EFFECTS OF LOWER EXTREMITY MUSCLE STRENGTHENING EXERCISE AND FOOT ORTHOSES ON MEDIAL LONGITUDINAL ARCH HEIGHT IN INDIVIDUALS WITH FLEXIBLE FLATFOOT

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ผลของการออกกำลังเพื่อเพิ่มความแข็งแรงกล้ามเนื้อรยางค์ขากับการใส่แผ่นรองฝ่าเท้า ต่อความสูงของอุ้งเท้าด้านในในผู้ที่มีภาวะเท้าแบนแบบยืดหยุ่น

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ภูมิชัย อิงคนานุวัฒน์ : ผลของการออกกำลังเพื่อเพิ่มความแข็งแรงกล้ามเนื้อรยางค์ขากับการใส่แผ่นรองฝ่าเท้าต่อความสูงของอุ้งเท้าด้านในในผู้ที่มีภาวะเท้าแบนแบบยืดหยุ่น. (EFFECTS OF LOWER EXTREMITY MUSCLE STRENGTHENING EXERCISE AND FOOT ORTHOSESON MEDIAL LONGITUDINAL ARCH HEIGHT IN INDIVIDUALS WITH FLEXIBLE FLATFOOT) อ.ที่ปรึกษาหลัก : รศ. ดร.รสลัย กัลยาณพจน์พร

บทคัดย่อ

ที่มาและความสำคัญ: การใส่แผ่นรองเท้าและการออกกำลังกายรยางค์ส่วนล่างเป็นวิธีรักษาที่นิยมใช้ในการช่วยเพิ่มความสูงอุ้งเท้าของผู้ที่มีภาวะเท้าแบน อย่างไรก็ตาม หลักฐานสนับสนุนการเลือกใช้ระหว่างการรักษาทั้ง 2 วิธีมีจำนวนน้อย

จุดประสงค์: งานวิจัยนี้ประกอบด้วยสองงานวิจัย โดยงานวิจัยที่ 1 มีวัตถุประสงค์เพื่อค้นหาโปรแกรมการออกกำลังกายที่มีประสิทธิภาพเพิ่มความสูงของอุ้งเท้าด้านในได้ดีกว่า ด้วยการเปรียบเทียบกลุ่มที่ออกกำลังกายเท้าเพียงอย่างเดียวกับกลุ่มที่ออกกำลังกายเท้าร่วมกับกล้ามเนื้อ gluteus medius (GMed) และงานวิจัยที่ 2 มีวัตถุประสงค์เพื่อเปรียบเทียบประสิทธิภาพของวิธีออกกำลังกายที่ได้จากงานวิจัยที่ 1 กับการใส่แผ่นรองฝ่าเท้า

ตัววัดผลหลัก: Navicular drop (ND), ดัชนีความสูงอุ้งเท้า arch height index (AHI), แรงกดใต้ฝ่าเท้า, การทรงตัวขณะอยู่นิ่ง, การทรงตัวขณะเคลื่อนไหว และความแข็งแรงของกล้ามเนื้อรยางค์ขา ที่วัดเมื่อเริ่มงานวิจัย, สัปดาห์ที่ 4 และสัปดาห์ที่ 8 ของงานวิจัย

ผลการศึกษา: งานวิจัยที่ 1 มีผู้เท้าแบนทั้ง 2 ข้าง จำนวน 52 คน เข้าร่วมงานวิจัย ซึ่งถูกสุ่มเข้ากลุ่มออกกำลังกายเท้าอย่างเดียว (n = 26) และกลุ่มออกกำลังกายเท้าร่วมกับกล้ามเนื้อ GMed (n = 26) เมื่อวัดผลสัปดาห์ที่ 4 และ 8 ผลการวิจัยพบว่า กลุ่มออกกำลังกายเท้าร่วมกับกล้ามเนื้อ GMed มีค่าตัววัดผลดีกว่าการออกกำลังกายเท้าทุกตัว ยกเว้นการทรงตัวขณะเคลื่อนไหว งานวิจัยที่ 2 มีผู้เท้าแบนทั้ง 2 ข้าง จำนวน 38 คน เข้าร่วมงานวิจัย ซึ่งถูกสุ่มแบ่งเป็นกลุ่มออกกำลังกายเท้าร่วมกับกล้ามเนื้อ GMed (n = 19) และกลุ่มใส่แผ่นรองฝ่าเท้า (n = 19) พบว่ากลุ่มออกกำลังกายเท้าร่วมกับกล้ามเนื้อ GMed มีค่าตัววัดผลหลักทุกตัวดีกว่ากลุ่มใส่แผ่นรองฝ่าเท้า ยกเว้นการวัดแรงกดใต้ฝ่าเท้ารวมถึงการทรงตัวขณะอยู่นิ่ง และการทรงตัวเคลื่อนไหวบางทิศทาง

สรุปผลงานวิจัย: การออกกำลังกายกล้ามเนื้อ GMed ร่วมกับการออกกำลังกายเท้ามีประสิทธิภาพกว่าการออกกำลังกายเท้าอย่างเดียวในการช่วยพยุงอุ้งเท้าด้านใน อีกทั้งการออกกำลังกายรยางค์ขายังมีประสิทธิภาพในการเพิ่มความสูงของอุ้งเท้าด้านในและพารามิเตอร์ที่เกี่ยวข้องได้ดีกว่าการใส่แผ่นรองฝ่าเท้าในผู้ใหญ่สุขภาพดีที่มีเท้าแบน

สาขาวิชา	กายภาพบำบัด	ลายมือชื่อนิสิต	....
ปีการศึกษา	2565	ลายมือชื่อ อ.ที่ปรึกษาหลัก	....

6176953437 : MAJOR PHYSICAL THERAPY
KEYWORD: Bilateral flatfoot, Foot exercise, Foot orthoses, Hip exercise, Medial longitudinal arch, Navicular drop

Phoomchai Engkananuwat : EFFECTS OF LOWER EXTREMITY MUSCLE STRENGTHENING EXERCISE AND FOOT ORTHOSESON MEDIAL LONGITUDINAL ARCH HEIGHT IN INDIVIDUALS WITH FLEXIBLE FLATFOOT. Advisor: Assoc. Prof. ROTSALAI KANLAYANAPHOTPORN, Ph.D.

Background: Foot orthoses and lower extremity exercises have been widely recommended to improve medial longitudinal arch (MLA) height in adults with flexible flatfoot. However, there is little evidence to guide the choice between foot orthoses or lower extremity exercises.

Objectives: This study comprised two separate studies. Study 1 aimed to establish the more effective exercise protocol by comparing the MLA height in groups performing foot exercises with and without gluteus medius (GMed) muscle strengthening exercise. Study 2 compared the established exercise protocol in Study 1 with foot orthoses to determine the actual effectiveness of each intervention.

Main outcome measures: Navicular drop (ND), arch height index (AHI), plantar pressure, static balance, dynamic balance, and lower extremity muscle strength were measured at baseline, 4 weeks, and 8 weeks.

Results: Study 1 included 52 participants with bilateral flatfoot who were randomly assigned to either the foot exercise group (n = 26) or the foot plus GMed exercise group (n = 26). After 4 and 8 weeks, the foot plus GMed exercise group showed significant improvements in all outcome measures, except dynamic balance, compared to the foot exercise group. Study 2 included 38 bilateral flatfoot participants who were randomly assigned to either the foot plus GMed exercise group (n = 19) and the foot orthoses group (n = 19). The foot plus GMed exercise group showed significant improvements in all outcome measures, except plantar pressure, static and dynamic balance in certain directions, compared to the foot orthoses group.

Conclusion: Adding GMed muscle strengthening exercise to foot exercise proved to be more effective in supporting the MLA compared to performing foot exercise alone. In healthy adults with flexible flatfoot, lower extremity exercise was found to be more effective than foot orthoses in improving MLA height and related parameters.

Field of Study:	Physical Therapy	Student's Signature ....
Academic Year:	2022	Advisor's Signature ....

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Phoomchai Engkananuwat

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CHAPTER 1

INTRODUCTION

1.1 Background and rationale

Flatfoot or pes planus is defined as a foot condition that is characterized by partial or complete collapse of the medial longitudinal arch (MLA) of the foot.[1,2] The condition can occur in one foot or both feet and may be symptomatic or asymptomatic. With this condition, the foot usually assumes a pronated posture, wherein the forefoot is abducted and the calcaneus is positioned in valgus.[3]

Flatfoot can be classified into two categories based on the preservation of the MLA in non-weight bearing conditions: rigid and flexible flatfoot.[4] Flexible flatfoot is commonly observed in adults with reported prevalence rates ranging from 13.6% to 25%, whereas rigid flatfoot is rare.[5,6] Two recent systematic reviews have identified an increased risk of lower limb injuries associated with flatfoot or high arch foot.[7,8] The underlying mechanism of these injuries is proposed to be related to the alterations in foot kinetics and kinematics,[9,10] as evidenced by changes in gait, plantar pressure, balance, and lower extremity alignment demonstrated in individuals with flatfoot.[2,11,12]

The MLA can be supported by both passive and active systems.[13] The passive system includes the bones of the medial longitudinal column of the foot (i.e., talus, navicular, medial cuneiform, and the first metatarsal), which are connected with plantar ligaments and plantar fascia. The active system consists of the extrinsic and intrinsic foot muscles. Various management methods have therefore been developed targeting at enhancing these passive and active systems to alleviate flatfoot with different rates of success.

Foot orthoses and exercises have been widely recommended as effective methods for improving the MLA in individuals with flexible flatfoot.[14,15] However, foot orthoses rely on external devices to provide passive support to the MLA, while exercises involve active participation by individuals. One systematic review examined the effects of foot orthoses in individuals with flatfoot; the authors could not produce definitive positive conclusions because of variations in the study populations, the types of foot orthoses used, and the outcome measures.[16] Regarding exercise, a systematic review[17] and a meta-analysis[18] suggest that short foot exercise to strengthen the intrinsic foot muscles effectively for supports the MLA.

To date, there is little evidence to guide the choice between foot orthoses or exercise in adults with flexible flatfoot. However, foot alignment may additionally be affected by the strength and function of proximal muscles of the lower extremity.[19] It is therefore plausible that the addition of hip abductor strengthening exercise to the foot exercise would further improve the MLA height. However, no previous studies have investigated this notion. As the gluteus medius (GMed) muscle is the largest hip abductor muscle, it was chosen for evaluation in this study.

Existing studies mostly compare foot orthoses to a combination of orthoses and exercise or compare exercise alone to a combination of orthoses and exercise.[20-24] Only one study directly compared the use of foot orthoses to exercise; the authors reported a greater improvement in MLA height and dynamic balance with short foot exercise.[25] However, due to the limited number of studies directly comparing foot orthoses to exercise, it remains challenging to determine the actual effectiveness of each intervention.

1.2 Research questions

1. Would the addition of gluteus medius muscle strengthening exercises to foot exercises result in greater improvements in the MLA compared to performing foot exercises alone in individuals with flexible flatfoot?
2. Would the combined strengthening exercises of gluteus medius and foot muscles be more effective in improving the MLA than the use of foot orthoses in individuals with flexible flatfoot?

1.3 Objectives of the study

To address two research questions, this current study consisted of two studies.

Study 1: To establish the more effective exercise protocol by comparing the MLA height (navicular drop, arch height index, plantar foot pressure, static balance, and dynamic balance) in groups performing foot exercises with and without gluteus medius muscle strengthening exercise after 8-week interventions in individuals with flexible flatfoot.

Study 2: To compare the established exercise protocol in Study 1 with foot orthoses to determine the actual effectiveness of each intervention on the MLA (navicular drop, arch height index, plantar foot pressure, static balance, and dynamic balance) after 8-week interventions in individuals with flexible flatfoot.

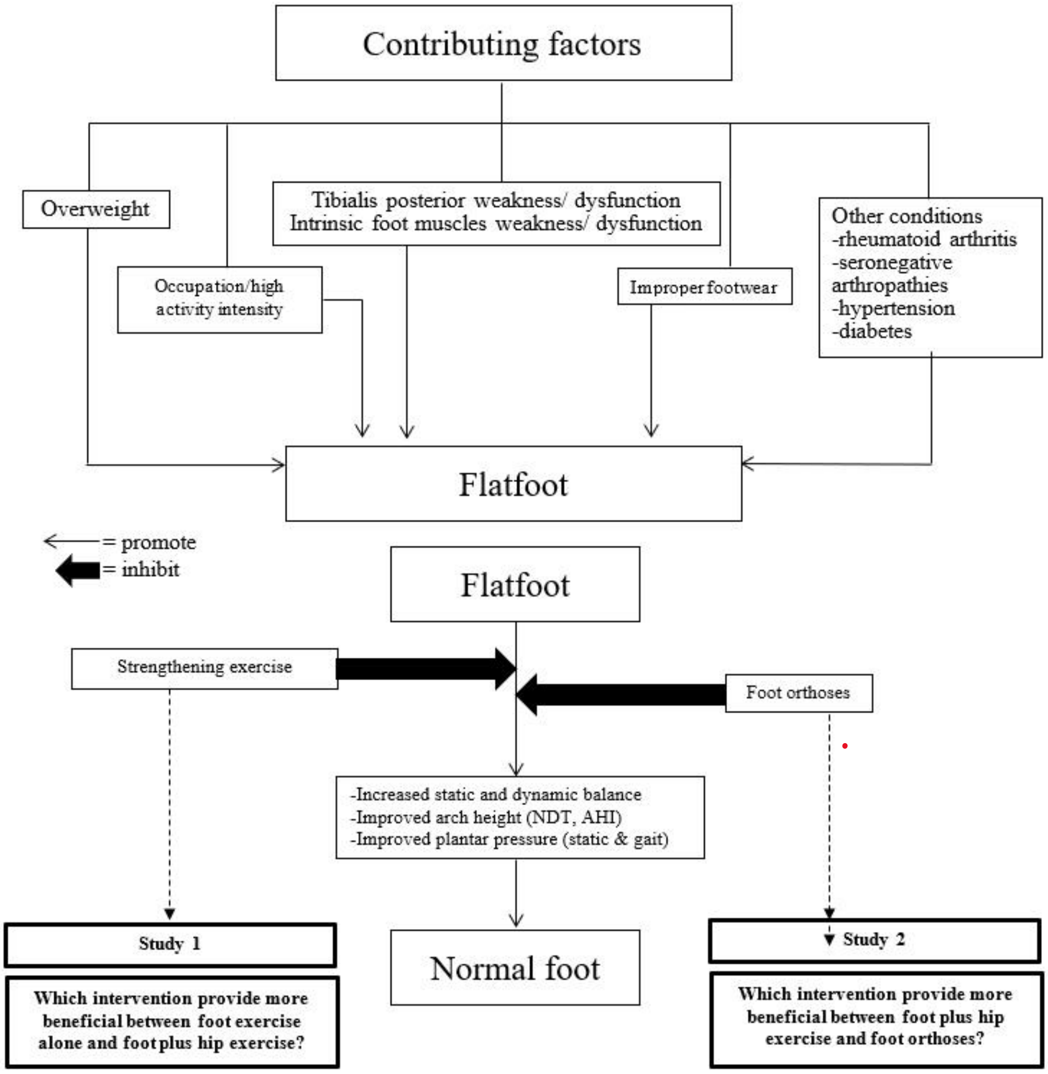
1.4 Hypotheses of the study

Study 1: After 8-week intervention, the group performing foot exercises with gluteus medius muscle strengthening exercise would result in greater improvements in the

MLA (navicular drop, arch height index, plantar foot pressure, static balance, and dynamic balance) than the group that performed foot muscle strengthening exercises alone in individuals with flexible flatfoot.

Study 2: After 8-week intervention, the group that performed established exercise protocol from Study 1 would result in greater improvements in the MLA (navicular drop, arch height index, plantar foot pressure, static balance, and dynamic balance) than the group that used foot orthoses in individuals with flexible flatfoot.

1.5 Conceptual framework



1.6 Scope of the study

Individuals aged between 18 and 39 years, both male and female, who had asymptomatic flexible flatfoot were recruited.

1.7 Expected benefit and application

The results of this study would provide physical therapists evidence for the effects of strengthening exercises and foot orthoses which may improve the management for adults with asymptomatic flexible flatfoot.

CHAPTER 2

LITERATURE REVIEW

This section describes the definition of flatfoot and its prevalence, etiology of flatfoot, influences of flatfoot, assessment of flatfoot types, and management of flatfoot.

