to moderate dysmenorrhea and has never been sexually active, a pelvic examination is not necessary (Lea *et al.,* 2005).

2.2 Burden and Management of Dysmenorrhea

Dysmenorrhea is an important health problem concerning public health, occupational health and family practice, affecting both the quality of life and the national economy due to short-term school absenteeism and loss of labour. Brito *et al.* (2012) reported that menstrual pain can slow down the normal routine and impacts the activities at home, work and school, and the study involving 634 students found that 32.2% failed to attend academic activities because of cramps.

One study found that 51% of women had been absent from school or work at least once and 8% had been absent with every menstruation (Abbaspor, Rostami & Najjar, 2006). Armour *et al.* (2019) reported that PD is responsible for a decrease in quality of life, absenteeism from work or school, reduced participation in sport and social activities. Maruf *et al*, (2013) reported that female with PD endured menstrual pain mostly (55.1%) during menstruation and the mostly reported pain intensity was moderate (38.7%). Those who has menstrual pain used medication (77%) reported having pain relief while a majority of 80.5% did not report using medication for the pain (Maruf *et al.,* 2013).

Management of PD can be treated through pharmacological and non-pharmacological methods. Pharmacological therapy includes the use of oral contraceptives pills (OCP), non-steroidal anti-inflammatory drugs (NSAIDSs) and analgesic tablets (paracetamol), which reduce menstrual pain by affecting the level of prostaglandins (Berek & Novak, 2012). On the other hand, there are complementary and alternative medicine include essential fatty acid, vitamins, supplements, Transcutaneous Electrical Nerve Stimulation (TENS), acupuncture, medicinal plants, aromatherapy, reflexology, acupressure, massage therapy, and exercises (Onur *et al.*, 2012).

2.2.1 Epidemiology of Primary Dysmenorrhea

The prevalence rates of PD are as high as 90% (Andrew, 1999). In Brazil, 86% prevalence of dysmenorrhea was reported in female undergraduate health students at an institution of higher education (Brito *et al.*, 2012). Meanwhile, in a Mexican study, 62.4% prevalence of dysmenorrhea was observed in medicine, nursing, nutrition, dentistry, pharmacy and psychology students. The pain that these women suffer can be severe, disabling and result in short-term absenteeism (Ortiz, 2010).

A local cross-sectional study in the Federal Territory of Kuala Lumpur found 74.5% dysmenorrhea prevalence in 1092 girls from 15 public secondary schools and these girls reported that it affected their concentration in class (51.7%), restricted their social activities (50.2%), caused them to miss school (21.5%) and caused poor school performance (12.0%) (Wong, Ip & Lam, 2016). In addition, a cross-sectional study conducted in rural districts of Kelantan, involving 16 public secondary schools found that 76.0% of the participants reported to having dysmenorrhea with concentration at school (59.9%) and participation in social events (58.6%) were most affected. This study also discovers that being in upper secondary level with dysmenorrhea was the strongest predictor for poor concentration, absenteeism, and poor school grade (Wong, 2011).

In another study conducted in Health Campus Universiti Sains Malaysia involving 172 participants of medical students, Thevaraja (2013) reported that the prevalence of dysmenorrhea was 77.9% with most of the students described their menses as regular and only 20.9% students having irregular menses. As for the menstrual cycle length, 29.7% of students had a cycle of 20 days or less, 62.2% of 21-34 days and only 8.1% of 35 days or more (Thevaraja, 2013).

2.2.2 Primary Dysmenorrhea and Physical Activity

In terms of non-pharmacological treatments, it is commonly thoughts that exercise participation reduces the severity of premenstrual syndrome (PMS) and PD. PMS symptoms begin before the menstrual cycle and resolve shortly after menstrual flow begin. The pain associated with PMS is generally related to breast tenderness, tiredness, mood swings and abdominal bloating rather than a lower abdominal cramping pain (Andrew, 1999). Studies have shown that clinicians often recommended exercise and women frequently use it for symptom management (Daley, 2009). Lee *et al.* (2006) reported that low PA levels have been associated with having PD but on contrary, PA is reportedly not associated with pain.

In another study conducted by Maruf *et al.* (2013), fewer participants with PD (61.3%) engaged in PA for more than one hour daily than those without PD (73.8%), and more participants reported experiencing severe pain than those who reported mild-moderate pain intensities engaged in PA for more than one hour per day. The American College of Obstetricians and Gynaecologists has stated that aerobic exercise lessens PMS symptoms for many women. Similarly, in the UK, the National Health Service (NHS) (n.d) direct website offers advice to women about possible treatment for menstrual pain which stated that moderate physical exercise may help to relieve the pain.

