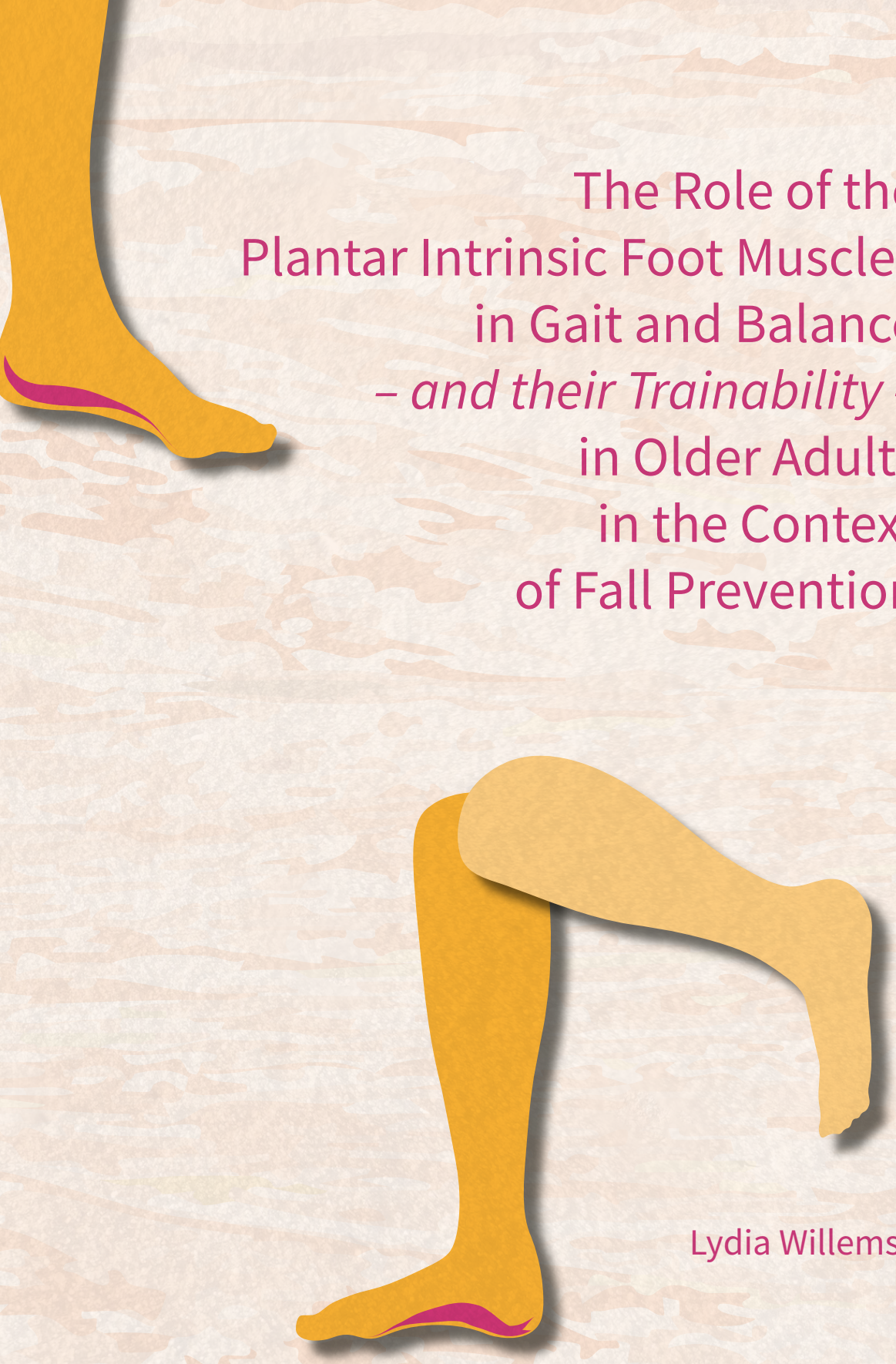
The Role of the Plantar Intrinsic Foot Muscles in Gait and Balance *– and their Trainability –* in Older Adults in the Context of Fall Prevention



Lydia Willemse

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Aan mijn moeder, Thea Willemse, die mij leerde door te zetten.

LIST OF ABBREVIATIONS

Abbreviations appearing in the Summary, General Introduction and General Discussion (abbreviations used in other chapters are explained within those chapters):

ABC scale	Activities-specific Balance Confidence (ABC) Scale
ANCOVA	Analysis of Covariance
EARS	Exercise Adherence Rating Scale
FES-I	Fall Efficacy Scale-International
IQR	Interquartile range
MTP	Metatarsophalangeal
PIMs	Plantar Intrinsic foot Muscles
RCT	Randomized Controlled Trials
SF36	Short Form Health Survey
STIFF	STrengthening the Intrinsic Foot Flexor muscles

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VOORWOORD

Alvorens over te gaan tot de inhoud van dit proefschrift, neem ik u graag mee in de totstandkoming en het verloop van mijn promotietraject. Achteraf gezien is het allemaal begonnen met het verkennen van digitale technologieën ter inspiratie voor een nieuwe minor van Fontys Paramedisch. Vanuit het idee 'biofeedback' voor podotherapie deed ik een oriënterend literatuuronderzoek en het viel me op dat de wetenschappelijke kennis over de intrinsieke voetspieren in de kinderschoenen stond. Een onderwerp op een onontgonnen terrein dat aansloot bij mijn interesse in functionele anatomie en de biomechanica van het bewegingsapparaat en dan ook nog aansluitend op het thema 'technologie' van ons profileringsteam binnen Fontys Paramedisch. Het verlangen om me weer meer bezig te gaan houden met het doen van onderzoek was gewekt.

Een bemoedigend gesprek met Benedicte werd de volgende stap in de richting van een beursaanvraag. Benedicte bleek al een promovenda te begeleiden op het gebied van de intrinsieke voetspieren en zag mogelijkheden. We besloten ons te richten op de rol van deze spieren in de context van valpreventie – een onderwerp met maatschappelijke urgentie. Niet veel later sloten Martijn en Eveline aan en kreeg het plan vastere vorm. Met de toekenning van de 'promotiebeurs voor leraren' van de Nederlandse Organisatie voor Wetenschappelijk Onderzoek (NWO) kon het project in maart 2019 echt beginnen.

Terugkijkend stond deze periode voor mij in het teken van verbinding: tussen onderwijs, onderzoek en praktijk. Meer dan zeventig studenten droegen op waardevolle wijze bij aan het onderzoek, vaak in direct contact met de deelnemende ouderen en praktijken. Met

veel plezier kijk ik terug op deze leerzame samenwerking. Ook voel ik me bevoorrecht de, vaak nieuwste, technologieën te hebben kunnen inzetten die het bewegingsanalyse lab van Fontys Paramedisch rijk is. De coronaperiode beperkte me tijdelijk tot het doen van literatuuronderzoek, wat achteraf gezien voor een waardevolle wending zorgde. De oorspronkelijke focus op biofeedback maakte hierdoor plaats voor de fundamentelere vraag: kunnen we deze spieren eigenlijk wel trainen bij ouderen, en leidt dat ook tot het gewenste effect?

Door dit promotietraject heb ik een betekenisvolle invulling kunnen geven aan mijn docentrol bij Fontys Paramedisch en mijn steentje bijgedragen aan de maatschappelijke uitdaging om mensen langer in goede gezondheid te kunnen laten leven. Menigmaal prijsde ik me gelukkig met hoe soepel het traject verliep en de voldoening dat het werken aan dit project me gaf. In het dankwoord, achter in dit proefschrift, geef ik aandacht aan de mensen die hieraan hebben bijgedragen.

Voor nu wens ik u veel plezier bij het lezen van dit proefschrift waarbij u er stap voor stap achter komt hoe de opgedane kennis over de intrinsieke voetspieren bijdraagt aan het verbeteren van de valpreventie onder oudere mensen.

Oss, september 2025
Lydia Willemse

General introduction

1

PREVENTING FALLS IN OLDER ADULTS

Falling is a serious health issue in the worldwide ageing population. Within this project, we adopted the definition of a fall as proposed by the Prevention of Falls Network Europe: an unexpected event in which the participants come to rest on the ground, floor, or lower level [1]. Falling is the leading cause of severe injuries among older adults. Eventually, these injuries may lead to losing independence or even death. The rate of falls, as well as the severity of their consequences, increases with age. Therefore, as the population continues to age, fall prevention is of utmost urgency.