2.1 Definition of flatfoot and its prevalence

Flatfoot or pes planus is defined as a foot condition that is characterized by partial or complete collapse of the MLA of the foot (Figure 1).[1,5] The condition can occur in one foot or both feet and may be symptomatic or asymptomatic. The foot is usually in pronated posture in which the forefoot is abducted and the calcaneus is in valgus position.[3]

Figure 1 *Collapse of the medial longitudinal arch of flatfoot during weight bearing (from Lee et al. 2005, p. 81).*[1]

Flatfoot can be classified into two categories based on whether the MLA is preserved in non-weight bearing condition.[4] The absence of the MLA both in non-weight bearing and weight bearing conditions is termed rigid flatfoot.[26,27] The presence of the MLA in non-weight bearing condition but absence in weight bearing condition is termed as flexible flatfoot.[27] The majority of condition is flexible flatfoot while rigid flatfoot is rare.[5]

The prevalence of flexible flatfoot in adults was reported to range from 13.6% to 25%.[5,6] It was 13.6% in Indian population aged 18-21 years[6], 25.3% in Bayelsa-Nigerian population aged 18-47 years[28], 26.62% in population aged ≥ 40 years[29], and 19% in multiethnic older adults population aged ≥ 65 years.[30] In Thailand, the prevalence of flexible flatfoot in students aged 19-22 years was 62%.[31] Among those who have flatfoot, approximately 60% to 75% show bilateral flatfoot.[31,32]

2.2 Supporting systems of the MLA

2.2.1 Passive system

The MLA of the foot is supported by passive and active systems.[13] Passive system that supports the MLA are the bones of the medial longitudinal column of the foot i.e. the talus, the navicular, the medial cuneiform, and the first metatarsal which are connected with plantar ligaments, and the plantar fascia.[14] Spring ligament that originates from the anterior margin of the sustentaculum tali and inserts at the plantar medial aspect of the navicular bone supports the plantar medial aspect of the talar head and MLA.[33,34] The superioromedial part of spring ligament is blended with deltoid ligament and commonly problem in patient with posterior tibial tendon dysfunction.[34,35] The distal of the deltoid ligament blend with the spring ligament and talonavicular joint capsule. This structure may affect a repetitive stress during weight bearing.[34,35] The calcaneus, midtarsal joints, and metatarsal bones form the truss arch while the plantar fascia that attaches between the calcaneus and the phalanges forms a tie-rod, which related to a windlass mechanism (Figure 2).[14,36,37] When the hallux is extended, tension in the plantar fascia increases and causes the first ray plantarflexion[38] which creates a shortened foot, raised arch, supinated rearfoot, and externally rotated leg.[13] However, the windlass mechanism may not be able to be activated for meaningful arch raising with the presence of malalignment of any bones or impaired joint mobility in the foot. A radiographic study of 100 weight-bearing feet found a positive correlation between first metatarsal pronation and the height of the MLA (r = 0.93, p < 0.001).[39]

Figure 2 *The triangular configuration of the plantar fascia and ligaments of foot (from Bolgla and Malone 2004, p. 78).*[37]

2.2.2 Active system

Active system consists of the extrinsic and intrinsic foot muscles. The **extrinsic foot muscles** include deep posterior compartment muscles of the leg, fibularis longus, and tibialis anterior. The deep posterior compartment of the leg consists of three muscles, i.e. the tibialis posterior, the flexor digitorum longus (FDL), and the flexor hallicus longus (FHL).[40] Among these three muscles, the tibialis posterior muscle is considered to be the most important muscle as it occupies approximately 57% of the physiological cross sectional area of the entire deep posterior compartment.[41] Tibialis posterior has an origin at posterior surface of tibia, posterior surface of fibula and interosseous membrane, it inserts into the navicular tuberosity and spreads over the plantar aspects of the midfoot (the three cuneiforms; the base of first, second, and third metatarsals) including sustentaculum tali of the calcaneus.[40] In case of elongation/weakness of tibialis posterior muscle, lead to medial column displacement and rearfoot eversion, resulting in flatfoot.[35,40]

The fibularis longus muscle originates from lateral shaft of the fibula, head of fibula and superior tibiofibular joint and inserts at plantar aspect of base of first metatarsal and medial cuneiform. It functions in opposition to the tibialis anterior and tibialis posterior muscles on the position of the first ray. With the pull of the fibularis longus in closed kinetic chain, the first metatarsal and medial cuneiform became more everted and plantarflexed which restored medial column stability and the MLA.[42] Weakness of the fibularis longus muscle would therefore development of flatfoot.

The intrinsic foot muscles consist of the abductor hallucis, flexor hallucis brevis, flexor digitorum brevis, and interosseous muscles. Observation of an increase in navicular drop of 3.8 millimeters when the activity of the intrinsic muscles decreased 26.8% of the control condition after the nerve block indicates that the intrinsic foot muscles play an important role in support of the MLA.[43] Disrupting the function of these muscles through fatigue resulted in an increase in pronation as assessed by navicular drop.[44]

The abductor hallucis muscle is the predominant muscle that supports the MLA. It is the first layer of intrinsic muscles at the foot. It originates from the posteromedial calcaneus and inserts into the medial sesamoid of the hallux or proximal phalanx.[40] A cadaveric study simulated contraction of the abductor hallucis muscle and recorded flexion and supination of the first metatarsal, inversion of the calcaneus, and external rotation of the tibia which was consistent with elevation of the MLA.[44,45] Because it locates under midtarsal joint, it contributes to stabilization and supination of the midtarsal joint against the pronating force during propulsive phase.[46]

Regarding the flexor hallucis brevis muscle, a study in 88 community-dwelling older adults (mean age 74.2 ± 6.2 years) found that a thicker flexor hallucis brevis muscle contributed to a higher navicular height and a smaller navicular drop.[47] No similar associations with the thickness of the flexor digitorum brevis or abductor hallucis muscles were found.

2.3 Etiology and contributing factors of flatfoot

The etiology of flatfoot is difficult to discern[27,48] as the cause of flatfoot condition may be acquired as a compensatory mechanism such as abnormal development of the foot arch or inherited condition as seen in hypermobility (Ehlers-Danlos syndrome) disorders involving excessive ligament laxity and joint instability.[48] For the acquired cause, certain factors can increase an individual's chances of developing flatfoot. They are obesity, age, inappropriate footwear, improper lower limb alignment, and weakness of proximal muscles.[48-53]

2.3.1 Obesity

Higher prevalence of flat foot was observed in obesity. The prevalence of flatfoot in children aged between three to six years who were obese and normal-weight was 62% and 42%, respectively.[50] In children aged seven to ten years, 80% of overweight/obese children had flatfoot while 17.5% of normal-weight children had flatfoot.[54] A significant relationship between body mass index and flatfoot severity was also reported in people aged 19 to 22 years (r = 0.287, p < 0.001).[31] However, two studies reported no association between body mass index and the MLA height.[55,56] One study also reported no relationship between the Foot Posture Index and body mass index.[51]

2.3.2 Age

Two studies reported no association between age and the MLA height. One study in 254 volunteers aged 18 to 68 years reported no association between age and the MLA height.[56] The other study examined arch height index of 145 subjects, who were 68 men and 77 women (18 to 65 years), reported no difference between the arch height index of men and women as well as between increasing age.[57] However, those whose age was less than 18 or greater than 59 years exhibited significantly higher FPI-6 scores than the adults aged 18 to 59 years.[51]

2.3.3 Inappropriate footwear

Footwear has an influence on flatfoot especially in early childhood. It is suggested that shoe wearing in early childhood has adverse effect on the development of the MLA. It was reported that children with aged ⩽ 6 years who started to wear shoe has a higher prevalence than who did not wear shoe.[13] The prevalence of flatfoot in children who wore shoe was 8.6% compared to who did not 2.8% ($p < 0.001$).[52]

2.3.4 Improper lower limb alignment

Improper forefoot alignment in varus or supinated position that characterizes as a decrease contact area between foot and ground during weight bearing.[48] To increase the contact area, the rearfoot needs to pronate and the calcaneus will be in everted position. The foot will therefore be in pronated position or flatfoot. Rearfoot valgus or calcaneal eversion that is associated with tibial internal rotation or genu valgus also places more weight on medial foot which can lead to flatfoot.[48,49]

2.3.5 Weakness of proximal muscles

Weakness of the gluteus medius (GMed) muscle, which is the main muscle of hip abduction, was found to induce foot pronation and flatfoot. Weakness of the gluteus medius muscle would lead to pelvic drop in the frontal plane that is associated with internal hip rotation[53] and a valgus stress at the knee during a single leg stance.[9,53] The tibia would be in the position of internal rotation which affects the alignment of the subtalar joint. It was reported that 1° of tibial internal rotation can generate approximately 1° of pronation.[49] Thus, the more weakness of the gluteus medius muscle would produce the more tibial internal rotation, the more subtalar joint pronation, and the more severity of flatfoot.

2.3.6 Tightness of calf muscles

Tightness of the calf muscles and flatfoot frequently coexist in which the available evidence supports that these two abnormalities are related as being either a cause or effect.[58] With tightness of the calf muscles, ankle dorsiflexion is limited. To dorsiflex the ankle sufficiently enough to allow the heel to contact the supporting surface, the subtalar or midtarsal joint needs to pronate. The tension from tight calf muscles would also create tension in the plantar fascia and oppose the active function of the tibialis posterior muscle during the stance phase of gait in which the tibialis posterior muscle is contracting to resist the collapse of the MLA.[59]

2.4 Influences of flatfoot

Flatfoot can induce several impairments or symptoms both locally and remotely. Locally, it reduces the efficiency of foot during gait. Remotely, it alters stress imposing on the lower extremity and the spine.

2.4.1 Influences of flatfoot on gait

Persons with flatfoot will have gait alteration. With flatfoot, the tibialis posterior tendon is in a stretched position and it cannot provide a strong rigid lever before push off. This leaves the rearfoot remain in an everted position which causes the midtarsal joint to be in an unlocked position and become unstable in the transverse plane.[1,34] The foot is less capable of undertaking the coordinated supinatory motion that occurs during terminal stance and pre-swing.[60] Moreover, individuals with flatfoot showed a higher physiological cost index than those with normal-arched foot [61].

2.4.2 Influences of flatfoot on plantar pressure

Plantar pressure in flatfoot differs from normal. Higher plantar pressure in the areas of the 2^{nd} to 3^{rd} metatarsal heads and medial heel was found in the flatfoot while it was lower at the 4^{th} to 5^{th} metatarsal head areas.[18,62]

2.4.3 Influences of flatfoot on balance

Based on center of pressure velocity and total velocity, there was a significant difference between static stability of flat foot and normal-arched individuals.[11] The means center of pressure velocity of normal-arched and flat foot were 982.318 ± 300.36 and 2221.95 ± 554.3 mm/min in the anteroposterior plane compared to 1009.5 ± 200.8 and 1621.65 ± 405.6 mm/min in the mediolateral plane, respectively. The total velocity of center of pressure sway was 1410.36 ± 359.9 in normal and 2752.12 ± 683 millimeters in flatfooted individuals. The other study found no significant differences on static balance between flatfoot and normal-arched foot.[63]

For dynamic balance test, it was reported that flatfoot had a shorter reach distance compared to the normal-arched foot in all directions of the star excursion balance test.[64] The flatfoot showed significantly decrease in the reach distance in the anterior and anteromedial aspects compared to the normal-arched foot.[63]

These findings might be related to the altered alignment of the lower extremity in flatfoot that may cause impairment in the proprioception at talocalcaneal joint and lead to poor balance.

2.4.4 Influences of flatfoot on lower extremity alignment

There is a biomechanical relationship between subtalar, talocrural, and tibiofemoral joints during closed chain activity. For every 4° of calcaneal eversion, there are simultaneous movements of the talus in adduction and plantarflexion 1° and tibial internal rotation 4°.[16] This 1:1 movement ratio between subtalar adduction and tibial internal rotation occurs about a normal subtalar joint axis.[16,49] Femur will relatively rotate internally and adduct with tibia[53] and the pelvis may drop in the frontal plane.[9,53]

2.5 Assessment methods of foot type

There are many methods for assessing foot types; i.e. visual inspection, anthropological measurements, calculation of arch height index (AHI), and radiograph. These methods can be assessed both in non-weight bearing condition or in weight-bearing condition. Three non-invasive techniques that are commonly used for assessing foot type are reviewed.

2.5.1 Visual inspection

Visual inspection can be performed directly while an individual stand with bilateral barefoot. It was reported that a trained assessor could reliably use direct visual inspection to classify foot type into supinated, pronated, and neutral foot with the Kappa value for interrater reliability was 0.72.[65] Details criteria for classification are as follows:

2.5.1.1 Supinated foot

To be classified as excessively supinated, the foot had to present with three mandatory criteria (items 1-3) and two elective criteria (items 4, 6):

1.) The calcaneus must be noticeably inverted in which a vertical bisector of the calcaneus was more than about 3° from a perpendicular position from the ground.

2.) There must be no medial bulge at the talonavicular joint. The foot may have a lateral bulge of the talus at the sinus tarsi.

3.) The MLA height must be high in which the angle formed by lines connecting the medial malleolus, the navicular tuberosity, and the first metatarsal head approaches 180°

4.) The forefoot must be adducted in relation to the rearfoot.

5.) The leg may be excessively externally rotated.

6.) The width of the foot at the midtarsal joint must be decreased.

2.5.1.2 Pronated foot

To be classified as excessively pronated, the foot had to present with three mandatory criteria (items 1-3) and two elective criteria (items 4-5):

1.) The calcaneus must be noticeably everted in which a vertical bisector of the calcaneus was more than about 3° from a perpendicular position from the ground.

2.) A medial bulge must be present at the talonavicular joint.

3.) The MLA height must be low in which the angle formed by lines connecting the medial malleolus, the navicular tuberosity, and the first metatarsal head approaches 90°.

4.) The forefoot must be abducted in relation to the rearfoot at the transtarsal joint.

5.) There must be excessive lower extremity internal rotation.

2.5.1.3 Neutral foot

The foot is classified as neutral when:

1) The calcaneus is perpendicular to the ground.
2) The MLA height must be low in which the angle formed by lines connecting the medial malleolus, the navicular tuberosity, and the first metatarsal head is between about 30 and 150°.

2.5.2 Anthropological measurements of the foot

The measurements can be performed using a measuring tape, a ruler, or a specifically designed device. Two tests are commonly conducted. They are the Navicular Drop Test and the Arch Height Index.

2.5.2.1 Navicular Drop Test

The Navicular Drop Test is measured by asking a person to stand bilateral barefoot on the floor and the navicular tuberosity is marked.[66-68] The distance between the navicular tuberosity and the floor is then measured (Figure 3). The difference (in millimeters) of the height of the navicular tuberosity is measured in two positions: subtalar neutral position and relaxed posture. The subtalar neutral position is determined by having the foot everted and inverted until the lateral and medial aspects of the talar dome of the foot could be palpated with equal prominence. Besides direct measurement of the navicular height, some studies took a digital photograph of the medial view of the foot and digitized for the distance.[24,69]

Excellent intrarater reliability (ICC ranged from 0.85 to 0.97) was found in persons with flatfoot.[67,68,70] The standard error of measurement of the navicular drop was found to range from 0.4 to 0.8 millimeters.[68,70] The non-invasive measurement of navicular height in a relaxed standing could be regarded as a valid measure of the MLA height when testing against radiograph, in which the findings from the two techniques correlated well with each other (r = 0.79).[71]

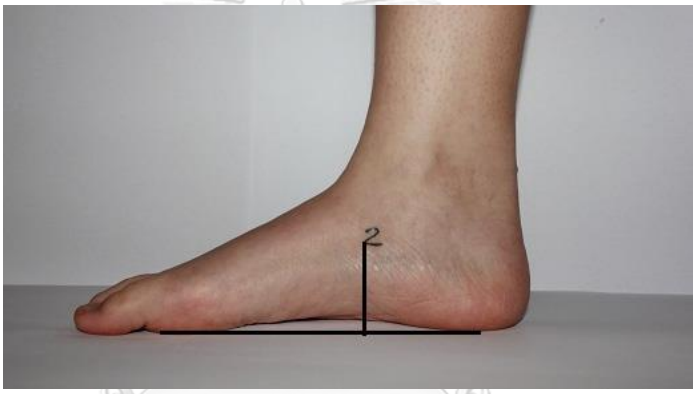


***Figure 3** Navicular height (from Nilsson et al. 2012, p. 3).[55]*

A study in 254 volunteers aged 18 to 68 years found a normal navicular height within the range of 36 to 55 millimeters while a normal navicular drop was within the range of six to 18 millimeters.[55] Traditionally, several studies consider the navicular drop between five and nine millimeters as normal foot arch, the score more than or equal to 10 millimeters as flatfoot, and less than 4 millimeters as high arch foot.[14,70,72,73]

Some studies assessed the Navicular Drop Test by setting an individual in sitting with the hips and knees flexed to 90° for measuring the navicular height with the subtalar joint in a neutral position.[14,24] However, the level of intrarater reliability was relatively lower than the standing test (ICC ranged from 0.37 to 0.71).[74]

Although the Navicular Drop Test is an inexpensive method for evaluating the MLA height, the test requires previous training so that assessor is proficient in identifying the relevant anatomical landmarks.[68]

2.5.2.2 Arch Index

A footprint is obtained with an individual standing in a relaxed position.[75] A line is drawn from the center of the heel to the tip of the second toe which will be used to divide the footprint into three equal parts (A, B, and C) (Figure 4). Arch index is calculated by dividing the middle foot area (B) by the total foot area (A+B+C). The MLA is considered as high with arch index ≤ 0.21, normal arch between 0.21 and 0.26, and low arch ≥ 0.26.[75] Excellent intrarater reliability was obtained with this method (ICC = 0.99).[71,76] However, this method has more error when comparison to caliper methods.[75]