The trials involving general populations have proved that participation in regular exercise can enhance some of the symptoms such as mood disturbance, fatigue, cognitive dysfunction and bloating which typically experienced by women who suffer from PD (Department of Health London, 2004). For the past decades, Izzo and Labriola (1991) showed that dysmenorrhea was less prevalent in athletes who had begun their sport activities and athletes participating in more intense sport activities had less severe menstrual symptoms.

2.3 Exercise and Primary Dysmenorrhea

For almost half of century, exercise has been thought to relief PD and in the last 15-20 years, reports on the link between PA and menstrual disorder have increased significantly. Results indicated a significant different between the two groups regarding intensity and duration of menstrual pain after intervention. Shavandi *et al.* (2010) conducted a quasi-experimental study on 30 female students suffering from dysmenorrhea. The exercise group did 8 weeks of isometric exercises. The pain intensity and duration of pain decreased after 4 weeks (Shavandi, Taghian & Soltani, 2010).

Noorbakhsh *et al*. (2012) reported that doing 8 weeks of physical activity significantly decreased drug consumed, amount and duration of bleeding and intensity of pain in students with PD. Contrary to the above results, Balkey *et al.* (2009) studied the effects of different exercises on dysmenorrhea of students and did not observe any association between exercise and PD. Also, Daley (2008) reported that in studies with sample size of more than 500 people, reduction of dysmenorrhea has not been observed. This review revealed that small studies were less likely to have blinded the study purpose or controlled for possible confounders, making their findings uncertain (Daley, 2008). Daley (2008) and Brown (2009), from clinical trials, albeit of limited methodological quality, suggested that exercise may reduce some symptoms during the menstrual phase.

2.3.1 Pain Reduction Mechanism

The notion that exercise might help to relieve menstrual pain is not new as Billig (1943) proposed that women with dysmenorrhea had contracted ligamentous bands in the abdomen and subsequently a series of developed stretching exercise claimed to have a high rate of symptom relief. The physiologic basis for dysmenorrhea is associated to the increased or imbalance levels of prostaglandins which result in uterine contraction and

ischemia. Falling of progesterone level during the luteal phase brings about the elevation specifically of $PGF_{2\alpha}$ and PGE_2 (Ju, Jones & Mishra, 2013).

The pain reduction mechanism is due to the release of prostaglandin synthesis inhibitors from uterus after exercising which reduce the symptoms accompanying menstrual discharge (Chan & Dawood, 1981). Anti-diuretic hormone is also released during exercise and the vasoconstriction in pelvic blood flow may breakdown of prostaglandins (Noorbakhsh *et al.*, 2012). Furthermore, physical exercise increased the blood flow and metabolism in uterus and consequently reduce the occurrence of dysmenorrhea (Shavandi, Taghian & Soltani, 2010). Hence, women who exercise may have a decreased incidence of dysmenorrhea due to exercise related hormonal effects on the uterus lining or increased circulating endorphins level. Also, PD has been correlated with stress, and physical exercise has been used to lessen the stress perception or inducing biochemical changes in the immune system. Thus, reduction of stress, through the exercise, is perceived to also have reducing effect on PD.

CHAPTER 3

METHODOLOGY

3.1 Study Design

This study was an intervention study that used the randomised control trial (RCT) study design. In this study, participants were randomly assigned by using permuted block randomization into either control or exercise group. Those in the control group was not involved in the exercise programme while those in the exercise group performed exercise 5 times per week for 8 weeks (Figure 3.1). The study protocol had been reviewed and grated ethical approval for implementation by Jawatankuasa Etika Penyelidikan Manusia Universiti Malaysia (JEPeM-USM) with a study protocol code of USM/JEPeM/20040216 (Appendix A).

3.2 Study Location

The study location referred to the place where the data was collected. In this study, data was collected in Kota Bharu, Kelantan. The data was analysed at the Sport Science Laboratory, Health Campus Universiti Sains Malaysia.