Impact of falling

Approximately 30% of older adults, aged 65 years or older, fall at least once a year [2]. For people aged 85 years or older, this rate nearly doubles [2]. Falling is particularly worrying in older adults due to the increased susceptibility to injury from geriatric diseases (e.g., osteoporosis) or age-induced physiological changes (e.g., slowed protective reflexes) [3]. This makes falling the leading cause of admissions to emergency care departments. Falling causes serious injury in approximately 10% of cases among older adults [4], among which fractures and brain damage are most prevalent [5]. Falling also leads to a substantial rate of hospital or care home admissions. The older age group (≥ 85 years) is more prone to these consequences [6]. For instance, a proportion of 20% is being institutionalized after a fall. Falling may also lead to death and is the fifth leading cause of mortality in this population, following cardiovascular disease, cancer, stroke and pulmonary disorders [3]. Medical costs directly related to fall incidents among older adults account for approximately 1% of the total healthcare budget in the Netherlands [7], which emphasizes the financial burden for society. In the next 25 years, the population of adults aged 60 years or older is expected to nearly double, with the largest rate of increase occurring in the oldest age group [8]. Apart from this phenomenon, known as population ageing, it is anticipated that the incidence of falling will also rise because of the increasing prevalence of multimorbidity and frailty among older adults [9].

The majority of falls in older adults do not result in injuries [2]. However, having fallen compromises physical and mental well-being and can consequently negatively influence healthy ageing. In a study among community-dwelling older adults [10], falling appeared to be associated with a subsequent functional decline. This study also showed that when people fall repeatedly, they tend to participate less in social activities. Further, when falling had led to a serious injury, physical activity levels decreased. These consequences may be mediated by concerns about falling, which often develop after a fall [11]. Another consequence of concerns about falling is the restriction of mobility activities, a factor that has been correlated with physical decline [12]. In turn, concerns about falling and restriction of daily life activities, including mobility activities, predicted the incidence of falling within one-year follow-up [12]. It is important to avoid or to stop this downward spiral to physical frailty by reducing concerns about falling, and by preventing the first fall or recurrent falls.

Impaired gait and balance are primary risk factors

Falling in older adults has a multifactorial nature which needs to be effectively addressed to prevent falls. Numerous risk factors are associated with falling and include, for example, female gender, mobility limitations, cognitive deficits, medical conditions, visual impairments and history of falls [3,13]. However, gait and balance impairments, second to only muscle weakness, are the most strongly related to falling [3]. To illustrate this, community-dwelling older adults with impaired gait or balance were approximately 2.5 times more likely to experience a fall compared to those without such impairments [14,15]. Impaired gait and balance is the major risk factor for both first-time falls and recurrent falls [5,15]. Fortunately, gait and balance impairments are risk factors amenable to improvement through fall prevention interventions [3]. Given that impaired gait and balance is a strong predictor of falls, it is important not only to treat these impairments, but also to preserve gait and balance capabilities in older adults who have not yet developed impairments.

Exercising is most effective in preventing falls

Among the fall prevention interventions targeting intrinsic factors, those that include an exercise component are most effective in reducing the rate and risk of falls [16]. However, their effectiveness is open to improvement. Evidence shows that exercise interventions incorporating balance and functional exercises reduce the rate of falls by 24% [17]. This reduction probably increases to 34% when resistance exercises are included [17]. There is also evidence that Tai Chi-like interventions may reduce the rate of falls by 19% [17]. In addition to contemporary interventions, ongoing exercise to improve gait, balance and lower extremity strength is frequently suggested as an effective fall prevention strategy [3,14,15,17,18]. The exercises in programs proven effective by a systematic review [17] primarily target muscles proximal to the feet. Excluded from this review were multifaceted podiatry interventions [19–21] that incorporated a substantial foot and ankle exercise program. One of the excluded studies [20] reported a 36% reduction in the rate of falls, comparable to the effectiveness of fall prevention exercise programs incorporating balance, functional and resistance exercises [17]. Furthermore, a meta-analysis confirmed the pooled effectiveness of these multifaceted podiatry interventions to reduce the rate of falls [22]. The feet should therefore not to be overlooked in fall prevention programs. However, recommended fall prevention programs are often based on the previously cited systematic review [17]. As a result and contrasting to the observed potential of foot and ankle exercises [20], these programs rarely include targeted exercises for the intrinsic foot. To illustrate this, out of the three fall prevention exercise interventions acknowledged by the Dutch National Institute for Public Health and the Environment [23] (i.e., ‘Otago’[24], ‘In balans’ [25], ‘Vallen Verleden Tijd’ [26], only one (i.e., ‘In Balans’ [25]) includes a single exercise targeting the intrinsic foot. A better understanding of the role of the intrinsic foot in falling or fall-related risk factors may provide valuable insights for improving the effectiveness of exercise programs to prevent falling.

The role of the feet in age-induced gait and balance impairments

Falls in older adults most often occur while walking [27]. While walking, the human body interacts with its surroundings through the feet, making these body parts vitally important for gait. This is particularly true since – for most part of the walking cycle – the body is balanced on a single foot in contact with the ground. The structures within the foot enable both flexibility and rigidity. A flexible foot allows accommodation to uneven terrains and aids in shock absorption. Rigidity is required to let the foot act as a leverage to transmit forces generated by the body to the ground. Only recently, attention has shifted from larger body parts to the feet to explain mobility impairments in older adults from a biomechanical perspective [28]. This shift was initiated by the emergence of multi-segment kinetic foot models that enabled the assessment of mechanics and energetics within the foot [29]. Until then, the foot had been primarily modelled as a single rigid segment, limiting biomechanical gait studies to include the ankle joint as the most distal joint. Such studies concluded that older adults produce less ankle power than younger adults and, therefore, exhibit a less propulsive gait [30,31]. Based on these studies, ankle power training has been applied in older adults extensively [32]. However, any improvement in power output lacked association with improved gait ability [32]. This has put the role of ankle power deficits in older adults' gait into question. Later studies demonstrated that ankle power was overestimated up to 77% when modelling the foot as a single rigid segment compared to the use of a multi-segment foot model [33]. The belief that reduced ankle power is the primary determinant of impaired propulsion in older adults may therefore be a misconception.

Ignoring the multi-articular motions within the foot [34] – and thus its power generation –, contradicts the unique power profiles identified in distinct foot segments during gait [29,33,35–37]. Indeed, studies have shown that older adults produce less positive foot work (i.e., the time integral of power) and walk with more negative net foot work, while net ankle work remains similar between younger and older adults [28]. The authors of this study also showed that, during push-off, older adults perform net negative foot work as opposed to younger adults performing net positive foot work [28]. This indicates a loss of mechanical energy in the distal foot in older adults, contributing to diminished push-off intensity [28], which is a common target to improve mobility. This phenomenon may have been mediated by reduced foot stiffness, which compromises the leverage to transmit ankle plantar flexor force effectively to the ground at late stance, crucial to move the body forward [38]. Additionally, throughout the whole stance phase, older adults are observed to walk with increased foot pronation [39,40]. This likely increases forefoot flexibility to a larger extent than is required to accommodate to the ground [41]. Inappropriate forefoot flexibility may hinder the foot's function to provide a stable base of support, meaning that balance is compromised. These findings highlight the need for further investigations into contributing factors to the age-related alteration in foot mechanics involved in gait and balance.

The role of the plantar intrinsic foot muscles (PIMs) in age-induced gait and balance impairments

The plantar intrinsic foot muscles (PIMs; i.e., originating and inserting within the foot) appear to be significant contributors to propulsive gait and balance in addition to other foot structures. This emphasizes the need to investigate the role of the PIMs in gait and balance impairments in older adults.