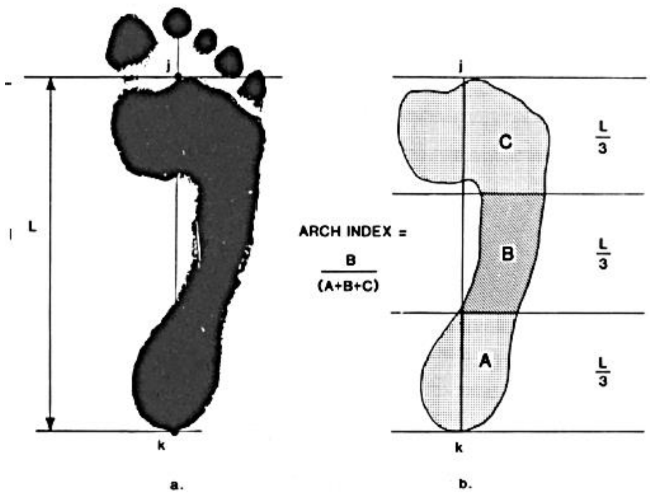


***Figure 4** The footprint used for calculating arch index (from Cavanagh 1987).*[75]

2.5.2.3 Arch height index

Arch height index is measured by dividing the dorsum height at 50% foot length by the truncated foot length expressed (Figure 5).[77] The truncated foot length is a distance between center of the first metatarsophalangeal joint to posterior calcaneus.[77,78] The measurement can be done both in relaxed standing (weight bearing) and sitting (non-weight bearing) conditions.[79] Individuals aged between 18 and 77 years old, means of arch height indices in standing was 0.33 ± 0.03 in flatfoot, 0.36 ± 0.03 in normal-arched foot, and 0.38 ± 0.03 in high-arched foot.[80] The good intrarater reliability study in children aged six to 12 years (ICCs ranged from 0.84 to 0.87).[81]

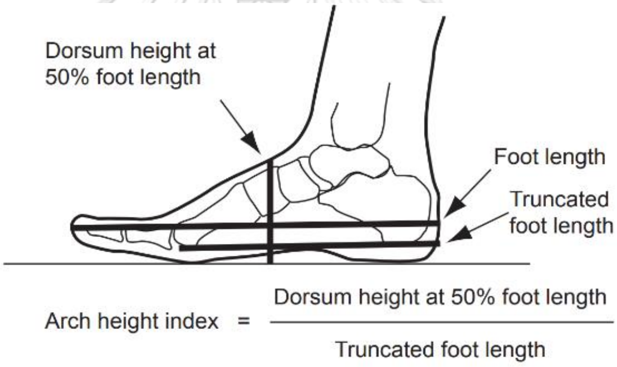


Figure 5 *The measurement of arch height index (from Miller et al. 2014, p. 78).*[77]

2.5.2.4 Foot Posture Index – 6

Foot posture index (FPI-6) is an instrument for assess foot posture with multiple views while being in a relaxed standing consisting of six criteria. Each criterion with a 5-point scale that ranges from -2 for signs of supination to +2 for signs of pronation.[82]

The criteria include talar head palpation; supra- and infralateral maleolar curvature; calcaneal frontal plane position; prominence in the region of the talonavicular joint; congruence of the MLA; and abduction/adduction of the forefoot on the rear foot. The total FPI-6 result allows one to classify the 1,198 feet of adults age 18 to 59 years into the following categories: from +1 to +7 is neutral foot, from +8 to +10 is slight foot pronation, from +11 to +12 is excessive foot pronation, from -3 to 0 is slight foot supination, and from -4 to -12 is excessive foot supination.[51] The FPI-6 also showed almost perfect agreement for both intrarater reliability (κ = 0.87) and interrater reliability (κ = 0.83).[70]

2.6 Management of flatfoot

Three nonoperative methods have been proposed for improving flatfoot. They are foot orthoses, taping, and foot strengthening exercise.

2.6.1 Foot orthoses

Foot orthoses are external devices being inserted on the plantar surface of the foot that act as a passive arch to resist excessive pronation and improve biomechanics of the lower extremity. They aim to maintain the subtalar joint in the neutral or close to neutral alignment. They cause motion restriction in a specific area and alter pressure distribution in the foot.[83] Foot orthoses are usually seen in two types, i.e. prefabricated orthoses and custom-molded orthoses. Prefabricated orthoses are readily available with low cost and time saving. The custom-molded orthoses are manufactured from individual's foot and have the advantage of compliance to variations in individual conditions.

Foot orthoses can be categorized based on the material used into three subtypes including soft, rigid, and semi-rigid foot orthoses. Soft foot orthoses are made from soft and nondurable materials. They provide shock attenuation and reduce shear forces.[83] They accommodate for persons with impaired sensation or fixed foot deformities which may be combined with a semi-rigid to improve a better mechanical property. Rigid foot orthoses are made from hard and durable materials so they provide less shock absorption and protection from shear forces.[83] They provide a strong arch support and control for flexible foot deformities. Semi-rigid foot orthoses are the most commonly used orthoses. They have low density surface layer for shock absorption and firm layer base for support. The semi-rigid foot orthoses with medial arch support are recommended for flexible flatfoot.[83]

Many studies investigated on the effects of the semi-rigid foot orthoses. It is reported that foot orthoses reduce rearfoot eversion[24,84,85], tibial internal rotation[86], and foot pronation during dynamic weight bearing[87]. The height of MLA in flatfoot was found to increase at 10 minutes (4.3 ± 0.7 millimeters) and 20 minutes (3.6 ± 0.8 millimeters) after jogging with orthoses.[88] Mean MLA angles for persons who used rigid and soft orthoses were significantly different from the barefoot with range of 2.6-3.5 degrees ($p < 0.05$).[2] A force reduction at medial midfoot was also found when using foot orthoses.[89] The group that used semi-rigid prefabricated orthoses for four weeks showed significant difference in mediolateral sway ($p = 0.02$).[90] An improvement of balance in mediolateral sway after application of foot orthoses may suggest an improvement in flatfoot and restoration of MLA.[91]

Immediate effect of foot orthoses on activity of muscles that support the MLA was shown. During contact phase of gait cycle, a group with foot orthoses had a decrease in muscle activity of tibialis posterior.[92] During midstance and propulsion phase, an increase in fibularis longus muscle activity was found.[92] The tibialis posterior act an important role to resist rearfoot everted, the decreased amplitude of the tibialis posterior can be suggested that foot orthoses help to resist rearfoot everted lead to reduce the tibialis posterior contraction.[92]

The participants with flatfoot that used foot orthoses showed an increase in muscle activity of vastus medialis during single leg squat and lateral step down but decrease in muscle activity of vastus lateralis during maximum vertical jump.[93] Another study found increased muscle activity of vastus lateralis, vastus medialis, and fibularis longus with foot orthoses during running.[94] Two systematic reviews (one randomized controlled trial and one prospective cohort study) showed no significant differences in pain reduction or functional improvement at 6 weeks, 12 weeks, and 12 months between the use of prefabricated foot orthoses and custom-made foot orthoses.[95]

Instead of using foot orthoses, the use of contoured footwear can also increase arch height and slightly help the subtalar joint reach the neutral position.[96] By using footwear with 4-millimeter contour support for 12 weeks, a 21% increase in cross-sectional area of the flexor digitorum brevis muscle and 60% increase in longitudinal arch stiffness were found.[77]

2.6.2 Arch taping

These interventions are usually applied for acute settings in combination with medication. Different types of tape provide different benefits, i.e. support, pain reduction, muscle activation, and plantar pressure alteration. With low-dye taping, the non-elastic tape is superior than elastic tape on increasing arch height.[97] The non-elastic tape could reduce foot pain but it does not improve rearfoot pronation.[98] However, there was no significant difference in Foot Posture Index score between group of kinesiotape and sham kinesiotape.[99]

2.6.3 Foot strengthening exercise

Two main strengthening exercises have been recommended for improving flatfoot. They consist of short foot exercise and tibialis posterior exercise. The short foot exercise is used to strengthen the intrinsic foot muscles.[46] The exercise is performed barefoot by bringing the head of the first metatarsal towards the heel without toe flexion while keeping the forefoot and the heel on the ground.[100] One previous study that used a pre- versus post-test design without a control group in people without flatfoot reported that performing a 4-week short-foot exercise program everyday improved the navicular drop (from 12.7 ± 6.0 to 10.9 ± 5.5 millimeters) and arch height index (from 28 ± 2 to 29 ± 2%) and that these effects were maintained for 4 weeks after exercise intervention.[14] For persons with flatfoot, performing a short-foot exercise program in sitting for three times a week for eight weeks could reduce navicular drop (from 12.5 ± 3.3 to 10.6 ± 2.5 millimeters) and foot posture index (from 10 to 8.5 scores).[100] The other study reported significant decrease in navicular drop and foot posture index in persons who were assigned to perform the short foot exercise daily for six weeks.[101]

A recent study that included tibialis posterior strengthening and iliopsoas stretching in addition to the conventional towel curl exercise program for six weeks could improve navicular drop, muscle activity, and dynamic balance in flatfoot.[73] The navicular drop of the strengthening group improved from 13.5 ± 2.0 to 8.5 ± 1.4

millimeters while it was from 13.0 ± 1.8 to 11.3 ± 1.5 millimeters in the control group. These findings suggest that the strengthening exercises of the tibialis posterior and the intrinsic foot muscles provide greater benefit in navicular drop than the strengthening exercise of the intrinsic foot muscles alone.

Besides the strengthening exercises of the intrinsic foot and the tibialis posterior muscles, it was also found that the closed-chain strengthening exercises of the hip abductors and external rotators for six weeks, with no specific exercises for the foot muscles, can increase rearfoot varus during gait.[102] However, no studies have investigated this assumption. Furthermore, individuals with flatfoot who performed both gluteus maximus and toe spread exercises showed a significant decrease in the navicular drop more than the group that performed only toe spread exercises for four weeks.[103] The navicular drop of the former group changed from 11.9 ± 2.0 to 5.5 ± 1.6 millimeters while the latter group changed from 11.4 ± 1.4 to 7.6 ± 2.3 millimeters. This finding suggests that strengthening exercises of the hip muscles can help improve the MLA.

2.7 Comparison of the effectiveness of management techniques for flatfoot

Some studies compared the effectiveness of different management techniques for flatfoot. Although both taping and foot orthoses can significantly alter foot kinematics in adults with flatfoot, foot orthoses appear most effective acting on the rearfoot whereas the effects of taping are more confined to the midfoot and MLA.[104] Foot orthoses combined with short-foot exercise is more effective in increasing the cross-sectional area of the abductor hallucis muscle and the strength of flexor hallucis muscle compared with foot orthoses alone.[46] LowDye tape and orthotic treatments produced approximately a 19% (10.8 ± 1.3 millimeters) and 14% (8.0 ± 0.4 millimeters) increase in navicular height, respectively immediately after the application but a significant decrease was found after jogging for 10 minutes.[15]

A study the effects of short foot exercises and application of arch support insoles for five weeks in patients with flexible flatfoot found short foot exercises more effective than application of arch support insoles. The navicular drop reduced from 11.4 ± 1.6 to 7.7 ± 1.1 millimeters.[25]

2.8 Summary

Two main strengthening exercises, namely the short foot exercise and tibialis posterior exercise, have been recommended for improving flatfoot. Nevertheless, it has been found that the combined strengthening exercise of the tibialis posterior and the intrinsic foot muscles provides greater benefits in reducing navicular drop than the strengthening exercise of the intrinsic foot muscles alone. Additionally, two studies have reported improvements in the MLA through the strengthening exercises of the hip muscles, apart from the foot muscles. However, there is a lack of studies comparing the effects of strengthening exercises targeting tibialis posterior and intrinsic foot muscles with those targeting both the hip and foot muscles. No report on the effects of gluteus medius muscle strengthening exercises on the MLA has been found. Moreover, there is a lack of studies comparing the effects of foot and hip muscle exercises with foot orthoses.

This study comprised two separate studies to address these research questions. Study 1 established the more effective exercise protocol by comparing the MLA height in groups performing foot exercises with and without gluteus medius muscle strengthening exercise after 8-week interventions in individuals with flexible flatfoot. The study outcome measures were navicular drop, arch height index, plantar foot pressure, static balance, and dynamic balance at baseline, after 4 weeks, and after 8 weeks of intervention. Study 2 compared the established exercise protocol in Study 1 to foot orthoses to determine the actual effectiveness of each intervention on the MLA in individuals with flexible flatfoot. The same outcome measures as Study 1 were assessed at baseline, after 4 weeks, and after 8 weeks of intervention.

CHAPTER 3

STUDY 1 – METHOD, RESULTS, DISCUSSION, AND CONCLUSION

3.1 Method

The aim of Study 1 was to establish whether performing foot exercises with and without gluteus medius (GMed) muscle strengthening exercise would be more effective on the MLA (navicular drop, arch height index, foot posture index, plantar foot pressure, static balance, and dynamic balance) than performing foot exercises alone for eight weeks, in individuals with flexible flatfoot.

3.1.1 Research design

A randomized clinical trial was conducted.

3.1.2 Participants

Fifty-two participants who met the inclusion and exclusion criteria of the study were recruited and randomized into two groups; foot exercise group (FG) and foot plus hip exercise group (FHG). Participants were recruited through advertised posters (Appendix XIV) and social media. The sample size calculation was described in Appendix IV.

3.1.2.1 Inclusion criteria

- Were male and female with age 18 to 39 years (due to age ≥ 40 had been shown to have more risk of fall).[105]

- Had asymptomatic bilateral flexible flatfoot. Flatfoot was defined as the navicular drop test more than or equal to 10 millimeters[14,70,72,73] or FPI-6 score more than 7.
- Had a body mass index in the range of 18.5 – 22.9 kg/m^2.
- Had ankle dorsiflexion range of motion at least 10°.
- Could read and write Thai language.

3.1.2.2 Exclusion criteria

Individuals were excluded if they met any of the following criteria:

- Had undergone lower extremity surgery.
- Had a history of trauma or accidents in the lower extremities.
- Had lower extremity deformities: pes cavus, pes equinus, hallux valgus with greater angle than 15°, or clubfoot.
- Had a sign of neurological deficit over the lower extremities.
- Female subjects if they were pregnant.

3.1.3 Instruments

3.1.3.1 JTech Commander PowerTrack II Manual Muscle Testing

Dynamometer (JT-CM305, Jtech medical industries, Inc, United States) was used for muscle strength assessment. (Figure 6)

Figure 6 *JTech Commander PowerTrack II Manual Muscle Testing Dynamometer.*

3.1.3.2 The DIERS Pedoscan (The DIERS International GmbH, Schlangenbad, Germany)

The DIERS system was a mobile computer-assisted measurement system that was used for measuring plantar pressure and static balance. It had a measurement plate with dimensions of 480 millimeters × 360 millimeters that was embedded with 4,096 sensors. It had a sensitivity range of 0.27 to 127 N/cm^2 and was operated at a measurement frequency of 300 Hz.[28]

To standardize the feet placing area, we used the tape measure. A horizontal line was placed 15 centimeters below the edge of foot force plate (Figure 7) and a vertical line was placed at the midpoint of the horizontal line. Participants placed the feet in alignment with the width of their shoulders, ensuring that each foot was equidistant from the vertical line.

Figure 7 *The DIERS Pedoscan.*

3.1.3.3 FITband (Union Pioneer Public Company, Thailand)

This was an elastic band with six different levels of resistance, ranging from 1 to 9 kilograms. These elastic bands were used for the foot adduction exercise conducted in this current study. (Figure 8)

Figure 8 *FITband (elastic bands)*

3.1.4 Outcome measures

3.1.4.1 Navicular drop test

The method for measuring the navicular drop test described in Section 2.5.2.1 was used. In brief, the assessor palpated the medial and lateral sides of the head of the talus while the participants were in a standing position. Then, they were asked to invert and evert the foot until the assessor's thumb and index could equally feel the talar head on both sides. This position indicated a neutral position of the subtalar joint. After that, the assessor measured the height between the navicular tubercle and the ground in millimeters using a metal ruler and recorded the value. Finally, the heights when the participants stood with full weight bearing and a relaxed foot posture were measured. This measurement process was performed three times for both feet, and the average value of the measurements was recorded (Appendix II).

3.1.4.2 Arch height index

The measurement was conducted while the participants were in a relaxed standing (weight bearing) conditions.[79] The AHI was calculated by dividing the dorsum height at 50% of foot length by the truncated foot length. The truncated foot length was the distance between center of the first metatarsophalangeal joint to posterior heel.[77,78] This measurement was performed three times for each foot, and the average of the measured values was recorded (Appendix II).

The guidelines from Pohl et al. (2010)[79] were used for measuring the AHI. Four wooden blocks with two pieces of block A were placed under the ball of the foot and the heel and the medial side of foot was in contact with an acrylic plate (Figure 9). A ruler was attached to the acrylic plate to increase measurement accuracy. The other foot was placed on block B, and a smartphone camera with 50 million pixels was placed on block C at 55 cm from the medial aspect of the foot and 10 cm from the posterior aspect of heel. This measurement setup was repeated on the other foot by moving block B and the camera to the other side.