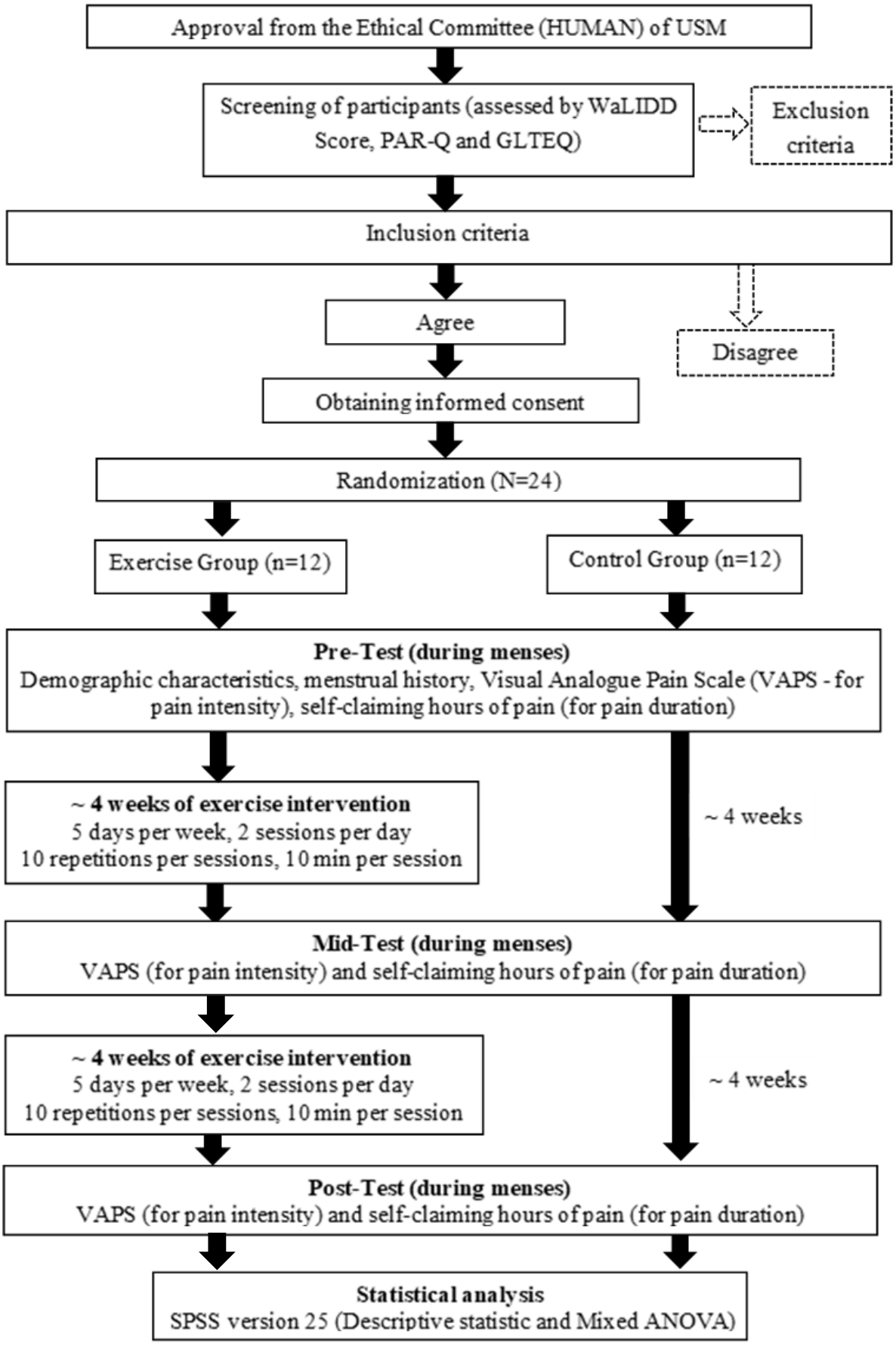

Figure 3.1: Flow chart of the study procedures

3.3 Study Population and Selection Criteria

Participants were recruited among young females in Kota Bharu. The selection criteria were as follows:

3.3.1 Inclusion criteria

- Age 18-29 years' old
- Physically inactive (assessed via GLTE questionnaire-Appendix B)
- Healthy (PAR-Q-Appendix C)
- Having primary dysmenorrhea in accordance to Primary Dysmenorrhea Consensus Guideline and obtained the WaLIDD Score of ≤ 7 (Appendix D)
- Did not have lower abdominal pain at any other times than just before or during menstruation
- Never giving birth

3.3.2 Exclusion Criteria

- Smokers
- Married
- Currently on oral contraception pills/medications (paracetamol, analgesic etc.)/other non-pharmacological methods (hot water bag/heat massage/TCAM etc.) for pain relief in the previous two weeks
- Has limitation to perform isometric exercise such as having cardiovascular disease, etc.