The energetic behavior of the foot has traditionally been linked to passive structures, but over the past decade, attention has shifted towards the PIMs. Two paradigms describe the role of these passive structures – including the long and short plantar ligaments, the spring ligament, and the plantar fascia – in propulsion. The first is the spring-like function of the foot that describes the elastic recoil in late stance, returning energy that is stored in the foot's soft tissues during early and midstance [42]. The second is the windlass mechanism that describes the tensioning of the plantar fascia in late stance when it winds around the extending metatarsophalangeal (MTP) joints [43]. The assumption was that the tensioned plantar fascia raises the foot arch, turning the foot into a rigid lever for effective push-off force transmission. However, later studies (e.g., [44]) disproved the idea that the foot's propulsive function is purely passive. For example, experimental studies [45,46] demonstrated that the windlass mechanism alone could not be responsible for the stiffening of the foot in late stance. In line with this finding, it was additionally shown that the PIMs actively provide stiffness to the foot during push-off through resisting MTP joint extension [47,48]. This likely contributes to greater push-off power generation in the ankle and midfoot [48,49]. Experimental studies also showed that, throughout gait, the energetic behavior of the foot is modulated by the PIMs. For instance, the PIMs activate when the foot is being loaded, indicating their role in storing and regulating energy [50,51]. The PIMs were further found to be active in late stance to contribute to the generation of push-off power [48,50]. The activation of the PIMs may also explain the contribution of the foot to changing energy demands imposed by a change in gait speed [52], stepping up or down [50], or adjusting to compliant surfaces [53]. In addition to these studies focusing on gait, other studies support the role of the PIMs in balance. For example, the PIMs become more active when postural control is increasingly challenged [54,55]. Presumably, this is because the PIMs contribute to postural control by stabilizing the foot [56,57].

This fundamental knowledge concerning the role of the PIMs supports the urge to investigate the contribution of the PIMs to impaired gait, characterized by less propulsive power, and impaired balance in older adults. This is particularly important since it has been observed that the PIMs are weakened in older adults [58]. Previous research most relevant to this topic has focused on the association between toe flexor strength and functional outcomes in older adults. This research showed that toe flexor weakness is able to predict dynamic balance performance [59] and falling [60,61]. However, toe flexor strength results from both the PIMs as well as the extrinsic foot muscles [55]. Furthermore, these studies have a cross-sectional design and thus no conclusions on causality can be

drawn. Therefore, the gap in knowledge about the specific role of the PIMs in gait and balance in older adults still needs to be addressed. Understanding the role of the PIMs in gait and balance could help refine exercise programs to prevent falling.

The trainability of the PIMs

As muscle weakening in older adults is a process that can be slowed down or even reversed [62], an effective way to study the role of the PIMs in gait and balance may be to investigate the effectiveness of PIM strengthening training on gait and balance. This aligns with the recent proposition that strengthening the PIMs would be a promising approach to treating age-related impairments in gait and balance [63]. However, this assumes that PIMs can be trained or evaluated in isolation, which is challenging to achieve.

Strengthening or evaluating the PIMs in isolation is challenged by the complex anatomical arrangement of the PIMs and extrinsic foot muscles located at the plantar aspect of the foot [64]. The assessment of PIM's strength in vivo is limited to the assessment of combined muscle actions, as there is no single muscle solely responsible for the force that is produced to generate motion or to oppose an applied force. Among the 13 plantar foot muscles (9 intrinsic and 4 extrinsic that originate in the lower leg), 8 PIMs insert on the toes, complementing 2 extrinsic toe flexor muscles [65]. Therefore, examination or training foot muscle strength generally includes toe flexion. However, toe flexion is caused by PIMs inserting on the proximal and middle phalanges of the toes and by the extrinsic toe flexor muscles inserting on the distal phalanges of the toes [65]. Some efforts have been made to separate the action from the intrinsic muscles from that of the extrinsic muscles during toe flexion. For example, by putting the ankle in a plantar flexed position [66,67] and the interphalangeal joint in an extended position [68] or by restricting to isometric contraction [68]. Nevertheless, it remains impossible to completely isolate the action of the PIMs when performing toe flexion. Alternatively, foot doming – also known as the 'short-foot exercise' – involves raising the foot arches and relies on the anatomical alignment of the PIMs with the longitudinal and transversal arches of the foot. These arches are considered key structures in foot function [65]. However, even younger participants failed to master this doming movement after two weeks of daily practice [69]. Therefore, doming may be inappropriate too to target or evaluate the PIMs in older adults.

Because targeting the PIMs and evaluating their strength in isolation is challenging, particularly in older adults, measuring PIMs' morphology based on imaging may be a suitable alternative to assess their trainability. Muscle's morphology serves as an estimate of the muscle's capacity to exert force (i.e., force capacity) and enables to indirectly assess PIM's strength in response to training the PIMs [64]. Studies [70–73] have shown excellent reliability for ultrasound imaging to assess PIMs' morphology in younger adults. Subsequent studies [74–76] have used ultrasound imaging to study individual foot muscles in younger adults, showing its applicability. However, the reliability of this instrument to assess PIMs' morphology in older adults has not yet been investigated.

Up till now, intervention studies in older adults that target the feet were aimed to improve toe flexor strength – the combined effort of intrinsic and extrinsic foot muscles – and made no attempts to evaluate PIMs' morphological responses [77–79]. Therefore, it is not yet known whether the PIMs of older adults adapt to training. To conclude on the role of the PIMs in gait and balance through an intervention study, it is necessary to relate potential changes in PIMs' morphology to potential changes in gait and balance. Such an intervention study will not only provide further insight into the trainability of these muscles in older adults, but it will also enable an investigation of the effectiveness of the training on gait and balance, and other fall risk factors, such as concerns about falling. Insight into the trainability of the PIMs in older adults and their role in fall risk factors will guide fall preventive exercise programs to include exercises that aim to strengthen the PIMs.

Main project aim and hypotheses

The general aim of this doctoral project is to improve fall prevention by gaining insight into the trainability of the PIMs and their role in gait and balance in older adults. We hypothesize that training the PIMs in older adults will increase their force capacity and, concomitantly, improve gait and balance.

Methodological approach

The main research aim of this project is addressed by a final intervention study investigating the effect of a PIM strengthening program on PIM's force capacity and gait and balance. This intervention study needs several studies in advance to substantiate the design choices of the intervention study. Therefore, the methodological approach of this project consists of a chronological sequence of studies, each with its own methodology and purpose. The final intervention is evaluated by mixed methods.

Ultrasonography using a tablet-based device is deemed the most suitable instrument to evaluate the trainability of the PIMs. The reliability of ultrasonography in assessing PIMs' morphology, as a measure of their force-generating capacity, is convincing in younger adults using a main frame machine. However, its reliability using a tablet-based machine in older adults is not yet clear. Therefore, **study 1 aimed to assess the intra-assessor reliability and measurement error of ultrasound measures for the morphology of selected foot muscles in older adults using a tablet-based ultrasound machine (Chapter 2)**.

The rationale for investigating a PIM strengthening program in older adults may be informed by the current state of the art regarding PIM strengthening interventions. Several studies investigated the effect of PIM strengthening interventions in younger adults on outcomes that relate to gait and balance impairments as observed in older adults [74,80,81]. These studies may contribute to the understanding of the potential of PIM strengthening training to improve gait and balance in older adults. However, the evidence for this is not yet systematically synthesized. Therefore, **study 2 aimed to**

provide evidence for the effect of interventions anticipated to improve plantar intrinsic foot muscle strength on fall-related dynamic function in adults with a systematic literature review (Chapter 3).

Different modes of exercise may be used to target the PIMs. Exercises targeting the PIMs, as applied in previous research, typically involve isolated contractions of the PIMs. The voluntary contraction of the PIMs required for these exercises appeared to be difficult for older adults [82]. Therefore, these exercises may not be appropriate for this population. Isolated exercises also contrast with exercises typically included in effective fall prevention programs, which are functional in nature. Functional exercises exist that are anticipated to rely on the PIMs. In order to know the potential of functional exercises to activate the PIMs, **study 3 aimed to compare the mean muscle activation of PIMs between functional and isolated foot exercises in an experimental study (Chapter 4)**.

To investigate the trainability of the PIMs and their role in gait and balance in older adults – the central aim of the project – a randomized controlled trial (RCT) is used. This research design is the most rigorous way of determining the existence of a cause-effect relation between strengthening the PIMs and gait and balance [83]. Although there is rational to believe that strengthening the PIMs may improve gait and balance in older adults, studies are lacking that investigate the effectiveness of such interventions in older adults. The effectiveness of interventions to improve gait and balance is typically examined with gait speed as the outcome measure as this reflects both qualities at the same time. Therefore, **study 4 (study protocol) and 5 aimed to evaluate the effects of a 12-week intrinsic foot muscle strengthening training (STIFF: STrengthening the Intrinsic Foot Flexor muscles) on gait in older adults using an RCT (Chapter 5 and 6)**. By additionally evaluating PIMs' morphology and other fall risk factors (e.g., concerns about falling), this study enabled us to investigate the trainability of the PIMs and to infer on the intervention's contribution to fall risk.