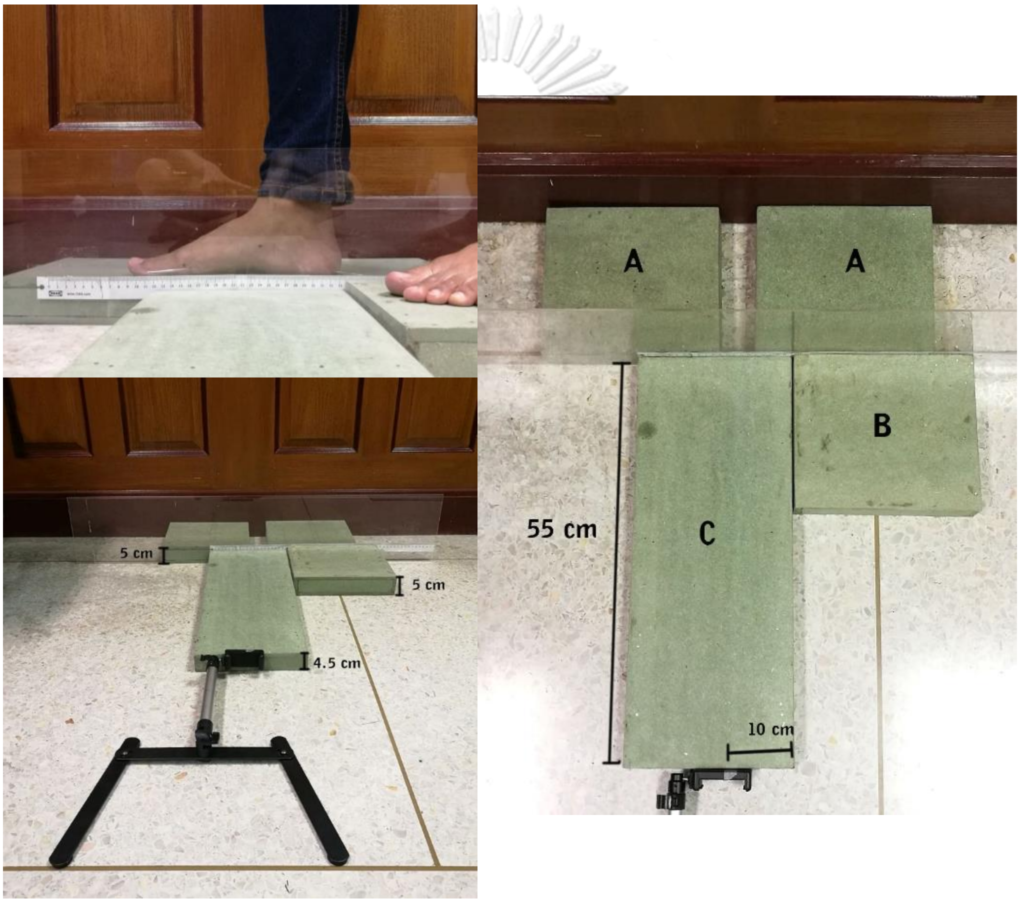


***Figure* 9** *AHI measurement and device*

3.1.4.3 Plantar foot pressure (static)

The Pedoscan was used to measure maximum pressure, average pressure, and pressure distribution.[28] Participants were asked to stand barefoot on the DIERS Pedoscan measurement plate (Figure 10) for 30 seconds with their eyes opened and looked straight at a mark on the wall.[27] Three measurements were taken with a 60-second rest between each measurement. The average value of the three measurements was recorded (Appendix II).

Excluding the toes, the foot plantar area was divided equally into 3 parts representing the forefoot, midfoot, and hindfoot regions. The forefoot and hindfoot were further divided into medial and lateral areas. Three measurements were taken with a 60-second rest between each measurement. The average pressure (kPa) of each foot area was used for analysis.

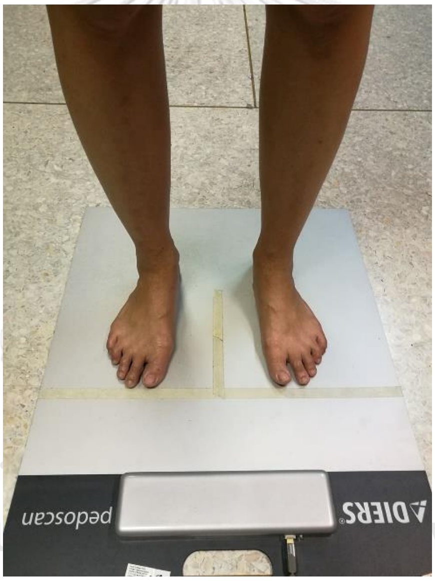


Figure 10 *Plantar foot pressure assessment*

3.1.4.4 Static balance test (single leg standing)

The maximum displacement of the center of pressure was obtained in centimeters by using the DIERS Pedoscan (Figure 11). The participants began in a starting position with placing their feet in the same manner as for the plantar pressure measurement. They were asked to stand on one leg with their eyes closed and their hands placed on their anterior superior iliac crests. The other leg was flexed at the hip and knee to a 90-degree angle. Three test trials with each trial lasting for 10 seconds were conducted. A 60-second rest period was provided between each trial. The average value of the three trials was recorded for analysis. During testing, the test was retested if the other foot touched the plate or floor, the standing leg lifted off the ground, the participants opened their eyes, or any hand left its position on the iliac crests.[91]

Figure 11 *Static balance test*

3.1.4.5 Dynamic balance test

Dynamic balance assessment in the anteroposterior and mediolateral planes was assessed as they were found to be affected in adults with flexible flatfoot.[11] A modified star excursion balance test was used in this study.[19,63] Measured tapes, each with 150 centimeters length, were placed on the floor in four directions, i.e., anterior, posterior, medial, and lateral. Participants stand at the center where the tapes crossed each other. Next, they were instructed to reach one leg to make slight contact with the tape in each direction, extending as far as possible while another leg stood on the ground. (Figure 12) The contact had to be maintained for at least one second. The distance between center and the edge of the big toe in four directions were recorded[63] (Appendix II). Then, these distances were represented as a percentage of the participants' leg length.[19] Leg length was measured from medial the malleolus to the anterior superior iliac spine.[27]

Each direction was measured three times with a 10-second rest period in between measurements. The average value was calculated. The order of testing directions was randomized into two groups, i.e., those that started with clockwise and counterclockwise reach pattern. For example, those that started with clockwise reach pattern began testing as follows: clockwise, counterclockwise, and clockwise. The test was retested if the leg touched the line with weight bearing, the leg could not maintain touching for at least one second, or the standing leg lifted from the point.[63]

Figure 12 *Dynamic balance test*

3.1.4.6 Muscles strength test

All muscles strength assessment was recorded in data collection sheet presented in Appendix II.

1.) Tibialis posterior muscle

The tibialis posterior muscle coordinates with gastrocnemius and soleus muscles for plantar flexion and ankle inversion together with tibialis anterior so it was difficult to differentiate the tibialis posterior strength alone. This study assessed strength of the tibialis posterior muscle by asking the participants to plantarflex and invert their foot against a hand-held dynamometer (Figure 13).[106] The participants were set in side-lying position on the tested side with the knee slightly flexed. The foot placed over the end of table with foot and ankle were in neutral position. Participant was asked to invert foot full range of motion with slightly plantarflexion. Assessor stabilized the lower leg proximal to the ankle joint while providing a resistance to foot inversion on the medial border of the forefoot.[106]

Figure 13 *Tibialis posterior strength test*

2.) Flexor hallucis brevis muscle

The participants were set in supine position with hips and knees straight and ankle dorsiflexion at end range. Participants were asked to perform toe flexion. The hand-held dynamometer was placed under interphalangeal joint of the hallux.[106] (Figure 14)

Figure 14 *Flexor hallucis brevis strength test*

3.) Gluteus medius muscle

The participants were set in side-lying position with the tested leg on top and the non-tested leg flexed at hip and knee to stabilize the trunk.[106] The tested leg was in a slight hip extension and neutral rotation. Participant performed hip abduction full ROM and try to avoid hip flexion, hip internal rotation, and hip elevation. Assessor stabilized the anterior superior iliac spine while providing a resistance to hip abduction on the lateral aspect of the thigh proximal to the knee.[106] (Figure 15)

Figure 15 *Gluteus medius strength test*

3.1.5 Interventions

Two strengthening exercise protocols were used.

3.1.5.1 Protocol 1: Strengthening exercise for tibialis posterior and intrinsic foot muscles

The participants were instructed to perform three exercises as follows:

1) Exercise 1 – Foot adduction exercise

Participants were asked to sit on a chair with barefoot. Elastic band was wrapped around the exercised foot by aligning the band at 45 degrees from the floor. Participants were instructed to adduct the foot like floor sweeping against the elastic band while maintaining the heel and toes contact with the floor (Figure 16). This exercise was found to selectively activate the tibialis posterior muscle.[107] The exercise performed for 30 repetitions per set, three sets per day (1-minute rest between sets; for the second and third set allowed the participants performed in range 20-30 repetitions), and five days per week for eight weeks.

Participants received the elastic band tension that matches their muscle strength. They were assessed every week via telephone. The color of the elastic band was chosen if the participants can perform the exercise for at least 20 repetitions but not more than 30 repetitions. A progression was allowed when they could perform the exercise correctly (>30 repetitions for 3 sets) without significant muscle soreness on the following day by changing color of the elastic band with more resistance.[27] The exercise difficulty was progressed by changing the color of the elastic band so that it required a greater load to be stretched.

Figure 16 *Foot adduction exercise*

2) <u>Exercise 2 – Foot supination exercise</u>

Participants were asked to stand over the edge of a step of the stairs. The lateral foot (3rd to 5th toes) was placed on the edge whereas the medial foot (1st and 2nd toes) was placed outside the edge (Figure 17). Participants were instructed to perform foot supination.[27,107] This exercise was found to selectively activate the tibialis posterior muscle at approximately 50% of that recorded during resisted foot adduction.[107] The exercise was performed for 30 repetitions per set, three sets per day (1-minute rest between sets), and five days per week for eight weeks.

Figure 17 *foot supination exercise*

3) <u>Exercise 3 – Short foot exercise</u>

The exercise starts in sitting position which was progressed to a double leg stance and single leg stance.[14,46] In sitting position, participants were instructed to draw metatarsal heads back towards the heel without toe curling while placing the foot on the floor (Figure 18). Each repetition should be held for five seconds and three sets of 10 repetitions should be performed. A 45-second rest period is allowed between sets. The exercise comprised three variations, where each variation possesses gradually increased level of difficulty: the sitting position, the double-leg standing position and the single-leg position.[14,100] Exercise difficulty was increased when a person can perform the exercise correctly for five minutes without significant muscle soreness on the following day. The participants should perform 30 repetitions per day and five days per week for eight weeks.

Figure 18 *Short foot exercise (left: sitting, middle: double leg stance, right: one leg stance)*

3.1.5.2 Protocol 2: Strengthening exercise for tibialis posterior, intrinsic foot, and hip muscles

The participants were instructed to perform the same three exercises as Protocol 1 (Exercises 1 to 3) with the additional exercise for hip abductor muscles – clamshell exercise. (Figure 19). The clamshell exercise was known to strengthen the gluteus medius muscle and it has four progressions.[108] Participants began with Clamshell progression 1-4 that corresponds to their muscle strength. Researcher 1 assessed the participants every week. Progression was provided when they can perform the exercise correctly without significant muscle soreness on the following day.

Progression 1: Participants start in side lying with exercised leg on top, hips flexed 45°, knee flexed, and feet together. Participants were asked to external rotate the top hip by moving the knees apart while keeping the feet together and holding for five seconds. The exercise was performed for 10 repetitions per day with a 10-second rest between repetitions.

Progression 2: Participants were in the same starting position as progression 1. The participants kept knees together and perform internal rotation of the top hip to move the top foot away from the bottom foot, which should be held for five seconds, then returned to start position. The exercise was performed for 10 repetitions per day with a 10-second rest between repetitions.

Progression 3: Participants were in the same starting position as progression 1. The top leg was raised and held parallel to the ground with knee flexed. By keeping the hip at the height of the knee, the participants performed hip internal rotation so that the top foot moved toward the ceiling and held for five seconds, then returned to start position. The exercise was performed for 10 repetitions per day with a 10-second rest between repetitions.

Progression 4: Participants were in the same starting position as progression 3 but with hip fully extended. Participants held the height of the top knee with top hip internal rotation and top foot moved to the ceiling holds for 5 seconds then returned to start position for 1 set, rest 10 seconds between set, performs 10 sets per day.[108]

Figure 19 *Clamshell exercise (progression 1-4)*

3.1.6 Procedures

All participants were required to sign an informed consent before taking part in the study. Two researchers, who were physical therapists with 8-year experience in musculoskeletal disorders, involved in this study. Researcher 1 was responsible for instructing the exercise protocols. Researcher 2 was blinded to the group assignment, was responsible for screening asked the participants to fill out a screening questionnaire

(Appendix I), performing physical examination based on inclusion and exclusion criteria, and taking all the outcome measures.

All baseline data were measured and this included the navicular drop, arch height index, plantar pressure, static balance, dynamic balance, and muscle strength. Next, the baseline muscle strength of the exercise muscles was measured using a hand-held dynamometer, and recorded in (Appendix II).

This current study would match these 4 subgroups as closed as possible. FG would perform exercise Protocol 1 while FHG would perform exercise Protocol 2 for eight weeks. The exercises performed on both legs. The correctness of the exercise performance was monitored by Researcher 1 once a week during a meeting before training. To prevent muscle cramp, all participants asked to stretch their muscles, and to prevent falling during foot supination exercise, this exercise was performed only at first step of stair and allow to light touch the handrail.

All participants received a checklist notebook (Appendices VII and VIII) for recording the exercise intervention. Every week, Researcher 1 contacted each participant for reminding, suggesting, and answering about the interventions. At the end of the 8-week study, all participants were asked to stop all interventions. All outcome measures were assessed every four weeks until eight weeks at Phoomchai physical therapy 9.00 A.M.- 18.00 P.M. (Figure 20)

Prior to conducting the study, Researcher 2 was tested for the intra-rater reliability regarding the repeatability of the measurements on 10 participants (Appendix VI).

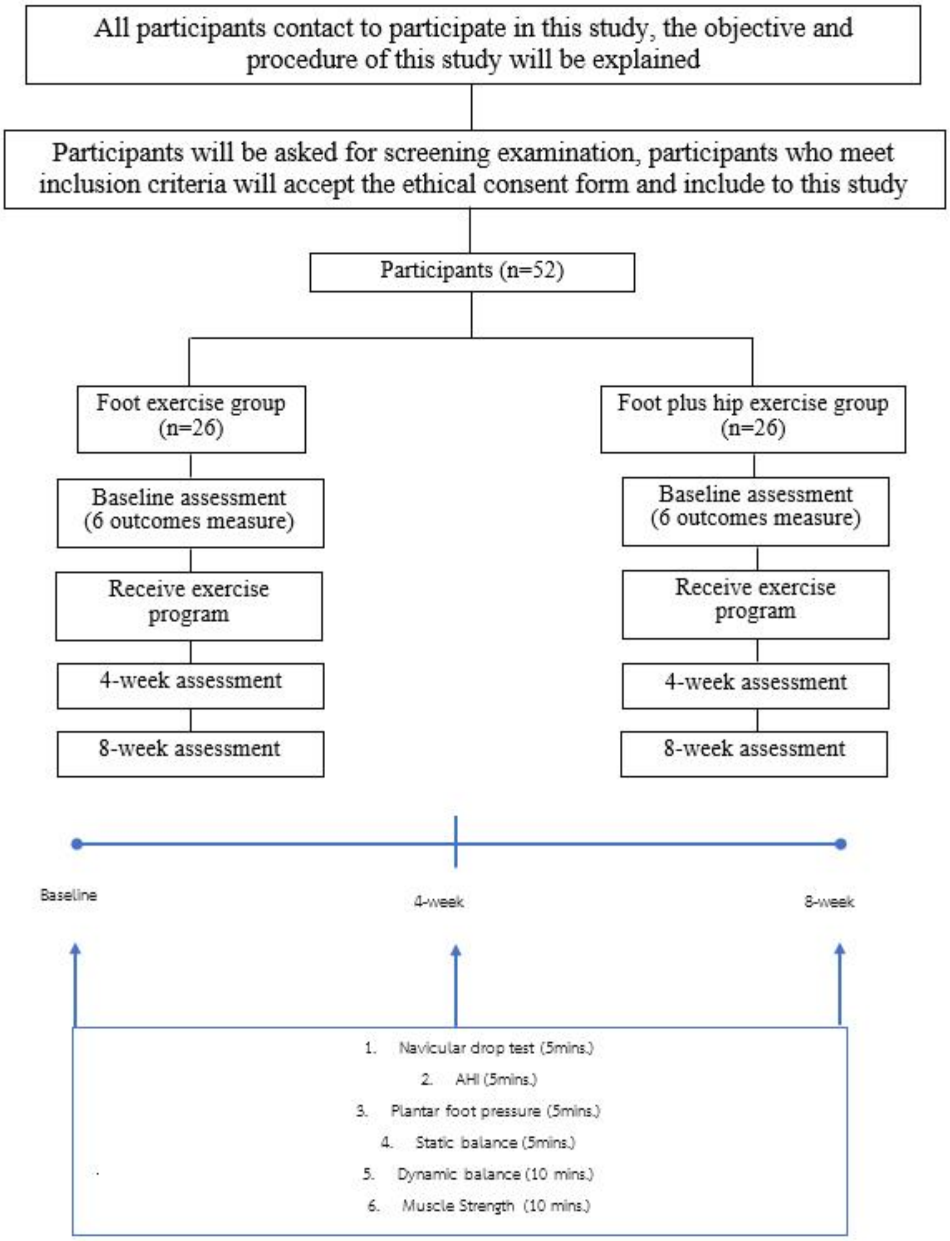


***Figure* 20** *Diagram of the procedure for Study 1*

3.1.7 Statistical analyses

The data normality was verified using the Shapiro-Wilk test. Means and standard deviations were used for the descriptive analysis of the continuous variables, and frequencies and percentages were used for discrete variables. The reliability of the measurements was evaluated using the intraclass correlation coefficient (ICC). Comparisons of all outcome measures between groups (FG and FHG) across time (baseline, 4-week, and 8-week) were analyzed by two-way repeated measures analysis of variance (ANOVA). Post-hoc pairwise comparisons were adjusted for multiple comparisons using Bonferroni procedure. Friedman test used for data non-normal distribution and using Wilcoxon test for pairwise comparisons**.**

The statistical analysis was conducted using SPSS 20.0 (IBM SPSS, Chicago, IL), and a p value of $< .05$ was considered statistically significant.