- Has irregular menstrual cycle (more than 35 days per cycle)
- Has history of secondary caused of dysmenorrhea (endometriosis, pelvic inflammatory disease etc) or other gynaecological problems (ovarian cysts, adenomyosis etc) diagnosed by gynaecologist

3.4 Sampling Method

The recruitment process consisted of distribution of recruitment posters (Appendix E) in nearby communities through online platform and advertisement in University Sains Malaysia Health Campus. Participants' selection was through purposive sampling method in which the participants interested must have the symptoms of PD accordance to Primary Dysmenorrhea Consensus Guideline to differentiate from secondary dysmenorrhea.

A focused history was usually sufficient to make the diagnosis of PD in participants with typical symptoms and no risk factors for secondary causes (Andrew, 1999). The history should focus on menstrual history, including age at menarche, length of cycle and duration of bleeding (Lea *et al.*, 2005). In participants who has never been sexually active and has a typical mild to moderate dysmenorrhea (≤7 WaLIDD Score), a pelvic examination is not necessary (Lea *et al.*, 2005). Table 3.1 showed the lists some of the circumstances in which the diagnosis of SD should be considered. If the screening process found participants with the history of pelvic pathology, the participants were dropped out from the study for having exclusion criteria.

Table 3.1: The circumstances that may indicate secondary dysmenorrhea (Lea *et al.*, 2005)

Circumstances That May Indicate Secondary Dysmenorrhea	
1	Dysmenorrhea occurring during the first one or two cycles after menarche (congenital outflow obstruction).
2	Dysmenorrhea beginning after 25 years of age.
3	Late onset of dysmenorrhea after a history without previous pain with menstruation (consider complications of pregnancy: ectopic or threatened spontaneous abortion).
4	Pelvic abnormality on physical examination; infertility (consider endometriosis, pelvic inflammatory disease or other causes of scarring); heavy menstrual flow or irregular cycles (consider adenomyosis, fibroids, polyps); dyspareunia.
5	Little or no response to therapy with nonsteroidal anti-inflammatory drugs, oral contraceptives, or both

Participants with PD were further screened through GLTEQ and PAR-Q before final selection. The screening process was carried out in Exercise and Sport Science Laboratory. Once the interested participants completed the screening baseline, a total of 24 eligible participants were randomly assigned to an exercise or a control group by permuted block randomization. In randomization, the researcher was blinded to group allocation. A computer generated, blocked random allocation sequence was generated with Microsoft Excel. Another researcher who was not involved with data collection provided the random number and groups assignment immediately to the independent

assessor in opaque, sealed envelopes. This procedure guaranteed that randomization concealment was adequate and not influenced by researchers or participants. Random allocation was performed after the participants provide informed consent and the researcher opened the corresponding envelope in front of participant. The envelopes were opened only after the enrolled participants have completed all baseline treatment.

3.5 Sample Size Calculation

PS Power Software was used for the sample size calculation. The intensity and duration of pain of dysmenorrhea is obtained by literature review on the parameters of intensity and duration of pain in primary dysmenorrhea (Azima *et al.,* 2015). The power of the study was set at 90% and $\alpha = 0.05$. Based on the calculation, the desired number of participants was set at 12 for each exercise and control group, after 20% dropout (Table 3.2). Hence, a total of 24 participants (N=24) were recruited for this study.

Table 3.2: Sample size calculation for each objective of the study

Parameters	**Mean**	**SD**	**n**	**Total sample size + 20% dropout**
Intensity of Pain	**2.41**	**1.53**	**10**	**12**
Duration of Pain	**5.41**	**3.25**	**9**	**11**

3.6 Study Instruments

WaLIDD Score

The WaLIDD Score (Appendix D) is a scale-type survey (working ability, location, intensity, days of pain, dysmenorrhea) designed to integrate features of dysmenorrhea as, frequently used criteria identified in the definitions of dysmenorrhea present in the literature: **(1)** frequency of disabling pain to perform their activities (never, almost never, almost always, always), **(2)** number of anatomical pain locations (no part of the body, lower abdomen, lumbar region lower limbs, inguinal region), **(3)** Wong-Baker pain rage (does not hurt, hurts a little, hurts a little more, hurts even more, hurts a lot, hurts a lot more) and **(4)** number of days of pain during menstruation (0, 1-2, 3-4, ≥ 5). Each tool's variable provided a specific score between 0 and 3 and the final score ranged from 0 to 12 points. In detail, the score is classified as without dysmenorrhea (0), mild dysmenorrhea (1-4), moderate dysmenorrhea (5-7) and severe dysmenorrhea (8-12).