The effectiveness of strengthening the PIMs depends on adherence to the prescribed training. Therefore, it is important to understand how adherence to the training was influenced. In addition, the trainability of the PIMs also relies on the capability to perform the exercises. As training the PIMs involves aspects that differ from those of physical exercises in general – for which adherence is well understood – **study 6 aimed to qualitatively explore older adults' perspective on and experiences with participating in the 12-week intrinsic foot muscle strengthening training (Chapter 7)**.

Outline of the thesis

This thesis comprises eight chapters, of which Chapter 1 is this General Introduction. Chapter 2 through 7 present the scientific studies conducted between March 2019 and December 2024. Chapters 2 to 5 have been published in peer-reviewed scientific journals, while Chapters 6 and 7 have been submitted for publication and are currently under review. The content of these chapters corresponds to the versions as published or submitted. Chapter 8 provides the General Discussion in which we reflect on the extent to which the results confirm the main hypotheses. Additionally, we discuss the findings in relation to existing literature and elaborate on their implications for practice and future research.

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Intra-assessor reliability and measurement error of ultrasound measures for foot muscle morphology in older adults using a tablet-based ultrasound machine (Study 1)

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ABSTRACT

Background: To gain insight into the role of plantar intrinsic foot muscles in fall-related gait parameters in older adults, it is fundamental to assess foot muscles separately. Ultrasonography is considered a promising instrument to quantify the strength capacity of individual muscles by assessing their morphology. The main goal of this study was to investigate the intra-assessor reliability and measurement error for ultrasound measures for the morphology of selected foot muscles and the plantar fascia in older adults using a tablet-based device. The secondary aim was to compare the measurement error between older and younger adults and between two different ultrasound machines.

Methods: Ultrasound images of selected foot muscles and the plantar fascia were collected in younger and older adults by a single operator, intensively trained in scanning the foot muscles, on two occasions, 1-8 days apart, using a tablet-based and a mainframe system. The intra-assessor reliability and standard error of measurement for the cross-sectional area and/or thickness were assessed by analysis of variance. The error variance was statistically compared across age groups and machines.

Results: Eighteen physically active older adults (mean age 73.8 (SD: 4.9) years) and ten younger adults (mean age 21.9 (SD: 1.8) years) participated in the study. In older adults, the standard error of measurement ranged from 2.8% to 11.9%. The ICC ranged from 0.57 to 0.97, but was excellent in most cases. The error variance for six morphology measures was statistically smaller in younger adults, but was small in older adults as well. When different error variances were observed across machines, overall, the tablet-based device showed superior repeatability.

Conclusions: This intra-assessor reliability study showed that a tablet-based ultrasound machine can be reliably used to assess the morphology of selected foot muscles in older adults, with the exception of plantar fascia thickness. Although the measurement errors were sometimes smaller in younger adults, they seem adequate in older adults to detect group mean hypertrophy as a response to training. A tablet-based ultrasound device seems to be a reliable alternative to a mainframe system. This advocates its use when foot muscle morphology in older adults is of interest.

BACKGROUND

Less propulsive gait and diminished balance capabilities, being consequences of the normal ageing process [1,2], are associated with an increased likelihood of falling in older adults [1,3–6]. Plantar intrinsic foot muscles (PIMs) play an important role in these two features of gait, at least when they are unaffected [7–9]. For instance, propulsion is aided by the PIMs by stiffening the foot during the push-off phase of walking, hence contributing to the effective force transmission onto the ground [7]. The PIMs also act to stabilize the foot arch, which is imperative for sound postural balance [8,9].

Concurrent with the PIMs' related mobility decline, a decreased capacity of the PIMs to produce force has been observed in older adults. [10]. In this population, toe flexor weakness is associated with a higher probability of falling [11]. Consequently, toe flexor strengthening is often one of the goals in fall prevention interventions [12]. However, toe flexor strength is the combined result of contraction of intrinsic foot muscles (i.e., origin and insertion in the foot) and extrinsic foot muscles (i.e., origin proximal to ankle joint, insertion in the foot), both having a shared as well as a distinct function [9,13]. It is thus important to distinguish the PIMs as a separate group of foot muscles, as well as to distinguish individual PIMs, in order to gain more insight in the unique role of PIMs in fall-related mobility parameters. These insights may lead to the enhancement of related treatment.

Recently, some studies investigated the role of individual PIMs in foot function [14] or evaluated a PIM strengthening intervention [15], using a measure for toe flexor strength or strength capacity. However, directly assessing the strength of individual foot muscles is unviable in vivo because of the redundant combinations of intrinsic and extrinsic foot muscles' contractions resulting in the same net force [16]. Therefore, measuring flexor strength of plantar foot muscles in units of force is restricted to measuring net toe flexor or toe grip force produced by the PIMs in conjunction with the extrinsic foot muscles [16]. To overcome this limitation, ultrasound has been applied to study individual foot muscles (i.e., both intrinsic and extrinsic) [17–19]. This imaging technique is used to obtain the dimensions of these muscles, as an estimate of its capacity to exert force. The validity of this approach is confirmed by the observation that both the cross-sectional area (CSA) and the thickness of the PIMs correlate well with maximum toe flexor force [10,20–22].

Although magnetic resonance imaging (MRI) is considered the gold standard in the assessment of muscle morphology, ultrasonography is often preferable in both clinical and research settings [23]. In comparison with an MRI machine, an ultrasound machine is more accessible, portable and has superior temporal and spatial resolution when used to image superficial structures [23,24]. The ongoing advancement of pocket-sized ultrasound equipment advocates the utility even more [25]. Despite the eminent tissue differentiating capabilities of MRI [26], ultrasound derived measures for lower extremity muscle morphology correlate well with values obtained by using MRI [26–29]. In contrast

to MRI, ultrasonography enables the operator to capture a muscle's contraction in a cine-loop, which facilitates the post-processing identification of a muscle's circumference [30].

Determining the morphology of specifically the PIMs, as part of the foot muscles, using ultrasound images is, however, challenging. This is due to the complex anatomical architecture of each of these muscles [31] and their non-parallel arrangement over several muscle layers [32]. Nevertheless, in general, studies revealed excellent inter- and intra-operator reliability and acceptable measurement errors for the ultrasound assessment of the thickness and CSA of PIMs in younger adults [21,33–36]. In addition, a study [37] that compared the reliability across machines for one of the PIMs (i.e., abductor hallucis), demonstrated at least good reliability, even when using a laptop-based machine. These findings indicate the potential of ultrasonography to discriminate between individuals and to measure changes over time [38].

However, these measurement properties (i.e., reliability and measurement error) cannot be simply generalized to older adults for two reasons. Most importantly, physiological changes that occur with ageing, such as a higher degree of intramuscular adiposity and connective tissue [39] or increased presence of callus [40], may interfere with image quality and thus may limit the accuracy of muscle morphology measurements [41,42]. Furthermore, the reliability, as expressed in the intra-class correlation coefficient (ICC), is mathematically dependent on the biological variability between subjects [38] and this may differ between younger and older adults. Although ultrasonography has been shown to be a reliable instrument to measure quadriceps and gastrocnemius morphology in older adults [43], this is still unknown for the foot muscles. These muscles, including the PIMs, extrinsic toe flexor muscles, but also extrinsic in- and evertors, should be jointly assessed together with the plantar fascia (PF), considering the synergistic contribution of this group of foot tissues to foot function [17–19]. The reliability of ultrasonography to assess the morphology for these foot muscles and the PF needs to be determined in order to judge the potential of this instrument to be used in future research concerning, for instance, the role of the foot muscles in relation to fall risk-related mobility parameters. For this future purpose, a single operator performing the ultrasound scans is recommended, as this is expected to result in more reliable measures [43].

Therefore, the main goal of this study was to investigate the intra-assessor reliability and measurement error of ultrasound measures for the morphology of selected foot muscles and the PF in older adults using a tablet-based ultrasound machine. In addition, we assessed a younger population using the same ultrasound machine and a mainframe machine to explore factors that could underlie these measurement properties. To investigate the effect of age, we compared the measurement error between older and younger adults using the tablet-based machine. To investigate if improved repeatability in older adults can be expected when changing to a mainframe machine, we compared the measurement error between the tablet-based and the mainframe machine in younger adults.

METHODS

Study design

The design used was a blinded single assessor test–retest reliability study

Ethical considerations

The medical ethical committee of Maxima MC declared that ethical approval was not required for this study protocol (N19.105). Written informed consent was obtained before the start of data collection.