3.1.8 Ethical considerations

The study protocol was registered at TCTR20211117003 (Appendix XI), and ethics approval was granted by the Research Ethics Review Committee of the University (COA No. 223/2563) (Appendix XII). Informed consent was obtained from all participants. The study protocol received approval from the ethical review committee for research involving human subjects at Chulalongkorn University. Participant information was kept confidential, and the data were presented as a whole group in the thesis and published papers, with only the code applied.

3.2 Results

All 52 participants completed the 8-week intervention. Twenty-six participants were female (n=11 in foot exercise group; FG and n=15 in foot plus hip exercise group; FHG). The participants' baseline demographics and characteristics were presented in **Table 1.** Both groups demonstrated no significant differences between feet in all outcomes measured at baseline ($P > 0.05$), allowing the data from both feet to be combined within each group. There were no significant between-group differences at baseline for all outcome variables (*P* > 0.05). There was a high degree of adherence to both interventions. Of the 40 days of the intervention, participants in the FG and FHG performed the exercises an average of 36.2 days and 35.7 days, respectively.

As two-way mixed model measures ANOVA showed significant interactions between group and time for all outcomes, post hoc analyses were conducted. Most outcomes at 4 and 8 weeks changed significantly from baseline (*P* < 0.001) (**Table 2**). GMed strength in the FHG increased significantly from baseline and was significantly greater than GMed strength in the FG at 8 weeks (*P* < 0.001). At 4 weeks, the FHG showed significantly less ND (*P* = 0.002), plantar pressure at the medial forefoot (*P* = 0.002), and mediolateral displacement (*P* = 0.001) while showing a significantly greater AHI (*P* = 0.019) than the FG. These significant between-group differences were also found at 8 weeks. Significantly less medial hindfoot pressure (*P* = 0.017) and anteroposterior displacement (*P* = 0.002) were found in the FHG than in the FG at 8 weeks. No significant between-group differences in dynamic balance were found.

Table 1 *Means (standard deviations) of outcomes measured at baseline when the data from both feet of each group were combined.*

Variables	**FG (n = 52 feet)**	**FHG (n = 52 feet)**	**MD (95% CI)**	***P*-value**
Age (yrs)	30.03 (4.36)	28.73 (4.61)	1.31 (-0.44, 3.06)	0.321
BMI (kg/m^2)	21.24 (0.97)	20.95 (1.06)	0.28 (-0.11, 0.68)	0.632
ND (mm)	11.83 (1.18)	12.08 (1.04)	0.25 (-0.18, 0.07)	0.256
AHI	0.31 (0.01)	0.31 (0.01)	0.00 (-0.004, 0.003)	0.811
Plantar pressure (kPa)				
Medial forefoot	51.47 (9.15)	50.86 (11.59)	-0.62 (-4.68, 3.45)	0.764
Lateral forefoot	49.79 (11.57)	48.85 (9.09)	-0.94 (-4.99, 3.12)	0.646
Midfoot	22.41 (7.62)	25.83 (10.99)	3.42 (-0.26, 7.10)	0.068
Medial hindfoot	108.80 (15.61)	108.96 (21.47)	0.16 (-7.15, 7.46)	0.966
Lateral hindfoot	110.52 (17.42)	106.28 (21.33)	-4.24 (-11.82, 3.34)	0.269
Static balance				
Anteroposterior displacement (cm)	5.76 (0.97)	5.62 (1.09)	-0.14 (-0.54, 0.27)	0.507
Mediolateral displacement (cm)	4.02 (0.77)	3.76 (0.76)	-0.26 (-0.56, 0.04)	0.084
Dynamic balance (distance/leg length) × 100%				
Anterior	68.63 (5.05)	67.04 (4.64)	-1.59 (-3.48, 0.30)	0.098
Posterior	98.30 (9.04)	95.26 (7.0)	-3.04 (-6.19, 0.11)	0.058
Medial	60.64 (7.55)	62.98 (7.22)	2.34 (-0.53, 5.22)	0.109
Lateral	76.10 (9.61)	75.10 (8.87)	-1.00 (-4.60, 2.60)	0.584
Muscle strength (N)				
Tibialis posterior	63.35 (8.67)	60.74 (9.84)	-2.62 (-6.23, 0.99)	0.154
Flexor hallucis brevis	26.35 (4.56)	25.11 (4.62)	-1.23 (-3.02, 0.56)	0.174
Gluteus medius	115.27 (13.43)	113.73 (12.57)	-1.54 (-6.60, 3.52)	0.547

AHI, Arch height index; BMI, body mass index; CI, confidence interval; FG, foot exercise group; FHG, foot plus hip exercise group; MD, mean difference; ND, Navicular drop.
** Significant with P < 0.05 compared between groups at baseline*

Table 2 *Means (standard deviations) of outcome measures at 4 weeks and 8 weeks and the results of the two-way mixed model ANOVAs of within-group and between-group comparisons (FG, n = 52 feet and FHG, n= 52 feet).*

Outcome measures/Group	Within-group comparison		*P*-value of between-group comparison Mean difference [95% CI]	
	4 weeks	8 weeks	4 weeks (FHG-FG)	8 weeks (FHG-FG)
ND (mm)				
FG	9.69 (1.17) $^{\#}$	7.10 (0.86) $^{\#, **}$	0.002†	< 0.001††
FHG	8.95 (1.26) $^{\#}$	6.32 (0.99) $^{\#, **}$	-0.74 (-0.27, -1.21)	-0.78 (-0.42, -1.14)
AHI				
FG	0.32 (0.007) $^{\#}$	0.34 (0.007) $^{\#, **}$	0.019†	< 0.001††
FHG	0.32 (0.008) $^{\#}$	0.35 (0.007) $^{\#, **}$	0.00 (0.00, 0.01)	0.10 (0.01, 0.13)
Plantar pressure (kPa)				
Medial forefoot				
FG	48.46 (8.88) $^{\#}$	46.21 (8.25) $^{\#, **}$	0.002†	< 0.001††
FHG	42.19 (10.86) $^{\#}$	37.60 (9.41) $^{\#, **}$	-6.63 (-10.13, -2.40)	-8.61 (-12.05, -5.17)
Lateral forefoot				
FG	57.90 (15.01)	58.60 (15.79) $^{\#, **}$	0.960	0.558
FHG	58.03 (11.84) $^{\#}$	60.28 (13.29) $^{\#, **}$	1.33 (-5.13, 5.40)	1.68 (-4.00, 7.36)
Midfoot				
FG	22.62 (8.16)	23.61 (8.57) *	0.385	0.709
FHG	24.16 (9.83) $^{\#}$	24.30 (10.16) $^{\#}$	1.55 (-1.97, 5.06)	0.69 (-2.97, 4.35)
Medial hindfoot				
FG	99.32 (16.71) $^{\#}$	96.47 (18.92) $^{\#}$	0.682	0.017†
FHG	97.71 (22.67) $^{\#}$	86.62 (22.29) $^{\#, **}$	-1.61 (-9.35, 6.14)	-9.86 (-17.90, -1.82)
Lateral hindfoot				
FG	112.67 (18.60)	116.37 (19.19) $^{\#, **}$	0.396	0.692
FHG	116.64 (27.98) $^{\#}$	118.27 (28.63) $^{\#, *}$	3.97 (-5.27, 13.21)	1.90 (-7.58, 11.38)

***Table 2** (Cont.) Means (standard deviations) of outcome measures at 4 weeks and 8 weeks and the results of the two-way mixed model ANOVAs of within-group and between-group comparisons (FG, n = 52 feet and FHG, n= 52 feet).*

Outcome measures/Group	Within-group comparison		*P*-value of between-group comparison Mean difference [95% CI]	
	4 weeks	8 weeks	4 weeks (FHG-FG)	8 weeks (FHG-FG)
Static balance (cm)				
Anteroposterior displacement				
FG	4.97 (1.18) $^{\#}$	4.16 (0.81) $^{\#, **}$	0.059	0.002†
FHG	4.55 (1.04) $^{\#}$	3.67 (0.69) $^{\#, **}$	-0.42 (-0.86, -0.02)	-0.48 (-0.78, -0.19)
Mediolateral displacement				
FG	3.36 (0.69) $^{\#}$	2.93 (0.53) $^{\#, **}$	0.001†	< 0.001††
FHG	2.92 (0.66) $^{\#}$	2.48 (0.48) $^{\#, **}$	-0.44 (-0.71, -0.18)	-0.45 (0-.65, -0.25)
Dynamic balance (distance/leg length) × 100%				
Anterior				
FG	71.80 (5.30) $^{\#}$	76.71 (5.66) $^{\#, **}$	0.394	0.062
FHG	72.07 (5.86) $^{\#}$	78.14 (5.89) $^{\#, **}$	0.27 (-1.90, 2.45)	1.43 (-0.82, 3.68)
Posterior				
FG	100.16 (8.47) $^{\#}$	103.20 (8.53) $^{\#, **}$	0.988	0.813
FHG	99.22 (6.84) $^{\#}$	102.58 (6.51) $^{\#, **}$	-0.94 (-3.94, 2.06)	-0.63 (-3.58, 2.33)
Medial				
FG	64.13 (8.36) $^{\#}$	70.60 (9.07) $^{\#, **}$	.058	0.277
FHG	66.54 (7.40) $^{\#}$	71.70 (7.24) $^{\#, **}$	2.41 (-0.66, 5.49)	1.10 (-2.10, 4.29)
Lateral				
FG	79.48 (9.84) $^{\#}$	84.49 (9.42) $^{\#, **}$	0.765	0.970
FHG	78.04 (8.53) $^{\#}$	83.61 (8.73) $^{\#, **}$	-1.44 (-5.02, 2.14)	-0.88 (-4.42, 2.65)

Table 2 *(Cont.) Means (standard deviations) of outcome measures at 4 weeks and 8 weeks and the results of the two-way mixed model ANOVAs of within-group and between-group comparisons (FG, n = 52 feet and FHG, n= 52 feet).*

Outcome measures/Group	**Within-group comparison**		***P*-value of between-group comparison Mean difference [95% CI]**	
	4 weeks	**8 weeks**	**4 weeks (FHG-FG)**	**8 weeks (FHG-FG)**
Muscle strength (N)				
Tibialis posterior				
FG	67.20 (9.01) #	71.60 (9.04) #, **	0.213	0.276
FHG	64.87 (9.89) #	69.59 (10.03) #, **	-2.33 (-6.01, 1.35)	-2.05 (-5.77, 1.67)
Flexor hallucis brevis				
FG	27.82 (4.93) #	30.43 (5.29) #, **	0.319	0.926
FHG	26.89 (4.57) #	30.34 (5.01) #, **	-9.35 (-2.79, 0.92)	-0.10 (-2.10, 1.91)
Gluteus medius				
FG	116.05 (13.93)	115.42 (13.92)	0.178	< 0.001 ††
FHG	119.64 (13.10) #	128.23 (11.95) #, **	3.60 (-1.67, 8.86)	12.81 (7.76, 17.86)

AHI, Arch height index; CI, confidence interval; FG, foot exercise group; FHG, foot plus hip exercise group; ND, Navicular drop.
** Significant within group with $P < 0.05$ compared to baseline*
 # Significant within group $P < 0.001$ compared to baseline
*** Significant within group $P < 0.001$ compared between 4 weeks and 8 weeks*
† Significant between group with $P < 0.05$
†† Significant between group with $P < 0.001$

3.3 Discussion

This study investigated the effects of GMed strengthening exercise on participants with flexible flatfoot. The results suggested that the addition of GMed exercise to short foot and tibialis posterior exercises was more effective than performing foot muscle exercises alone in all outcome measures except dynamic balance. The significant differences between groups in most outcome measures were observed after 4 weeks of the intervention. These findings supported the use of GMed exercise in individuals with flexible flatfoot.

ND after both interventions was in the range of normal arch height of 5–9 millimeters.[63] Both the FG and FHG showed significant decreases in ND at 4 weeks, with further decreases at 8 weeks. The decrease in ND in both groups that performed the same foot exercises supports the role of the intrinsic foot and tibialis posterior muscles in the maintenance of the MLA reported by previous studies. [14,46,100,101,109] As a result, the abnormal windlass mechanism with delayed or absent of arch lifting could be improved.[100]

However, the lower ND value in the FHG (6.32 millimeters) than in the FG (7.10 millimeters) after the 8-week period suggests a more rapid improvement in MLA height with the addition of GMed exercise. Furthermore, the decreases in ND between baseline and follow-ups at 4 weeks (FG = 2.14 mm and FHG = 3.13 mm) and 8 weeks (FG = 2.59 mm and FHG = 2.63 mm) were larger than the 95% confidence interval minimal detectable change of 1.1 mm calculated from the reliability study of this study (Appendix VI). To date, there have been no studies reporting the minimal clinically important difference value for asymptomatic flexible flatfoot reported in the literature. However, these amount of ND reductions that occurred in association with the improvements in other MLA parameters might suggest the clinically significant change in ND due to both interventions of this study.

Along with improved ND, the AHI in standing increased significantly from baseline with both interventions. As this value was calculated by normalizing to the participants' foot lengths, it might be a better representation of the MLA. At 4 weeks, while the AHI was improved, both groups demonstrated AHI values of less than 0.33, which was considered the criterion for a low-arched foot.[80,110] However, at 8 weeks, the FHG was closer than the FG to the AHI value of 0.34 required for normal arch height.[79,80,110-112] This result substantiated the impact of GMed strength on MLA height.

Both groups demonstrated alterations in plantar pressure distribution towards the distribution of the normal-arched foot. Medial forefoot and medial hindfoot pressures decreased while lateral forefoot and lateral hindfoot pressures increased at 8 weeks. The FHG showed significant changes from baseline in all foot regions after 4 weeks of exercise, which was a faster change than that seen in the FG. Our results were consistent with the findings of previous studies, in which the plantar pressures of the medial forefoot and medial heel were reduced after the application of the adhesive tape that lifted the MLA height.[95,113] Comparisons between groups in this study found significantly greater pressure reductions at the medial forefoot and medial hindfoot in the FHG compared to the FG. These findings supported the association between GMed strength and MLA height, potentially due to the improved lower extremity alignment caused by greater GMed strength, placing the intrinsic foot muscles in a better position to effectively support the MLA.[114]

During single-leg standing, both the FG and FHG demonstrated less mediolateral and anteroposterior displacements in the center of pressure. These results coincided with a previous study that observed a reduction in sway area during single-leg standing after 5 weeks of short foot exercises.[53] The lesser mediolateral displacement was also consistent with a previous study in which short foot exercise for 6 weeks improved center of pressure excursion in mediolateral direction.[115] The improvement in static balance in this study might be related to the increase in strength of the intrinsic foot muscles which showed greater recruitment and more muscle activity when increasing postural demand.[116] The smaller displacement seen in the FHG compared to the FG supports the concept that weight-bearing stability involves proximal joints of the lower extremity.[19] With greater hip abductor strength, hip balance strategy improved which consequently reduced pelvic drop and navicular drop.[114] However, it is noted that the magnitudes of change in static balance were in the vicinity of the MDC95% reported in Appendix VI.

Dynamic balance improved in all directions in the FG and FHG at both 4 weeks and 8 weeks in the present study, consistent with the recent meta-analysis that also demonstrated the benefit of intrinsic foot exercise on dynamic postural balance.[117] The addition of tibialis posterior exercises to short foot exercises for the intrinsic foot muscles might result in greater improvements in dynamic balance, as reported in a previous study that added tibialis posterior exercises to the toe curl exercise and showed improved dynamic balance in all directions when compared to performing the toe curl exercise alone.[73] However, there were nonsignificant differences in dynamic balance between the FG and FHG groups in this study.

Study limitations

This study had some limitations. Firstly, the study recruited only asymptomatic adults with flatfoot; thus, the results were not representative of the painful flatfoot population. Future research might assess this intervention in a therapeutic population to assess if the changes in MLA parameters caused by the combination of hip and foot exercises reduce pain caused by flatfoot. Secondly, the study did not assess lower extremity alignment. Future studies should investigate whether lower extremity alignment changed as a result of these exercises.

3.4 Conclusion

In conclusion, the results of this study suggested that the addition of GMed strengthening exercise to foot exercises was more effective in decreasing ND and medial plantar pressure and increasing AHI and static balance than performing foot exercises alone in individuals with flexible flatfoot.

CHAPTER 4

STUDY 2 – METHOD, RESULTS, DISCUSSION, AND CONCLUSION

4.1 Method

The aim of Study 2 was to compare the established exercise protocol from Study 1 (**foot plus hip strengthening exercise)** to foot orthoses on the improvement of the MLA (navicular drop, arch height index, plantar foot pressure, static balance, and dynamic balance) after four- and eight-week intervention.

4.1.1 Research design

A randomized clinical trial was conducted.

4.1.2 Participants

Recruitment for the study involved the enrollment of 38 participants who met the same inclusion and exclusion criteria of study 1. The recruitment process utilized advertised posters (Appendix XIV) and social media platforms. Sample size calculation was described in Appendix V.

4.1.3 Instruments

This study used the same instruments as study 1. Foot orthoses were fitted to a pair of adjustable sandals of the participants' foot size. A full foot length orthosis was made from natural latex foam with 3.5-mm thickness with additional medial forefoot and rearfoot wedges (Figure 21). Two wedges were specifically produced by the researcher. They were made from polyurethane of 40 shore A hardness (RA-PU40AB Rungart, Bangkok, Thailand) in which a prototype from 3D printing was molded by vacuum forming method.

Figure 21 *Orthosis with medial forefoot and rearfoot wedge.*

4.1.4 Outcome measures

All outcome measures in Study 1 were used in study 2, and added forefoot and rearfoot angle to this study. All outcome measures were recorded in Appendix III.