In this study, only those who obtained WaLIDD score ≤7 (mild and moderate dysmenorrhea) were recruited in accordance to Primary Dysmenorrhea Consensus Guideline (Lea *et al.,* 2005). The score of ≤7 was set to avoid the primary direction effects of variation existing among the WaLIDD Score (mild, moderate, severe) to isometric exercise and unnecessary pelvic examination in mild to moderate PD participants who has never been sexually active (Lea *et al.,* 2005).

The instrument had been designed and implemented for general population to allow identification of women with dysmenorrhea which has a strong correlation with Verbal Rating Scale (VRS), validated to assess pain in the paediatric population, which has also verified to be useful in studies involving adult populations with or without abdominal pain (Teherán *et al.,* 2018). Hence, it was applicable with Malaysia population

and in accordance with the features of Monthly Index of Medical Specialist (MIMS) Malaysia (MIMS, n.d.).

The use of WaLIDD scale offered two significant advantages: (1) smaller delay time in application as paraclinical support and images are not required and (2) the level of expertise for its application is not very demanding, does not require a gynaecologist specialist for its application (Teherán *et al*., 2018). The WaLIDD scale offered an adequate and acceptable internal consistency (Cronbach's alpha, 0.723) with a good likelihood ratio (LR) 14.2 (95% CI, 13.5–14.9), LR 0.00 (95% CI, undefined), and predictive risk (OR 5.38; 95% CI, 1.78–16.2) (Teherán *et al*., 2018). WaLIDD score is an excellent detection tool that presents a very low rate of false negatives with a high area under the curve (AUC) receiver operating characteristic and an adequate LR properties (Teherán *et al*., 2018). The time require to completely fill out the survey is ~ 5 minutes.

Physical Activity Readiness Questionnaire (PAR-Q)

Physical Activity Readiness Questionnaire (PAR-Q-Appendix C) is a self-screening tool that is used to determine the safety or possible risk of exercising for an individual based on the health history and current symptoms and risk factors. The PAR-Q was created by the British Columbia Ministry of Health and the Multidisciplinary Board on Exercise (Warburton *et al.,* 2011). This form had been adopted directly from the ACSM Standards and Guidelines for Health and Fitness Facilities. If the participants answered 'YES' to one or more questions and have been inactive or are concerned about the health, consultation from physician was needed before engaging in this exercise intervention. If the participants answered 'NO' to all the question, they can be reasonably sure to exercise safely and have low risk of having any medical complications from exercise.

Godin Leisure Time Exercise Questionnaire (GLTEQ)

Godin Leisure Time Exercise Questionnaire (GLTEQ-Appendix B) is a short and practical questionnaire used to classify the level of physical activity. Physical activity level was assessed according to the typical 7-day period in a week where how many times participants on average spent more than 15 minutes during their free time. The weekly leisure activity score was based on the following formula:

Godin Scale Score = (9 X Strenuous) + (5 X Moderate) + (3 X Light)

In detail, the score was classified as sedentary (less than 14 units), moderately active (14-23 units) and active (24 units or more). The questionnaire was attached in the Appendices section for further reference. Participants who scored less than 14 were recruited. Using the Kappa index, the reliability was 0.94 for the strenuous activity score and 0.74 for the total leisure-time physical activities (LTPA) score. The measure was reliable (Cronbach's alpha, 0.64) and the content validity index (CVI) was found to be 0.82 according to the assessment of the experts and were found to be coherent (Sari & Erdoğan, 2016).

Isometric Exercise

Participants in the exercise group were involved in 8 weeks of exercise programme. They were required to perform isometric exercises starting on the third day of their menstrual cycle, 5 days a week, 2 sessions a day, and 10 repetitions per session. Each session lasted about 20 min. Participants were first trained before the start of data collection. The protocol of isometric exercises in this study included 7 stages and as follows (Azima *et al.*, 2014) (Appendix F):