Study population

Recruitment

A sample of 18 older adults was recruited in the region of Eindhoven, The Netherlands, via advertisement in senior housing complexes and by sending a recruitment leaflet per e-mail to the social network of the investigator. Ten younger adults were recruited through personal communication within the University of Applied Sciences, Eindhoven, The Netherlands. Due to a lack of consensus on the required number of participants to achieve reliable measurement properties [38], the sample sizes were based on comparable studies [33,34].

Selection procedure

Individuals were eligible for participation in the older adult group if they were at least 65 years of age, in accordance with the categorization of the World Health Organization [44]. To participate in the younger adult group, volunteers had to be between the ages of 18 and 45 years, as lower extremity muscles start to atrophy after the age of approximately 45 years [45]. Further, volunteers had to be free of any known condition or disease affecting foot muscles and had to be able to ambulate ten meter without using a walking aid in order to represent a mobile population. Volunteers were excluded from study participation if they reported bilateral musculoskeletal injuries or bilateral symptoms distal to the knee (i.e., current musculoskeletal pain or overuse symptoms, orthopedic surgery or acute injury within the past 5 years, amputation) or if mobility or lower extremity motor function was likely to be affected by medical conditions (i.e., neurological condition, systemic disease, cardiovascular or pulmonary disease).

Measurement procedure

The measurement set-up is schematically depicted in Figure 1. In a first period, images of foot muscles and PF were acquired in the older participants using a tablet-based ultrasound machine only. Thereafter, we decided to repeat the protocol in younger adults to explore factors that could underlie the established measurement properties. Approximately one year after the data collection period in older adults, the data were collected in the younger participants using both the tablet-based and a mainframe

ultrasound machine for all measurements. This allowed us to investigate the influence of age on the measurement error and also to see if improved image quality, as expected from the mainframe machine, would reduce the measurement error. The ultrasound images in each participant were collected on two separate measurement occasions, at least one day apart [33], with a maximum of 8 days apart, assuming that foot muscle and PF morphology remains stable within this period. Participants were instructed not to engage in vigorous physical activities in the three days prior to the measurement sessions to avoid exercise-induced swelling of the muscles. The time of day was kept constant over the repeated measurements within participants. The older adults were measured at home. The younger adults were invited to the movement analysis laboratory at Fontys University of Applied Sciences (Eindhoven, the Netherlands).

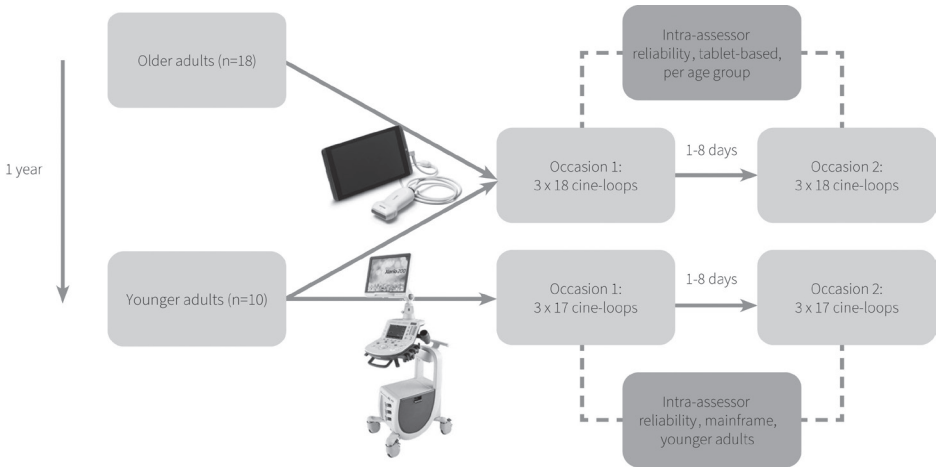

Figure 1: Schematic overview of the study set-up. The dotted lines link the measurement occasions that were selected as the repeated measurements for the reliability analysis.

At the first measurement occasion, demographics and characteristics were collected that are related to foot muscle and PF morphology or its ultrasound measurement reliability. Body length and weight were assessed manually in the older adults (213i and 750, Seca co., Hamburg, Germany) and electronically in the younger adults (DS-103, Dong Sahn Jenix co., Seoul, Korea). The participants were also asked about their physical activity behavior.

The ultrasound scans were performed by the investigator (LW), having a master degree in human movement sciences and several years of experience in teaching foot and ankle anatomy to podiatry students. She underwent a 10-month training program in imaging the foot muscles and PF prior to the study, without having previous experience in ultrasound imaging. The training started with three technical lectures and an individual training session from a formal ultrasound teacher specialized in musculoskeletal ultrasound. Throughout the training period, a few instructional sessions were supervised

by either a physiotherapist experienced in clinical musculoskeletal ultrasonography or by a researcher experienced in imaging the foot muscles. The remainder of the training consisted of unsupervised sessions in which the proposed scan protocol [33,34] was practiced on younger adult volunteers alternated by interpreting the ultrasound images using an interactive anatomy atlas of MRI images, cadaveric videos and schematic illustrations. After the training, a pilot study in younger adults revealed intra-assessor ICC and limits of agreement (LoA) values that were overall comparable to the ones found in a previous study with an experienced operator [33]. This was considered sufficient to start the data collection. Additionally, the collected data in the current study were examined for any inevitable ongoing improvement in the operator's skills, which is explained in more detail in the statistical analysis paragraph below.

In the older and younger participants, the foot tissues were imaged using a tablet-based ultrasound system (Lumify, Philips Ultrasound, Inc., Bothell, USA) consisting of a 4-12 MHz broadband linear array transducer with a footprint length of 34 mm, the Lumify app and a Samsung Galaxy S4 tablet (Samsung Electronics co., Suwon, South Korea). Because of practical feasibility reasons, the scan protocol was repeated only in the younger participants using a mainframe system (Xario 200g, Canon, Tochigi, Japan) with a 5-14 MHz linear array transducer (PLU-1005BT, Toshiba, Tochigi, Japan) with a footprint length of 58 mm. The order of the systems used was randomly chosen for each measurement occasion.

The dominant stance limb, decided by asking the participant to stand on one leg, or the asymptomatic limb, in case of unilateral symptoms, was scanned. Foot structures that were imaged consisted of intrinsic foot muscles (i.e., abductor hallucis (AbH), flexor digitorum brevis (FDB), quadratus plantae (QP), flexor hallucis brevis (FHB), abductor digiti minimi (AbDM)) and extrinsic foot muscles (i.e., tibialis anterior (TA), peroneus longus together with the peroneus brevis (PER), flexor digitorum longus (FDL), flexor hallucis longus (FHL)) and PF. TA, PER, FDL and AbH were imaged while the participants were in a supine position, their knee slightly bent and their distal thigh resting on a cushion, preventing compression of the lower leg muscles. To image FHL, FDB, QP, FHB, AbDM and PF, the participants lay in a prone position, their foot hanging freely off the plinth and their distal shank resting on a cushion. Using anatomical landmarks, washable lines were drawn on the skin to guide the placement of the transducer. The scan protocol was adopted from previous studies [33,34]. Based on our own pilot testing, we decided to image FHL slightly proximal to the ankle joint and TA at 25% of lower leg length. Figure 2 illustrates the transducer position and Supplementary Material 2A provides a detailed scan protocol. Considering their shape, we decided to image all muscles, except for the FDL, and the PF in the longitudinal plane and selected muscles (TA, PER, AbH, FHL, FDB, QP, FDL) additionally in the transverse plane. Imaging QP in the transverse plane was omitted in the protocol for younger adults, because of the indefinite appearance of QP in the transverse images. This was most probably due to the non-parallel orientation of QP and its surroundings and was not expected to be an effect of age.

A generous amount of water-based coupling gel was applied between transducer and skin to obtain a clear image while avoiding compression of the tissue of interest. The probe was held perpendicular to the tissue border to achieve optimal appearance of the tissues of interest. The depth, focal point and gain were adjusted for each participant and each tissue to optimize image quality. In case of difficulties with identifying individual muscles and whenever possible, participants were asked to perform a specific movement to provoke a contraction that assisted the offline identification of the muscle's border at the time of processing [46]. The contraction as well as the relaxed state of the muscle was captured in the same cine-loop of up to 5 seconds duration. Once the cine-loops were acquired for each muscle and the PF, the protocol was repeated twice resulting in three trials for each morphology measure. To minimize the discomfort for the participant of lying still, an efficient workflow was accomplished by fixing the order of tissues to be imaged. However, to avoid systematic interference (e.g., due to fatigue or familiarization) with the ultrasound measures, the starting position of the participant (i.e. supine or prone) was randomly chosen for each measurement occasion.