4.1.4.1 Forefoot and rearfoot angles.

The method described by Monaghan et al. was used. [3,118] Participants were asked to lay prone on a table with both legs in neutral rotation allowing ankles to go just beyond the edge of the table. By setting the ankles in 0° dorsiflexion, digital photographs of the feet were taken from above. Forefoot angle was defined as an angle between a line through metatarsal heads and a line parallel to the edge of the table which indicates the varus alignment of forefoot. Rearfoot angle was defined as an angle between a line bisecting the calcaneus and a line perpendicular to the edge of the table which indicates the varus alignment of rearfoot. (Figure 22) The average values obtained from three photographs were used for analysis.

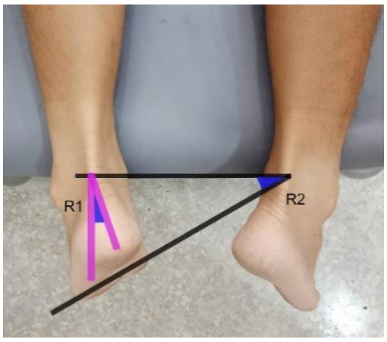


***Figure 22** Forefoot angle measurement (R2) and rearfoot angle measurement (R1)*

4.1.5 Interventions

In this study, two interventions were used. One intervention involved the use of strengthening exercises, as described previously in section 3.1.5.2 which was identified as effective for improving the MLA in Study 1.

The other intervention involved the use of foot orthoses, commonly prescribed to increase navicular height in adults with flexible flatfoot. The amount of posting was determined based on the measured angles at 60% of forefoot varus (maximum is 8 degrees).[119] and at 20% of rearfoot valgus.[120] This resulted in 5-15° posting in the forefoot and 0-4° posting in the rearfoot.[120] The angle values was recorded in Appendix III. The duration and frequency of orthoses usage were not well-documented, with limited data available on the actual duration and frequency of prescribed orthoses wear. Previous studies have reported a range of 5-8 hours of orthoses usage per day.[10,75,90] They were asked to wear the foot orthoses for at least 5 hours each day.[10,75,90]

Based on a systematic review[4], foot orthoses with medial forefoot posting or both a medial forefoot and a rearfoot posting reduced the peak rearfoot eversion, resulting in reduced an excessive foot pronation. It has been reported that, the prefabricated foot orthoses (semi-rigid) with medial forefoot posting: applied just behind the 1st metatarsophalangeal joint and extended to the 4th metatarsal (max 7 mm) were found to significantly reduce peak rearfoot eversion (p<0.003).[121] Additionally, medial rearfoot posting: applied to the medial aspect of the inferior surface of the calcaneus and extended half the width of the heel (max 6 mm), also showed a significant reduction in peak rearfoot eversion (p<0.008).[121]

According to another study, it was reported that the use of medial forefoot combined with rearfoot posting foot orthoses (semi-rigid) resulted in a reduction of peak rearfoot eversion. The forefoot posting was set at 60% (maximum 8°) of the forefoot deformity, while the rearfoot posting was set at 50% (maximum 6°) of the rearfoot deformity. This combination of postings proved effective in reducing the excessive rearfoot eversion.[122]

Foot orthoses with medial rearfoot posting, the level of the external rearfoot post was varied from 6° lateral to 10° medial in 2° increments can increase forefoot adduction (p = 0.02).[123]

The participants received semi-rigid foot orthoses that fit for individual's size. They were instructed to wear the foot orthoses for 5 hours each day or as much as possible. The participants were asked to record their daily wear duration in Appendix IX. If they wore the orthoses for less than 5 hours per day, they were required to document the reasons, such as any pain or adverse effects experienced from wearing the foot orthoses.

4.1.6 Procedures

In this study, the same two researchers who were physical therapists and involved in Study 1 were also involved. Researcher 1, with 8 years of experience in musculoskeletal disorders, was responsible for instructing the exercise protocol and the use of foot orthoses. Researcher 2, with 8 years of experience in musculoskeletal disorders and blinded to the group assignment, was responsible for conducting all the measurements. In this study, all participants were required to sign an informed consent before participating. They were then asked to fill out a screening questionnaire (Appendix I). Baseline data were measured, including navicular drop, arch height index, plantar pressure, static balance, dynamic balance, and muscle strength. The baseline muscle strength of the exercise muscles was then measured using a hand-held dynamometer, following the same procedure as described in Study 1.

After all measurements were taken, the participants were randomly assigned into two groups using a computer-generated randomization sequence. The foot orthoses group (FOG) received foot orthoses for eight weeks, while the exercise group (EG) performed the strengthening exercise. Both the exercise and foot orthoses were performed on both legs. The correctness of the exercise performance was monitored by Researcher 1 once a week during meetings before training.

All participants received a checklist notebook (Appendices IX or X) for recording their interventions. Every three days, Researcher 1 contacted each participant to remind, suggest, and answer any questions about the interventions. At the end of the 8-week study, all participants were asked to stop all interventions. All outcome measures were assessed every four weeks until eight weeks except for forefoot and rearfoot angle. (Figure 23)

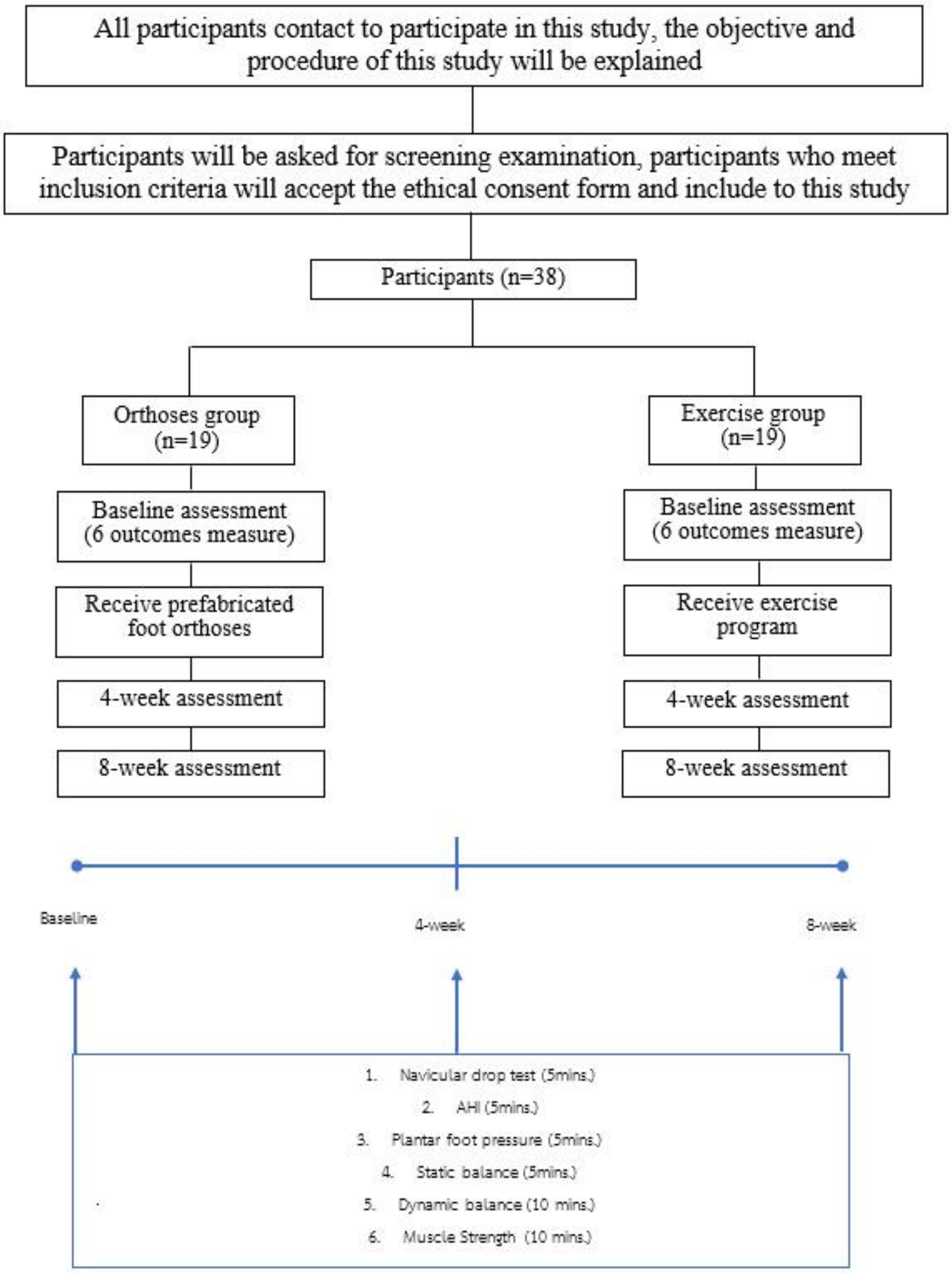


***Figure* 23** *Diagram of the procedure for Study 2.*

4.1.7 Statistical analysis

The SPSS 22 (SPSS, Chicago, IL, USA) was used for statistical analysis. Statistical significance was set at $p < .05$. Two-way repeated measures analysis of variances (ANOVAs) were performed to investigate the effects of intervention (strengthening exercise and foot orthoses) and time (baseline, 4-week, and 8-week post-intervention) for all outcome measures. *Post-hoc* pairwise comparisons were adjusted for multiple comparisons using the Bonferroni procedure.

4.1.8 Ethical considerations

The study protocol was registered at TCTR20221204001 (Appendix XI), and ethics approval was granted by the Research Ethics Review Committee of the University (COA No. 183/2565) (Appendix XIII). Informed consent was obtained from all participants. The study protocol received approval from the ethical review committee for research involving human subjects at Chulalongkorn University. Participant information was kept confidential, and the data were presented as a whole group in the thesis and published papers, with only the code applied.

4.2 Results

A total of 38 participants successfully completed the 8-week study, and no adverse events were reported with any of the interventions. Within each group, there were no significant differences in outcomes measured at baseline between the left and right feet ($p > 0.05$). Therefore, the data from both feet within each group were combined for analysis. There were no significant differences in baseline demographic characteristics between the groups, as shown in Table 3 ($p > 0.05$). On average, participants in the FOG group complied with the assigned intervention for 5.2 hours per day, while participants in the EG group completed the intervention for 35.5 days out of the total 40 days.

Significant interactions between group and time were observed for the navicular drop, AHI, static balance, dynamic balance in the anterior and lateral directions, and muscle strength. Post hoc analyses were conducted to further examine these interactions. Both groups showed significant improvements in most outcome measures at 4 weeks and 8 weeks compared to baseline ($p < 0.05$), as shown in Tables 4 and 5. The navicular drop decreased to 7.96 mm in the FG and 6.53 mm in the EG. There were no significant changes in midfoot plantar pressure in either group, and the strength of the gluteus medius muscle in the FOG did not significantly change at any time point ($p > 0.05$).

The EG demonstrated greater improvement compared to the FOG in all outcome measures when comparing between groups. Significant differences between groups were observed at 4 weeks and 8 weeks for navicular drop, AHI, static balance in the anteroposterior direction, dynamic balance in the posterior direction, and strength of the tibialis posterior, flexor hallucis brevis, and gluteus medius muscles ($p < 0.05$). Dynamic balance in the medial and lateral directions showed significant differences between groups only at 8 weeks. There were no significant differences between groups for plantar pressure at any time points ($p > 0.05$).

Table 3 *Means ± standard deviations for demographic characteristics of participants in each group. Data from both feet were combined. Foot orthoses group; FOG (n=38), exercise group; EG* ***(n=38)***

Variables	FOG (n = 38 feet)	EG (n = 38 feet)	*p*-value
Sex (M/F)	9/10	11/8	
Age (yrs)	30.47 ± 4.89	28.42 ± 5.05	0.076
BMI (kg/m^2)	20.57 ± 1.15	20.72 ± 1.04	0.576
Height (cm)	168.30 ± 5.50	167.05 ± 6.81	0.377
Weight (kg)	58.38 ± 5.68	57.98 ± 6.61	0.778
ND (mm)	12.25 ± 0.90	12.01 ± 1.06	0.299
AHI	0.302 ± 0.007	0.305 ± 0.009	0.117
Forefoot angle (degrees)	11.89 ± 4.11	12.60 ± 4.42	0.470
Rearfoot angle (degrees)	7.79 ± 2.35	7.66 ± 2.21	0.814
Plantar pressure (kPa)			
Medial forefoot	54.47 ± 8.41	53.46 ± 9.95	0.632
Lateral forefoot	51.41 ± 9.51	54.48 ± 9.97	0.173
Midfoot	25.21 ± 8.42	26.31 ± 8.17	0.565
Medial rearfoot	110.35 ± 16.16	109.10 ± 14.83	0.725
Lateral rearfoot	108.63 ± 18.82	111.55 ± 17.08	0.481
Static balance			
Anteroposterior displacement (cm)	6.11 ± 1.72	6.24 ± 1.39	0.722
Mediolateral displacement (cm)	4.51 ± 1.75	4.57 ± 1.42	0.859
Dynamic balance (distance/leg length) × 100%			
Anterior	68.52 ± 4.82	67.70 ± 6.11	0.521
Posterior	99.31 ± 6.23	101.30 ± 6.02	0.161
Medial	63.81 ± 4.82	65.27 ± 7.03	0.296
Lateral	69.41 ± 4.37	68.68 ± 4.57	0.483
Muscle strength (N)			
Tibialis posterior	59.81 ± 8.08	60.50 ± 8.80	0.724
Flexor hallucis brevis	24.69 ± 4.46	25.96 ± 4.57	0.222
Gluteus medius	114.06 ± 10.55	112.84 ± 11.18	0.643

* Significant with $P < 0.05$ compared between groups at baseline

Table 4 *Means ± standard deviations of outcomes of foot orthoses and exercise groups by interventions and time. The results of the two-way mixed model analysis of variance for foot alignment and plantar pressure (FOG, n = 38 feet and EG, n= 38 feet).*

Outcomes	Group	Baseline	Within-group comparison		*p*-value of between-group comparison Mean difference (Exercise – Orthoses) (95% CI)	
			4 weeks	8 weeks	4 weeks	8 weeks
Navicular drop (mm)	FOG	12.25 ± 0.90	10.18 ± 0.96 $^{\#}$	7.96 ± 0.87 $^{\#, **}$	0.001†	< 0.001††
	EG	12.01 ± 1.06	9.39 ± 1.04 $^{\#}$	6.53 ± 0.96 $^{\#, **}$	-0.79 (-1.25, -0.33)	-1.42 (-1.84, -1.00)
AHI	FOG	0.302 ± 0.007	0.318 ± 0.007 $^{\#}$	0.333 ± 0.006 $^{\#, **}$	0.008†	< 0.001††
	EG	0.305 ± 0.009	0.323 ± 0.007 $^{\#}$	0.344 ± 0.010 $^{\#, **}$	-0.005 (0.001, 0.008)	0.011 (0.007, 0.015)
Plantar pressure (kPa)						
Medial forefoot	FOG	54.47 ± 8.41	49.71 ± 11.91 $^{\#, **}$	46.02 ± 13.09 $^{\#, **}$	0.641	0.473
	EG	53.46 ± 9.95	48.48 ± 10.89 $^{\#, **}$	43.97 ± 11.72 $^{\#, **}$	-1.22 (-6.44, 4.00)	-2.05 (-7.73, 3.62)
Lateral forefoot	FOG	51.41 ± 9.51	57.67 ± 13.32 $^{\#, **}$	60.58 ± 13.60 $^{\#, **}$	0.565	0.530
	EG	54.48 ± 9.97	59.31 ± 11.31 $^{\#, **}$	62.47 ± 12.50 $^{\#, **}$	1.64 (-4.01, 7.30)	1.89 (-4.08, 7.86)
Midfoot	FOG	25.21 ± 8.42	24.39 ± 8.06	24.88 ± 8.48	0.358	0.665
	EG	26.31 ± 8.17	26.10 ± 8.12	25.69 ± 7.63	1.71 (-1.98, 5.41)	0.80 (-2.88, 4.49)
Medial rearfoot	FOG	110.35 ± 16.16	106.55 ± 19.18 $^{\#}$	97.59 ± 22.92 $^{\#, **}$	0.495	0.618
	EG	109.10 ± 14.83	103.78 ± 15.88 $^{\#}$	95.10 ± 20.34 $^{\#, **}$	-2.77 (-10.82, 5.28)	-2.48 (-12.39, 7.42)
Lateral rearfoot	FOG	108.63 ± 18.82	114.47 ± 20.30 $^{\#}$	117.67 ± 21.97 $^{\#}$	0.527	0.619
	EG	111.55 ± 17.08	117.32 ± 18.76 $^{\#}$	119.96 ± 17.91 $^{\#}$	2.85 (-6.08, 11.78)	2.30 (-6.87, 11.45)

AHI, Arch height index; CI, confidence interval; FG, foot exercise group; FHG, foot plus hip exercise group; ND, Navicular drop.