At the end of the session, the drawn scanning lines were removed from the skin. The captured videos were stored offline for the post-processing measurements. The whole procedure was repeated at the second measurement occasion, 1-8 days later.

Data processing

The assessor who performed the post-processing to determine the morphology of the foot muscles and the PF was the same person who acquired the images (LW). Cine-loops were post-processed per trial per participant several days to several weeks after the images were collected. To avoid recall bias, no more than one trial per participant was processed per day, followed by at least two trials of other participants. This ensured that no less than 34 other values were assigned before another trial of the same participant was administered. Muscle dimensions obtained in previous trials were not presented to the assessor to further minimize the risk of recall bias.

Image J software (National Institute for Health, Bethesda, MD, USA) was used for the offline processing of data. Within the cine loop, the best quality frame was selected in which the muscle was in a relaxed state. To measure the thickness of the muscles and the PF, the built-in digital caliper was applied on all longitudinal images and the transverse images of TA, PER and FHL. The thickness of a muscle was represented by the vertical distance between the muscle's epimysium, while the thickness of the PF was determined by the perpendicular distance between the deeper and superficial fascia borders. The CSA of FDL, AbH, FDB and QP was measured by delineating all intramuscular tissue using the polygon or freehand tool. Care was taken not to include hyperechoic surroundings of the muscles (e.g., epimysium or fascia) in the measurements for muscle morphology. The mean of three measurements (i.e., trials) for each morphology measure per occasion was administered as the final measure for further analysis.

Statistical analysis

SPSS 25.0 (IBM, Chicago, IL, USA) was used for statistical analysis. The study populations' characteristics were specified by describing gender, age, body length, body weight, BMI, daily time spent on their feet and whether or not the global recommendations on physical activity for health were met [44]. Measurement characteristics included whether the dominant stance leg was measured, actual number of days between the measurement occasions and the difference in time of day between the measurement occasions.

ICC (3,1; absolute agreement) for a single measurement was estimated by intra-assessor reliability analysis of the repeated ultrasound measurements (occasions) based on a 2-way mixed-effects model. Cut-off values were used to interpret the ICC as a measure for reliability (i.e., < 0.50: 'poor', 0.50-0.75: 'moderate', 0.75-0.90: 'good' and > 0.90: 'excellent') [47]. The standard error of measurement (SEM) and smallest detectable change (SDC) were calculated using the error variance, estimated using a 2-way mixed-effects model via the restricted maximum likelihood approach, according to the formulae:

$$SEM_{agreement} = \sqrt{{\sigma_{so,e}}^2} \quad (1)$$

$$SDC_{agreement} = 1.96 \times \sqrt{2} \times SEM_{agreement} \quad (2)$$

where ${\sigma_{so,e}}^2$ is the error variance consisting of variance due to both systematic and random error.

All measurement properties (i.e., ICC, SEM, and SDC) were calculated separately for 1) older and 2) younger adults using the tablet-based machine and 3) for younger adults using the mainframe machine (Figure 1). 'Occasion' was the only component that was varied across the repeated measurements.

In order to explore a possible learning curve, the older adults were divided over three sets of participants based on the chronological order of the first ultrasound measurement occasion [48]. The SEM for each morphology measure was calculated for each set of participants. When the SEM dropped with more than 50% from the one set to the next set of participants, without showing a previous increase, it was decided that the operator was still learning. The measurement properties (i.e., ICC, SEM, SDC), for the morphology measure(s) where this applied to, were then determined with the exclusion of the respective set(s) of participants.

Statistically (α=0.05), 1) the SEMs for the tablet-based ultrasound measurements were compared between the older and younger adults and 2) the SEMs in the younger adults were compared between the tablet-based and the mainframe machine by applying the 'variance ratio approach' and the 'paired approach', respectively [49].

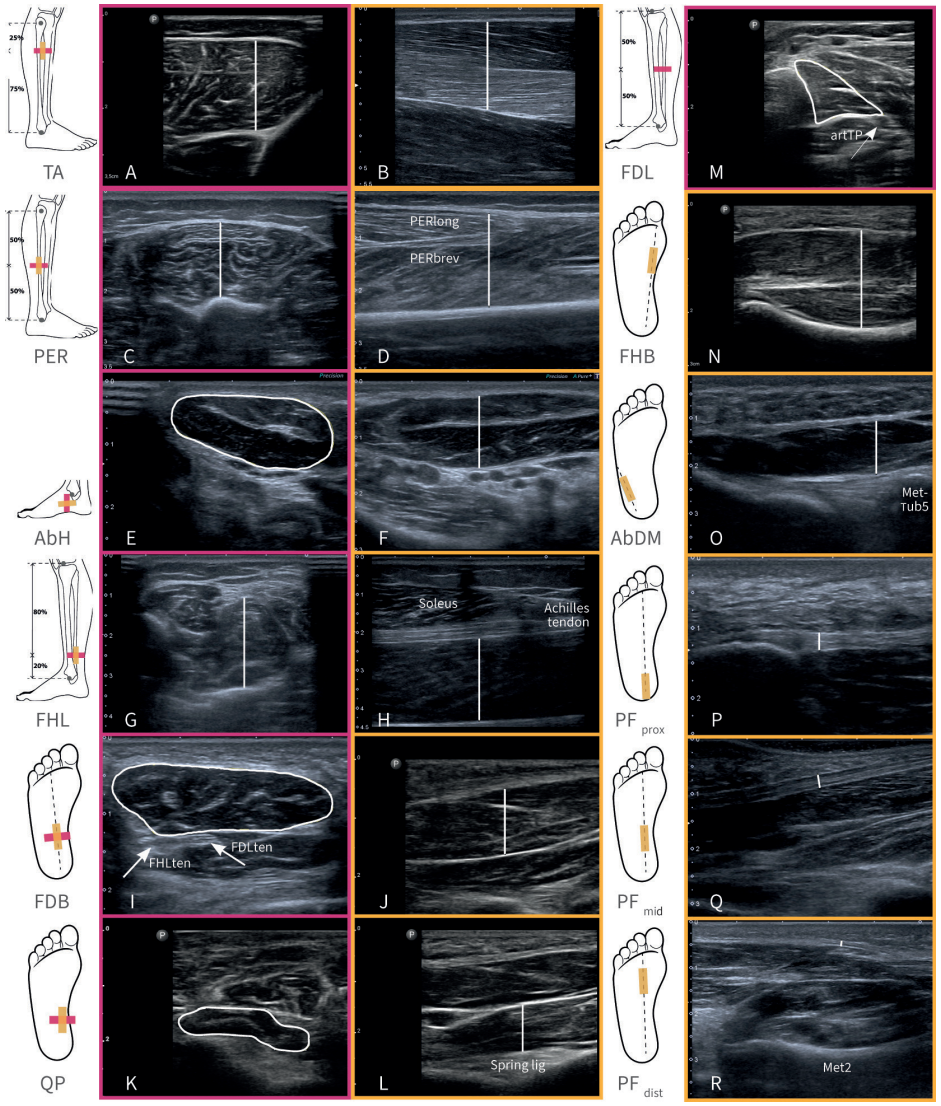

Figure 2. Probe position and representative ultrasound appearance for transverse (pink) and longitudinal (orange) images of the foot muscles and plantar fascia. Ultrasound images shown are obtained with both the tablet-based (A, J-N) and the mainframe machine (B-I, O-R). TA: m. tibialis anterior, PER: m. peroneus brevis (brev) + longus (long), AbH: m. abductor hallucis, FHL: m. flexor hallucis longus, FDB: m. flexor digitorum brevis, QP: m. quadratus plantae, FDL: m. flexor digitorum longus, FHB: m. flexor hallucis brevis, AbDM: m. abductor digiti minimi, PF: plantar fascia, ten: tendon, lig: ligament, art: artery, MetTub5: 5th metatarsal tuberosity, Met2: 2nd metatarsal bone.

RESULTS

Table 1 shows the characteristics for the study populations and the measurements. Eighteen older adults with a mean age of 73.8 (SD: 4.9) years, and ten younger adults with a mean age of 21.9 (SD: 1.8) years participated in the study. The older adults had a higher body weight and BMI compared to the younger adults (mean body weight: 75.9 (SD: 13.5) kg vs. 63.8 (SD: 10.9) kg, $p< 0.05$; mean BMI: 26.3 (SD: 3.2) kg/m^2 vs. 21.4 (SD: 2.5) kg/m^2, $p< 0.05$). Other participant characteristics were not statistically different between the age groups, nor were the measurement characteristics.