* Significant within group with $P < 0.05$ compared to baseline, # Significant within group $P < 0.001$ compared to baseline,

** Significant within group $P < 0.001$ compared between 4 weeks and 8 weeks, † Significant between group with $P < 0.05$, †† Significant between group with $P < 0.001$

***Table 5** Means ± standard deviations of outcomes of foot orthoses and exercise groups by interventions and time. The results of the two-way mixed model analysis of variance for balance and muscle strength (FOG, n = 38 feet and EG, n= 38 feet).*

Outcomes	Group	Baseline	Within-group comparison		*p*-value of between-group comparison Mean difference (Exercise – Orthoses) (95% CI)	
			4 weeks	8 weeks	4 weeks	8 weeks
Static balance						
AP displacement (cm)	FOG	6.11 ± 1.72	5.26 ± 1.29 #	4.75 ± 1.07 #, **	0.029†	0.027†
	EG	6.24 ± 1.39	4.68 ± 0.90 #	4.26 ± 0.80 #, **	-0.57 (-1.08, -0.06)	-0.49 (-0.92, -0.05)
ML displacement (cm)	FOG	4.51 ± 1.75	3.77 ± 1.13 #	3.51 ± 1.06 #, **	0.860	0.107
	EG	4.57 ± 1.42	3.81 ± 0.95 #	3.14 ± 0.87 #, **	0.42 (-0.43, 0.52)	-0.36 (-0.80, 0.08)
Dynamic balance (distance/leg length) × 100%						
Anterior	FOG	68.52 ± 4.82	70.96 ± 5.0 #	72.82 ± 5.08 #, **	0.204	0.127
	EG	67.70 ± 6.11	72.51 ± 5.53 #	74.90 ± 6.51 #, **	1.55 (-0.85, 3.95)	2.07 (-0.60, 4.74)
Posterior	FOG	99.31 ± 6.23	102.42 ± 5.65 #	104.89 ± 6.11 #, **	0.021†	0.027†
	EG	101.30 ± 6.02	105.52 ± 5.83 #	108.63 ± 8.20 #, **	3.10 (0.47, 5.73)	3.73 (0.43, 7.04)
Medial	FOG	63.81 ± 4.82	66.44 ± 4.28 #	68.13 ± 4.77 #, **	0.105	0.049†
	EG	65.27 ± 7.03	68.40 ± 5.97 #	70.74 ± 6.46 #, **	1.96 (-0.42, 4.33)	2.61 (0.01, 5.21)
Lateral	FOG	69.41 ± 4.37	71.71 ± 3.75 #	73.22 ± 4.19 #	0.330	0.017†
	EG	68.68 ± 4.57	72.70 ± 4.96 #	76.35 ± 6.63 #	0.99 (-1.02, 3.00)	3.12 (0.58, 5.66)

AHI, Arch height index; CI, confidence interval; FG, foot exercise group; FHG, foot plus hip exercise group; ND, Navicular drop.
* Significant within group with $P < 0.05$ compared to baseline, # Significant within group $P < 0.001$ compared to baseline,
** Significant within group $P < 0.001$ compared between 4 weeks and 8 weeks, † Significant between group with $P < 0.05$, †† Significant between group with $P < 0.001$

Table 6 *(Cont.) Means ± standard deviations of outcomes of foot orthoses and exercise groups by interventions and time. The results of the two-way mixed model analysis of variance for balance and muscle strength (FOG, n = 38 feet and EG, n= 38 feet).*

Outcomes	Group	Baseline	Within-group comparison		*p*-value of between-group comparison Mean difference (Exercise – Orthoses) (95% CI)	
			4 weeks	8 weeks	4 weeks	8 weeks
Muscle strength (N)						
Tibialis posterior	FOG	59.81 ± 8.08	59.27 ± 7.17	60.47 ± 7.53 *	0.009†	< 0.001††
	EG	60.50 ± 8.80	64.30 ± 9.05 #	67.36 ± 7.92 #, **	5.03 (1.30, 8.76)	6.90 (3.36, 10.42)
Flexor hallucis brevis	FOG	24.69 ± 4.46	26.25 ± 4.28 #	28.58 ± 4.50 #, **	0.007†	0.002†
	EG	25.96 ± 4.57	29.11 ± 4.78 #	32.06 ± 4.71 #, **	2.86 (0.78, 4.93)	3.48 (1.37, 5.58)
Gluteus medius	FOG	114.06 ± 10.55	113.38 ± 10.62	113.84 ± 10.26	0.029†	< 0.001††
	EG	112.84 ± 11.18	118.94 ± 11.07 #	126.76 ± 12.89 #, **	5.55 (0.59, 10.51)	12.92 (7.60, 18.25)

AHI, Arch height index; CI, confidence interval; FG, foot exercise group; FHG, foot plus hip exercise group; ND, Navicular drop.
* Significant within group with $P < 0.05$ compared to baseline, # Significant within group $P < 0.001$ compared to baseline,
** Significant within group $P < 0.001$ compared between 4 weeks and 8 weeks, † Significant between group with $P < 0.05$, †† Significant between group with $P < 0.001$

4.3 Discussion

The results of this study show a superior effect of exercise than foot orthoses in healthy adults with flexible flatfoot. Generally, the group undergoing exercise experienced significantly greater improvements in navicular drop, AHI, static balance, dynamic balance, and lower extremity muscle strength compared to the group using foot orthoses. These improvements were observed after 4 weeks of intervention and persisted up to 8 weeks. However, drawing direct comparisons between these findings with previous studies is challenging due to the differences in the types of foot orthoses and exercises employed.

Both groups of this study showed improvements in ND and AHI towards that reported for normal arch foot, i.e. a navicular drop ranging from 5 to 9 mm[63] and an AHI value of approximately 0.34.[79,80,110-112] The navicular drop decreased to 6.5-8 mm and AHI ranged from 0.33 to 0.34. The explanations for the improvements in ND and AHI in the EG were discussed in section 3.3 (discussion of study 1). The foot orthoses that restored normal biomechanical movements in the subtalar joint and joints of lower limb by reducing rearfoot eversion[124] which may in turn helped improved ND and AHI. However, the EG showed greater improvements in ND and AHI than the FOG both at 4 weeks and 8 weeks. These findings were consistent with a previous study that compared the effects of short foot exercise to wearing foot orthoses for 5 weeks.[25] But it differs from a study that found nonsignificant difference in navicular drop measured at 4 weeks after cessation of the 12-week program comparing between exercises and foot orthoses.[24] The conclusion of the latter study, however, is questionable as the exercises used were tailored to each participant and not standardized across participants as well as the report of low compliance to exercises in that study.

Plantar pressure in the FOG and EG was found to change in a pattern towards that reported in normal arch foot. They decreased in the medial forefoot and rearfoot regions and increased in the lateral forefoot and rearfoot regions.[125] A similar redistribution of plantar pressure was also found in previous studies after participants exercised tibialis posterior and intrinsic foot muscles.[27,126] The plantar pressure after wearing foot orthoses is commonly examined by in-shoe measuring system which differs from the current study. The results are therefore interpreted differently. Nevertheless, the findings of nonsignificant differences in plantar pressure between FOG and EG in all subregions of the foot suggest comparable effectiveness of both interventions in altering plantar pressure among individuals with flexible flatfoot.

Regarding static balance, the greater improvements in the EG than the FOG suggest a preference for exercise over foot orthoses. Both groups showed improvement in static balance as a lesser anteroposterior and mediolateral displacement compared to baseline. These findings in the EG were consistent with Study 1 of this study and with previous studies after performing short foot exercise for 5 weeks[53] and 6 weeks.[115] However, significant differences between EG and FOG were found only in the anteroposterior direction and not in the mediolateral direction. Since the EG also aimed at exercising gluteus medius muscle which predominantly controls the lower extremity alignment in the frontal plane, an improvement in the MLA in the mediolateral direction was expected. Likewise, foot orthoses inserted on the medial forefoot and medial rearfoot also affected the lower extremity alignment in the frontal plane. As a result, both EG and FOG might provide similar support for the

MLA which is unstable in the mediolateral direction. The significantly better static balance in the anteroposterior direction in the EG than the FOG might be related to the greater gluteus medius muscle strength which is responsible for controlling pelvic alignment during single leg stance in the EG.

Greater improvements in dynamic balance in the EG than the FOG were found which support a previous study. Improvement in dynamic balance with foot orthoses might be due to an increase in cutaneous afferent receptors during its application.[124] In comparison to foot orthoses, a greater improvement in Y-balance test was found in the group that performed short foot exercise for 6 weeks.[25] These findings might also be related to the significantly higher strength of the foot and gluteus medius muscles examined in the EG of the present study. With exercise, it is postulated that the muscle spindle function and the proprioceptive information within the exercised muscles would be improved.

However, the significant increase in flexor hallucis brevis muscle strength in the FOG is interesting as foot orthoses is considered a passive intervention. This finding is consistent with a study that required individuals to use foot orthoses for 8 weeks and found increase in strength of flexor hallucis muscle together with an increase in cross-sectional area of abductor hallucis brevis muscle.[21]

Overall, the findings of this study support the use of exercise as more effective intervention than foot orthoses in supporting the MLA, redistributing plantar pressure, and increasing balance in adults with flexible flatfoot. Due to the nature of active involvement of participants during exercise intervention, it therefore suggests that active intervention is better than passive intervention.

Study limitations

The current study has some limitations. Firstly, as the participants were healthy, the results might differ in a symptomatic flatfoot population. Secondly, the long-term effectiveness of the interventions was not evaluated in this study as the participants were not followed after the cessation of the interventions. Thirdly, the study did not examine the effects of the interventions on functional activities such as walking and running. Future studies should investigate whether exercise can yield greater improvements in foot function compared to wearing foot orthoses.

4.4 Conclusion

The exercise provided greater improvements in navicular drop, AHI, static balance, dynamic balance, and lower extremity muscle strength than foot orthoses when applying among healthy adults with flexible flatfoot.

CHAPTER 5

Conclusion of thesis

This study consists of 2 studies.

Conclusion for Study 1

Objective of study 1: To establish the more effective exercise protocol by comparing the MLA height (ND, AHI, plantar foot pressure, static balance, and dynamic balance) in groups performing foot exercises with and without gluteus medius muscle strengthening exercise after 8-week interventions in individuals with flexible flatfoot.

The results were in accordance with the hypotheses of the Study 1 (chapter 1). The results suggested that the addition of gluteus medius muscle strengthening exercise to foot exercises was more effective in decreasing ND and medial plantar pressure and increasing AHI and static balance than performing foot exercises alone in individuals with flexible flatfoot.

Conclusion for Study 2

Objective of Study 2: To compare the established exercise protocol in Study 1 with foot orthoses to determine the actual effectiveness of each intervention on the MLA (ND, AHI, plantar foot pressure, static balance, and dynamic balance) after 8-week interventions in individuals with flexible flatfoot.

From Study 1, the exercise protocol that strengthened gluteus medius and foot muscles was found to be more effective. The results were in accordance with the hypotheses of the Study 2 (chapter 1) that the exercise group provided greater improvements in ND, AHI, static balance, dynamic balance, and lower extremity muscle strength than foot orthoses when applying in healthy adults with flexible flatfoot.

Strength of this study

This study investigated the exercise and foot orthoses that have been used widely for improving the MLA height in individuals with flexible flatfoot. However, there has been inconsistent evidence to support the use of each intervention for managing flexible flatfoot. This study has several strengths. First, this was the first study to examine the addition of gluteus medius muscle strengthening exercise to foot exercises on the MLA height in individuals with flexible flatfoot. Second, this study had the participants performed each intervention up to 8 weeks which were longer than the previous studies that commonly ranged from 4 to 6 weeks. This allows the effects of exercise to be demonstrated as it needs approximately 8 weeks for changes in muscle fibers to be observed. Third, this study conducted in large sample size (52 participants in Study 1 and 38 participants in Study 2) in comparison to the previous studies which included 14 to 32 participants in the study. Fourth, this study measured several outcomes related to the MLA height. This has advantages in understanding the responses of the interventions. Fifth, the foot orthoses used in this study were custom-made and were derived from a recent systematic review study that recommended the characteristics of effective foot orthoses for flexible flatfoot. Previous studies commonly used prefabricated foot orthoses which may limit their effectiveness.

Clinical implications of this study

A key finding of this study is that the addition of gluteus medius muscle strengthening exercise to foot exercises provides greater improvement in MLA height than performing foot exercises alone or using foot orthoses.

Limitations and further studies

This study has some limitations. First, the participants were pain-free so the results may differ when conducting in symptomatic flatfoot population. Nonetheless, it is anticipated that this protocol would also yield improvements in symptomatic population. Second, this study did not assess the changes in lower extremity alignment, including rearfoot eversion, tibial rotation, and femoral rotation. Future research should explore whether these exercises would lead to changes in lower extremity alignment. Third, the long-term effectiveness of the interventions remains unknown since the participants were not followed after the cessation of the interventions. Further study is needed to examine how long the benefits of the interventions would be maintained. Lastly, the study did not investigate the potential benefits of these interventions on functional activities like walking and running.

APPENDICES

APPENDIX I

SCREENING QUESTIONNAIRE

แบบสอบถาม

วันที่…………………………………….(แบบสอบถามนี้สำหรับผู้เข้าร่วมงานวิจัย) PARTICIPANT NO:…………

1. น้ำหนัก………. กิโลกรัม ส่วนสูง……..เซนติเมตร BMI …………….

โรคประจำตัว…………………………………

2. ท่านสังเกตว่าตัวเองมีฝ่าเท้าแบน ☐ ใช่ ☐ ไม่ใช่

3. ท่านมีอาการปวดที่ฝ่าเท้า/ข้อเท้าหรือไม่ ☐ มี ☐ ไม่มี

4. ท่านมีฝ่าเท้าแบนข้างใด

☐ ข้างซ้าย ☐ ข้างขวา ☐ ทั้งสองข้าง

5. ท่านได้ใส่รองเท้าที่มีเนินรองรับฝ่าเท้าหรือไม่

☐ ใช่ ☐ ไม่ใช่

6. ในตลอดชีวิตท่านเคยได้รับอุบัติเหตุที่ฝ่าเท้า/ข้อเท้า/ขา/หลัง อย่างรุนแรงหรือไม่

☐เคย ☐ไม่เคย

7. ในตลอดชีวิตท่านเคยได้รับการผ่าตัดที่ฝ่าเท้า/ข้อเท้า/ขา/หลัง หรือไม่

☐เคย ☐ไม่เคย

APPENDIX II

DATA COLLECTION SHEET FOR STUDY 1

PARTICIPANT NO:…………

1. ND

	Baseline	4-week	8-week
Navicular drop (mm)			

2. AHI

	Baseline	4-week	8-week
Arch height index			

3. Plantar foot pressure

	Baseline	4-week	8-week
Plantar foot pressure (N/cm^2)			
-Medial forefoot			
-Lateral forefoot			
-Midfoot			
-Medial rearfoot			
-Lateral rearfoot			

4. Static balance

	Baseline	4-week	8-week
Maximum displacement AP direction (cm)			
Maximum displacement ML direction (cm)			

5. Dynamic balance

	Baseline	4-week	8-week
Anterior direction (% of participant leg length)			
Posterior direction (% of participant leg length)			
Medial direction (% of participant leg length)			
Lateral direction (% of participant leg length)			

6. Muscle Strength

Muscle	Baseline	4-week	8-week
Tibialis posterior (N)			
Abductor hallucis brevis muscle and flexor hallucis brevis (N)			
Gluteus medius (N)			

APPENDIX III

DATA COLLECTION SHEET (STUDY 2)

PARTICIPANT NO:…………

1. ND

	Baseline	4-week	8-week
Navicular drop (mm)			

2. AHI

	Baseline	4-week	8-week
Arch height index			

3. Forefoot and rearfoot angle

	Baseline
Rt. forefoot	
Lt. forefoot	
Rt. rearfoot	
Lt. rearfoot	

4. Plantar foot pressure

	Baseline	4-week	8-week
Plantar foot pressure (N/cm^2)			
-Medial forefoot			
-Lateral forefoot			
-Midfoot			
-Medial rearfoot			
-Lateral rearfoot			

5. Static balance

	Baseline	4-week	8-week
Maximum displacement AP direction (cm)			
Maximum displacement ML direction (cm)			

6. Dynamic balance

	Baseline	4-week	8-week
Anterior direction (% of participant leg length)			
Posterior direction (% of participant leg length)			
Medial direction (% of participant leg length)			
Lateral direction (% of participant leg length)			

7. Muscle Strength

Muscle	Baseline	4-week	8-week
Tibialis posterior (N)			
Abductor hallucis brevis muscle and flexor hallucis brevis (N)			
Gluteus medius (N)			

APPENDIX IV

SAMPLE SIZE CALCULATION (STUDY 1)

The sample size was calculated using the SPSS 28.0 (IBM, Chicago, IL, USA) software program in order to detect a 1.5 mm difference in ND between groups.[73] A total sample of 52 participants (26 per group) was required for a statistical power of 0.90, an alpha level of 0.05, and a drop-out allowance of 10%.

APPENDIX V
SAMPLE SIZE CALCULATION (STUDY 2)

The sample size was calculated using the IBM SPSS Statistics ver. 28.0 (IBM Co., Armonk, NY, USA) to detect a 1.5-mm difference in navicular drop between groups. Based on the standard deviation of approximately 1.4 mm observed between groups in a previous study,[25] a sample size of 38 participants, with 19 participants in each group, was required. This was to achieve a statistical power of 0.85, an alpha level of 0.05, and to account for a potential dropout rate of 10%.

Power Analysis - Independent Sample Means

Power Analysis Table

Test for Mean Difference[a]	N1	N2	Actual Power[b]	Test Assumptions			
				Power	Std. Dev.[c]	Effect Size	Sig.
1	15	15	.808	.800	1.4	1.071	.05
2	17	17	.857	.850	1.4	1.071	.05
3	20	20	.910	.900	1.4	1.071	.05
4	24	24	.953	.950	1.4	1.071	.05

a. Two-sided test.

b. Based on noncentral t-distribution.

c. Group variances are assumed to be equal.

APPENDIX VI

RELIABILITY STUDIES 1-2

One assessor will be blinded and involved in this study. He graduated Bachelor degree in Physical Therapy program with three-year experience. He conducted the measurements of navicular drop height, AHI, plantar foot pressure, and static and dynamic balance as described in method (Chapter 3). Intra-rater will be calculated.

Ten participants with the same characteristics of the main study took part in this study. Assessor will measure participant 2 trials with 100-120 minutes apart. All participants will be measured in the random order of all outcome measures. After finished of first trail, assessor has to rest for 30 minutes then start to second trail.

The reliability coefficients of the intra-rater reliability $ICC_{(3,2)}$ for the outcome measures measured on two occasions (n = 10).

Outcome measures	$ICC_{(3,2)}$	SEM	MDC 95%
NDT (mm)	.968	0.4	1.11
AHI	.996	0.002	0.005
Dynamic balance			
Dynamic balance, Lt. (cm)			
-Anterior	.980	0.58	1.62
-Posterior	.997	0.46	1.28
-Medial	.991	0.70	1.95
-Lateral	.961	0.92	2.55
Dynamic balance, Rt. (cm)			
-Anterior	.917	0.91	2.52
-Posterior	.995	0.63	1.75
-Medial	.992	0.86	2.38
-Lateral	.984	0.83	2.30
Forefoot and rearfoot angle (°)			
Forefoot angle (Lt.)	.922	1.38	3.82
Forefoot angle (Rt.)	.956	1.46	4.06
Rearfoot angle (Lt.)	.837	0.94	2.61
Rearfoot angle (Rt.)	.950	0.50	1.39

The reliability coefficients of the intra-rater reliability $ICC_{(3,3)}$ for the outcome measures measured on three occasions (n = 10).

Outcome measures	$ICC_{(3,3)}$	SEM	MDC 95%
Static balance			
Lt.			
-AP displacement (cm)	.858	0.67	1.86
-ML displacement (cm)	.846	0.36	1.01
Rt.			
-AP displacement (cm)	.795	1.02	2.84
-ML displacement (cm)	.806	0.39	1.09
Plantar pressure (kPa)			
Lt. over all plantar pressure	.968	2.91	8.05
Rt. over all plantar pressure	.972	2.55	7.07
Muscle strength (N)			
Lt. Tibialis posterior	0.97	1.69	4.69
Rt. Tibialis posterior	0.95	2.00	5.53
Lt. Flexor hallucis	0.91	1.60	4.42
Rt. Flexor hallucis	0.86	1.93	5.36
Lt. Gluteus medius	0.85	4.97	13.77
Rt. Gluteus medius	0.88	3.92	10.88

APPENDIX VII

CHECKLIST NOTEBOOK (STUDY 1; FG)

ลำดับผู้เข้าร่วม :............

โปรดทำเครื่องหมายกากบาทหรือไฮไลท์ลงในช่องว่าง เมื่อออกกำลังกายเสร็จสิ้น ในวันนั้นๆ

ครั้งที่ปฏิบัติ	วันที่	การออกกำลังกายด้วยยางยืด	การขมิบอุ้งเท้าที่ขอบบันได	การขมิบยกอุ้งเท้า
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APPENDIX VIII
CHECKLIST NOTEBOOK (STUDY 1; FHG)

ลำดับผู้เข้าร่วม :............

โปรดทำเครื่องหมายกากบาทหรือไฮไลท์ลงในช่องว่าง เมื่อออกกำลังกายเสร็จสิ้น ในวันนั้นๆ

ครั้งที่ ปฏิบัติ	วันที่	การออกกำลังกายด้วยยางยืด	การขมิบอุ้งเท้าที่ขอบบันได	การขมิบยกอุ้งเท้า	การออกกำลังกายสะโพก
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APPENDIX IX

CHECKLIST NOTEBOOK (STUDY 2; OG)

ลำดับผู้เข้าร่วม :............

โปรดทำเครื่องหมายกากบาทหรือไฮไลท์ลงในช่องว่าง เมื่อสวมใส่รองเท้าที่ทางผู้วิจัยมอบให้เสร็จสิ้น ในวันนั้นๆ

ครั้งที่ปฏิบัติ	วันที่	จำนวนชั่วโมงที่ใส่	หมายเหตุ
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APPENDIX X
CHECKLIST NOTEBOOK (STUDY 2; EG)

ลำดับผู้เข้าร่วม :............

โปรดทำเครื่องหมายกากบาทหรือไฮไลท์ลงในช่องว่าง เมื่อออกกำลังกายเสร็จสิ้น ในวันนั้นๆ

ครั้งที่ปฏิบัติ	วันที่	การออกกำลังกายด้วยยางยืด	การขมิบอุ้งเท้าที่ขอบบันได	การขมิบยกอุ้งเท้า	การออกกำลังกายสะโพก
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APPENDIX XI
REGISTERED TRIAL

Released Records List

Show 10 entries Search:

ID	Released Date	Study Title	Recruitment Status	Last Updated	Options
TCTR20211117003	17 November 2021	EFFECTS OF LOWER EXTREMITY MUSCLE STRENGTHENING EXERCISE AND FOOT ORTHOSES ON MEDIAL LONGITUDINAL ARCH HEIGHT IN INDIVIDUALS WITH FLEXIBLE FLATFOOT	Recruiting	07 December 2022	SHOW UPDATE PDF XML
TCTR20221204001	04 December 2022	EFFECTS OF LOWER EXTREMITY MUSCLE STRENGTHENING EXERCISE AND FOOT ORTHOSES ON MEDIAL LONGITUDINAL ARCH HEIGHT IN INDIVIDUALS WITH FLEXIBLE FLATFOOT (PHASE 2)	Recruiting	07 December 2022	SHOW UPDATE PDF XML

Showing 1 to 2 of 2 entries Previous 1 Next

APPENDIX XII

THE CERTIFICATE OF ETHICAL APPROVAL – STUDY 1

AF 02-12

คณะกรรมการพิจารณาจริยธรรมการวิจัยในคน กลุ่มสหสถาบัน ชุดที่ 1 จุฬาลงกรณ์มหาวิทยาลัย
254 อาคารจามจุรี 1 ชั้น 2 ถนนพญาไท เขตปทุมวัน กรุงเทพฯ 10330
โทรศัพท์: 0-2218-3202, 0-2218-3049 E-mail: eccu@chula.ac.th

COA No. 223/2563

ใบรับรองโครงการวิจัย

โครงการวิจัยที่ 135.1/63 : ผลของการออกกำลังเพื่อเพิ่มความแข็งแรงกล้ามเนื้อรยางค์ขากับการใส่แผ่นรองฝ่าเท้าต่อความสูงของอุ้งเท้าด้านในในผู้ที่มีภาวะเท้าแบนแบบยืดหยุ่น

ผู้วิจัยหลัก : นายภูมิชัย อิงคนานุวัฒน์

หน่วยงาน : คณะสหเวชศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

คณะกรรมการพิจารณาจริยธรรมการวิจัยในคน กลุ่มสหสถาบัน ชุดที่ 1 จุฬาลงกรณ์มหาวิทยาลัย ได้พิจารณา โดยใช้หลัก ของ Belmont Report 1979, Declaration of Helsinki 2013, Council for International Organizations of Medical Sciences (CIOM) 2016, มาตรฐานคณะกรรมการจริยธรรมการวิจัยในคน (มคจค.) 2560, นโยบายแห่งชาติและแนวทางปฏิบัติการวิจัยในมนุษย์ 2558 อนุมัติให้ดำเนินการศึกษาวิจัยเรื่องดังกล่าวได้

ลงนาม ....
(รองศาสตราจารย์ นายแพทย์ปรีดา ทัศนประดิษฐ)
ประธาน

ลงนาม ระวีนันท์ มิ่งภัคนีย์
(ผู้ช่วยศาสตราจารย์ ดร.ระวีนันท์ มิ่งภัคนีย์)
กรรมการและเลขานุการ

วันที่รับรอง : 2 ตุลาคม 2563 **วันหมดอายุ** : 1 ตุลาคม 2564

เอกสารที่คณะกรรมการรับรอง

1) โครงการวิจัย
2) เอกสารข้อมูลสำหรับผู้มีส่วนร่วมในการวิจัยและหนังสือแสดงความยินยอมของผู้มีส่วนร่วมในการวิจัย
3) ผู้วิจัย
4) แบบสอบถาม

เลขที่โครงการวิจัย 135.1/63
วันที่รับรอง -2 ต.ค. 2563
วันหมดอายุ -1 ต.ค. 2564

เงื่อนไข

1. ข้าพเจ้ารับทราบว่าเป็นการผิดจริยธรรม หากดำเนินการเก็บข้อมูลการวิจัยก่อนได้รับการอนุมัติจากคณะกรรมการพิจารณาจริยธรรมการวิจัยฯ
2. หากใบรับรองโครงการวิจัยหมดอายุ การดำเนินการวิจัยต้องยุติ เมื่อต้องการต่ออายุต้องขออนุมัติใหม่ล่วงหน้าไม่ต่ำกว่า 1 เดือน พร้อมส่งรายงานความก้าวหน้าการวิจัย
3. ต้องดำเนินการวิจัยตามที่ระบุไว้ในโครงการวิจัยอย่างเคร่งครัด
*4. ใช้เอกสารข้อมูลสำหรับกลุ่มประชากรหรือผู้มีส่วนร่วมในการวิจัย ใบยินยอมของกลุ่มประชากรหรือผู้มีส่วนร่วมในการวิจัย และเอกสารเชิญเข้าร่วมวิจัย (ถ้ามี) **เฉพาะที่ประทับตราคณะกรรมการเท่านั้น***
5. หากเกิดเหตุการณ์ไม่พึงประสงค์ร้ายแรงในสถานที่เก็บข้อมูลที่ขออนุมัติจากคณะกรรมการ ต้องรายงานคณะกรรมการภายใน 5 วันทำการ
6. หากมีการเปลี่ยนแปลงการดำเนินการวิจัย ให้ส่งคณะกรรมการพิจารณารับรองก่อนดำเนินการ
7. หากยุติโครงการวิจัยก่อนกำหนดต้องแจ้งคณะกรรมการฯ ภายใน 2 สัปดาห์พร้อมคำชี้แจง
*8. โครงการวิจัยไม่เกิน **1 ปี** ส่งแบบรายงานสิ้นสุดโครงการวิจัย (AF 01-15) และบทคัดย่อผลการวิจัยภายใน 30 วัน เมื่อโครงการวิจัยเสร็จสิ้น สำหรับโครงการวิจัยที่เป็น**วิทยานิพนธ์**ให้ส่งบทคัดย่อผลการวิจัย ภายใน 30 วัน เมื่อโครงการวิจัยเสร็จสิ้น*
9. โครงการวิจัยที่มีหลายระยะ จะรับรองโครงการเป็นระยะ เมื่อดำเนินการวิจัยในระยะแรกเสร็จสิ้นแล้ว ให้ดำเนินการส่งรายงานความก้าวหน้า พร้อมโครงการวิจัยและเอกสารที่เกี่ยวข้องในระยะถัดไป
10. คณะกรรมการฯ สงวนสิทธิ์ในการตรวจเยี่ยมเพื่อติดตามการดำเนินการวิจัย
11. สำหรับโครงการวิจัยจากภายนอก ผู้บริหารส่วนงาน กำกับการดำเนินการวิจัย

APPENDIX XIII

THE CERTIFICATE OF ETHICAL APPROVAL – STUDY 2

AF 02-12

คณะกรรมการพิจารณาจริยธรรมการวิจัยในคน กลุ่มสหสถาบัน ชุดที่ 1 จุฬาลงกรณ์มหาวิทยาลัย
254 อาคารจามจุรี 1 ชั้น 2 ถนนพญาไท เขตปทุมวัน กรุงเทพฯ 10330
โทรศัพท์: 0-2218-3202, 0-2218-3049 E-mail: eccu@chula.ac.th

COA No. 183/2565

ใบรับรองโครงการวิจัย

โครงการวิจัยที่ 135.1/63 : ผลของการออกกำลังเพื่อเพิ่มความแข็งแรงกล้ามเนื้อรยางค์ขากับการใส่แผ่นรองฝ่าเท้าต่อความสูงของอุ้งเท้าด้านในในผู้ที่มีภาวะเท้าแบนแบบยืดหยุ่น

ผู้วิจัยหลัก : นายภูมิชัย อิงคนานุวัฒน์

หน่วยงาน : คณะสหเวชศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

คณะกรรมการพิจารณาจริยธรรมการวิจัยในคน กลุ่มสหสถาบัน ชุดที่ 1 จุฬาลงกรณ์มหาวิทยาลัย ได้พิจารณา โดยใช้หลัก ของ Belmont Report 1979, Declaration of Helsinki 2013, Council for International Organizations of Medical Sciences (CIOM) 2016, มาตรฐานคณะกรรมการจริยธรรมการวิจัยในคน (มคจค.) 2560, นโยบายแห่งชาติและแนวทางปฏิบัติการวิจัยในมนุษย์ 2558 อนุมัติให้ดำเนินการศึกษาวิจัยเรื่องดังกล่าวได้ใน **การศึกษาที่ 2 ของโครงการวิจัย**

ลงนาม ....
(รองศาสตราจารย์ นายแพทย์ปรีดา ทัศนประดิษฐ)
ประธาน

ลงนาม ....
(ผู้ช่วยศาสตราจารย์ ดร.ระวีนันท์ มิ่งภัคนีย์)
กรรมการและเลขานุการ

วันที่รับรอง : 14 กันยายน 2565 **วันหมดอายุ** : 13 กันยายน 2566

เอกสารที่คณะกรรมการรับรอง

1) โครงการวิจัย
2) เอกสารข้อมูลสำหรับผู้มีส่วนร่วมในการวิจัยและหนังสือแสดงความยินยอมของผู้มีส่วนร่วมในการวิจัย
3) ผู้วิจัย
4) แบบสอบถาม
5) ใบประชาสัมพันธ์

เลขที่โครงการวิจัย 135.1/63
วันที่รับรอง 14 ก.ย. 2565
วันหมดอายุ 13 ก.ย. 2566

<u>เงื่อนไข</u>

1. ข้าพเจ้ารับทราบว่าเป็นการผิดจริยธรรม หากดำเนินการเก็บข้อมูลการวิจัยก่อนได้รับการอนุมัติจากคณะกรรมการพิจารณาจริยธรรมการวิจัยฯ
2. หากใบรับรองโครงการวิจัยหมดอายุ การดำเนินการวิจัยต้องยุติ เมื่อต้องการต่ออายุต้องขออนุมัติใหม่ล่วงหน้าไม่ต่ำกว่า 1 เดือน พร้อมส่งรายงานความก้าวหน้าการวิจัย
3. ต้องดำเนินการวิจัยตามที่ระบุไว้ในโครงการวิจัยอย่างเคร่งครัด
4. ใช้เอกสารข้อมูลสำหรับกลุ่มประชากรหรือผู้มีส่วนร่วมในการวิจัย ใบยินยอมของกลุ่มประชากรหรือผู้มีส่วนร่วมในการวิจัย และเอกสารเชิญเข้าร่วมวิจัย (ถ้ามี) ***เฉพาะที่ประทับตราคณะกรรมการเท่านั้น***
5. หากเกิดเหตุการณ์ไม่พึงประสงค์ร้ายแรงในสถานที่เก็บข้อมูลที่ขออนุมัติจากคณะกรรมการ ต้องรายงานคณะกรรมการภายใน 5 วันทำการ
6. หากมีการเปลี่ยนแปลงการดำเนินการวิจัย ให้ส่งคณะกรรมการพิจารณารับรองก่อนดำเนินการ
7. หากยุติโครงการวิจัยก่อนกำหนดต้องแจ้งคณะกรรมการฯ ภายใน 2 สัปดาห์พร้อมคำชี้แจง
8. โครงการวิจัยไม่เกิน 1 ปี ส่งแบบรายงานสิ้นสุดโครงการวิจัย (AF 01-15) และบทคัดย่อผลการวิจัยภายใน 30 วัน เมื่อโครงการวิจัยเสร็จสิ้น สำหรับโครงการวิจัยที่เป็นวิทยานิพนธ์ให้ส่งบทคัดย่อผลการวิจัย ภายใน 30 วัน เมื่อโครงการวิจัยเสร็จสิ้น
9. โครงการวิจัยที่มีหลายระยะ จะรับรองโครงการเป็นระยะ เมื่อดำเนินการวิจัยในระยะแรกเสร็จสิ้นแล้ว ให้ดำเนินการส่งรายงานความก้าวหน้า พร้อมโครงการวิจัยและเอกสารที่เกี่ยวข้องในระยะถัดไป
10. คณะกรรมการฯ สงวนสิทธิ์ในการตรวจเยี่ยมเพื่อติดตามการดำเนินการวิจัย
11. สำหรับโครงการวิจัยจากภายนอก ผู้บริหารส่วนงาน กำกับการดำเนินการวิจัย

APPENDIX XIV

ADVERTISED POSTER

เชิญชวนเข้าร่วมโครงการวิจัย

เรื่อง ผลของการออกกำลังเพื่อเพิ่มความแข็งแรงกล้ามเนื้อรยางค์ขากับการใส่แผ่นรองฝ่าเท้าต่อความสูงของอุ้งเท้าด้านในในผู้ที่มีภาวะเท้าแบนแบบยืดหยุ่น

คุณสมบัติ

-เพศชายและหญิงมีสุขภาพดีอายุระหว่าง 18-39 ปี

-มีภาวะเท้าแบนทั้ง 2 ข้าง

-มีดัชนีมวลร่างกายอยู่ในช่วง 18.5-22.9 kg/m^2

ผู้ที่สนใจสามารถติดต่อขอข้อมูลเพิ่มเติมและสมัครได้ที่

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REFERENCES

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