Table 1: Participant and measurement characteristics for the older and younger group of participants.

	Older (n=18)	**Younger (n=10)**
Gender		
Male	8 (44%)	4 (40%)
Female	10 (56%)	6 (60%)
Age in years [a]	73.8 (4.9)*	21.9 (1.8)
Body length in cm [a]	169 (11)	172 (7)
Body weight in kg [a]	75.9 (13.5)*	63.8 (10.9)
BMI in kg/m^2 [a]	26.3 (3.2)*	21.4 (2.5)
Daily time spent on feet		
< 1 hour	-	-
1-4 hours	9 (50%)	2 (20%)
4-8 hours	6 (33%)	7 (70%)
≥ 8 hours	3 (17%)	1 (10%)
Physical activity behavior as recommended	16 (89%)	7 (70%)
Dominant side measured	17 (94%)	9 (90%)
Number of days between measurement occasions [b]	6 (1-8)	6 (1-7)
Difference in time of day between measurement occasions (hours) [b]	0.5 (0-4.0)	1.0 (0-1.8)

[a] presented in mean (SD), [b] presented in median (range), * statistical difference between age groups: $p < 0.05$

The learning curves (Supplementary Material 2B), revealed that the SEM of the second set of older adults (n=6) was less than half the SEM of the first set of older adults (n=6) for the CSA of FDB, thickness of QP, AbDM, PF_{prox}, PF_{dist}, and FHL_{long}, whereas the SEM was stable (i.e., the learning curve flattened) between the second and the third set of participants. Therefore, for these morphology measures, the data of the first set of older adults was omitted from the reliability analysis. This resulted in the final SEM to be 18 to

50 % lower compared to when no data was omitted (Supplementary Material 2C). The SEM remained within the critical limits over the three sets of participants for all other morphology measures. Therefore, for these remaining morphology measures, the data of all participants were included in the analysis. The first set of participants (n=6) from which data was omitted was not statistically different from the remaining participants (n=12) on the demographics. The groups' mean morphology measures for each of the two occasions are listed in Table 2.

Table 3 and Figure 3A-C show the intra-assessor measurement properties (i.e., ICC, SEM and SDC) for each muscle and morphology measure (e.g., CSA and thickness). The exact p-values for the comparison of the error variances, are listed in Supplementary Material 2C. The raw data on which the measurement properties are based are graphically presented in Supplementary Material 2D.

Table 3 demonstrates that, in older adults, the ICC of intrinsic foot muscle and PF morphology measures ranged from 0.57 (PF_{dist}) to 0.96 (CSA AbH and FDB). In the older adult group, the SEM did not exceed an absolute value of 1.0 mm for the thickness of any of the foot muscles or the PF. Relative to the average tissue size, in older adults, the SEM was smallest for the thickness of FHL (2.8 and 3.2%) and TA (3.2 and 3.9%) and largest for the CSA of FDL (11.9%), followed by the CSA of QP (9.7%). Considering only the thickness measures in the older adult group, the largest relative SEM was found for PF_{mid} (7.7%) and PF_{dist} (8.0%). When the relative SEM in older adults was compared between the two morphology measures for the same muscle, smaller values were observed for the CSA of both the AbH and FDB (AbH: 5.0 % vs. 7.0%; FDB: 5.7% vs. 6.3%).

Comparing the age groups (Table 3, Figure 3A-C), it was shown that the SEM was significantly greater in older adults for the thickness of AbH, CSA of FDB, PF_{prox}, PF_{mid} and FHL_{long}. The corresponding relative SEM ranged from 3.2% (FHL_{long}) to 7.7% (PF_{mid}) in older adults versus 1.4% (FHL_{long}) to 5.8% (PF_{mid}) in younger adults. In contrast, the thickness of TA_{trans} was measured with a significantly smaller measurement error and more reliably in older adults compared to younger adults (SEM: 0.8 mm (3.2%) vs. 1.3 mm (5.9%), ICC: 0.94 vs. 0.67).

The comparison between the two ultrasound machines (Table 3, Figure 3A-C) revealed a statistically larger SEM for the thickness of AbH and PER_{long} when the mainframe machine was used compared to when the tablet-based machine was used (AbH: 0.4 mm (3.7%) vs. 0.2 mm (1.6%); PER_{long}: 1.0 mm (7.2%) vs. 0.7 mm (5.0%)). For PF_{dist}, a significantly smaller SEM was achieved when the images were obtained with the mainframe machine (0.06 mm (5.0%) vs 0.13 mm (11.0%)).

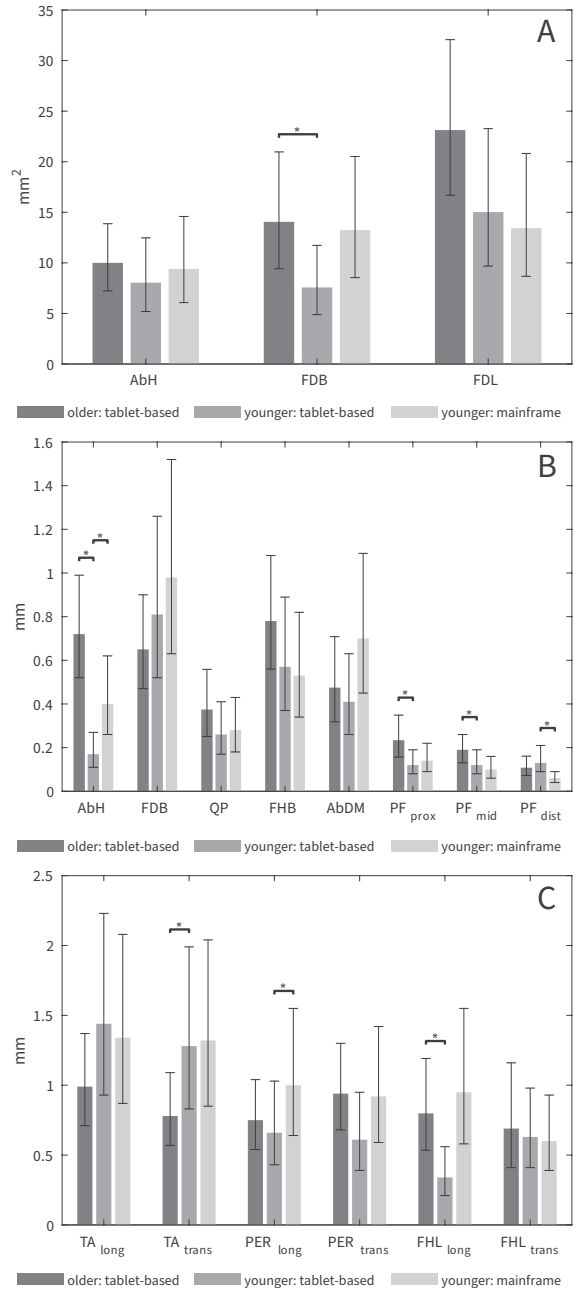

Figure 3A-C: Standard error of measurement (SEM) for cross-sectional area (2A) and thickness of intrinsic foot muscles and plantar fascia (2B) and extrinsic foot muscles (2C). * indicates a significant difference (P<0.05) across age groups and ultrasound machines. AbH: m. abductor hallucis, FDB: m. flexor digitorum brevis, FDL: m. flexor digitorum longus, QP: m. quadratus plantae, FHB: m. flexor hallucis brevis, AbDM: m. abductor digiti minimi, PF: plantar fascia, prox: proximal, mid: middle, dist: distal, TA: m. tibialis anterior, long: longitudinal, trans: transverse, PER: m. peroneus, FHL: m. flexor hallucis longus.

Table 2: Descriptive statistics for the repeated measurements for ultrasound morphology of selected foot muscles and plantar fascia.

		Older					Younger					
		Tablet-based					Tablet-based			Mainframe		
		n	Occ 1		Occ 2		n	Occ 1	Occ 2	n	Occ 1	Occ 2
			Mean	SD	Mean	SD		Mean SD	Mean SD		Mean SD	Mean SD
AbH	CSA	18	198	(52)	201	(50)	10	194 (65)	189 (65)	10	192 (65)	191 (71)
	Th	18	10.3	(2.0)	10.3	(2.0)	10	10.9 (2.3)	10.8 (2.4)	10	10.9 (2.3)	10.6 (2.2)
FDB	CSA	12	248.5	(66.1)	247.8	(80.1)	10	211 (50)	209 (51)	10	210 (56)	209 (52)
	Th	18	10.4	(2.0)	10.2	(2.2)	10	10.9 (2.5)	10.4 (1.9)	10	11.0 (2.6)	10.4 (2.0)
QP	CSA	18	176	(35)	177	(34)	0	- -	- -	0	- -	- -
	Th	12	8.8	(1.3)	9.1	(1.4)	10	10.0 (1.0)	9.8 (1.1)	10	9.9 (1.0)	9.9 (1.0)
FHB	Th	18	13.6	(1.7)	13.7	(1.6)	10	14.4 (2.3)	14.1 (1.9)	10*	14.9 (2.1)	15.3 (1.7)
AbDM	Th	12	8.9	(1.4)	9.4	(1.5)	10	11.1 (1.8)	11.1 (2.2)	10	11.0 (2.1)	11.3 (2.1)
PF_{prox}	Th	12	3.9	(0.8)	4.0	(1.0)	10	3.5 (0.6)	3.5 (0.7)	10*	3.3 (0.6)	3.2 (0.7)
PF_{mid}	Th	18	2.3	(0.4)	2.4	(0.3)	10	2.1 (0.4)	2.2 (0.3)	10*	2.1 (0.4)	2.0 (0.4)
PF_{dist}	Th	12	1.3	(0.2)	1.4	(0.2)	10	1.2 (0.2)	1.2 (0.2)	10	1.2 (0.2)	1.1 (0.2)
TA_{long}	Th	18	25.2	(3.6)	25.3	(3.2)	10	22.4 (3.0)	22.7 (1.6)	10	22.6 (2.9)	22 (1.7)
TA_{trans}	Th	18	24.4	(3.2)	24.6	(3.2)	10	22.0 (2.9)	21.8 (1.2)	10	22.4 (2.7)	21.7 (1.4)
FDL	CSA	18	191	(47)	197	(55)	10	154 (64)	138 (58)	10	146 (60)	142 (60)
PER_{long}	Th	18	14.1	(2.2)	14.5	(2.1)	10	13.6 (1.9)	13.2 (2.3)	10	14.3 (2.2)	13.6 (2.7)
PER_{trans}	Th	18	13.4	(2.3)	14.2	(2.2)	10	13.9 (2.0)	13.5 (2.6)	10	13.6 (2.3)	13.1 (2.8)
FHL_{long}	Th	12	25.1	(3.5)	25.3	(3.1)	8	24.4 (2.6)	24.2 (2.6)	8	23.8 (3.6)	24.6 (3.4)
FHL_{trans}	Th	7	24.8	(4.5)	24.8	(4.1)	10	22.7 (3.5)	22.4 (3.2)	10	22.7 (3.8)	22.5 (4.0)

Occ: occasion, CSA: cross-sectional area, th: thickness, AbH: m. abductor hallucis, FDB: m. flexor digitorum brevis, QP: m. quadratus plantae, FHB: m. flexor hallucis brevis, AbDM: m. abductor digiti minimi, PF: plantar fascia, prox: proximal, mid: middle, dist: distal, TA: m. tibialis anterior, long: longitudinal, trans: transverse, FDL: m. flexor digitorum longus, PER: m. musculus peroneus, FHL: m. flexor hallucis longus. Values are presented in mm (thickness) and mm2 (cross-sectional area). * indicates a statistical difference across machines: $p < 0.05$

Table 3: Intra-assessor measurement properties for ultrasound morphology of selected foot muscles and plantar fascia.

		Older								Younger													
		Tablet-based								Tablet-based								Mainframe					
		n	ICC	CI -	CI +	SEM	%SEM	SDC	%SDC	n	ICC	CI -	CI +	SEM	%SEM	SDC	%SDC	n	ICC	CI -	CI +	SEM	%SEM	SDC	%SDC
AbH	CSA	18	0.96	0.90	0.99	10	5.0	28	13.9	10	0.98	0.93	1.00	8	4.2	22	11.6	10	0.98	0.93	1.00	9	4.9	26	13.6
	Th	18	0.87	0.68	0.95	0.7*	7.0	2.0	19.3	10	0.99	0.98	1.00	0.2	1.6	0.5	4.5	10	0.97	0.84	0.99	0.4*	3.7	1.1	10.3
FDB	CSA	12	0.96	0.88	0.99	14*	5.7	39	15.7	10	0.98	0.91	0.99	8	3.6	21	10.0	10	0.94	0.77	0.99	13	6.3	37	17.6
	Th	18	0.91	0.77	0.96	0.7	6.3	1.8	17.4	10	0.87	0.58	0.97	0.8	7.6	2.3	21.0	10	0.82	0.47	0.95	1.0	9.2	2.7	25.4
QP	CSA	18[a]	0.75	0.44	0.90	17	9.7	47	26.8	0	-			-	-	-	-	0	-			-	-	-	-
	Th	12	0.92	0.70	0.98	0.4	4.2	1.0	11.6	10	0.93	0.77	0.98	0.3	2.6	0.7	7.3	10	0.93	0.73	0.98	0.3	2.8	0.8	7.8
FHB	Th	18	0.78	0.50	0.91	0.8	5.7	2.2	15.7	10	0.93	0.75	0.98	0.6	4.0	1.6	11.2	10	0.93	0.74	0.98	0.5	3.5	1.5	9.7
AbDM	Th	12	0.89	0.41	0.97	0.5	5.2	1.3	14.3	10[a]	0.96	0.85	0.99	0.4	3.7	1.1	10.2	10[a]	0.89	0.64	0.97	0.7	6.3	2.0	17.4
PF_{prox}	Th	12[b]	0.94	0.80	0.98	0.23*	6.0	0.65	16.5	10	0.96	0.87	0.99	0.12	3.5	0.34	9.6	10	0.95	0.80	0.99	0.14	4.3	0.40	12.0
PF_{mid}	Th	18	0.70	0.35	0.88	0.19*	7.7	0.51	21.4	10	0.88	0.60	0.97	0.12	5.8	0.34	16.0	10	0.93	0.75	0.98	0.10	4.8	0.28	13.2
PF_{dist}	Th	12	0.57	0.06	0.85	0.11	8.0	0.30	22.2	10	0.44	-0.18	0.82	0.13	11.0	0.37	30.6	10	0.89	0.65	0.97	0.06*	5.0	0.15	13.9
TA_{long}	Th	18[a]	0.92	0.79	0.97	1.0	3.9	2.7	10.8	10	0.62	0.02	0.89	1.4	6.4	4.0	17.7	10	0.68	0.17	0.91	1.3	6.0	3.7	16.7
TA_{trans}	Th	18	0.94	0.85	0.98	0.8*	3.2	2.2	8.9	10	0.67	0.08	0.91	1.3	5.9	3.6	16.2	10	0.63	0.09	0.89	1.3	6.0	3.7	16.6
FDL	CSA	18	0.79	0.53	0.92	23	11.9	64	33.1	10	0.94	0.39	0.99	15	10.3	42	28.5	10	0.95	0.82	0.99	13	9.3	37	25.9
PER_{long}	Th	18	0.88	0.69	0.95	0.8	5.3	2.1	14.6	10	0.90	0.67	0.97	0.7	5.0	1.8	13.7	10	0.84	0.49	0.96	1.0*	7.2	2.8	19.9
PER_{trans}	Th	18	0.84	0.43	0.95	0.9	6.8	2.6	18.9	10	0.93	0.76	0.98	0.6	4.5	1.7	12.4	10	0.87	0.59	0.97	0.9	6.9	2.6	19.0
FHL_{long}	Th	12	0.94	0.81	0.98	0.8*	3.2	2.2	8.8	8	0.98	0.92	1.00	0.3	1.4	1.0	3.9	8	0.93	0.61	0.99	1.0	3.9	2.6	10.8
FHL_{trans}	Th	7	0.97	0.86	1.00	0.7	2.8	1.9	7.7	10	0.96	0.87	0.99	0.6	2.8	1.8	7.7	10	0.98	0.91	0.99	0.6	2.7	1.7	7.3

ICC: intra-class correlation coefficient, CI- and CI+: lower and upper limit of the 95% confidence interval, SEM: standard error of measurement, SDC: smallest detectable change, CSA: cross-sectional area, th: thickness, AbH: m. abductor hallucis, FDB: m. flexor digitorum brevis, QP: m. quadratus plantae, FHB: m. flexor hallucis brevis, AbDM: m. abductor digiti minimi, PF: plantar fascia, prox: proximal, mid: middle, dist: distal, TA: m. tibialis anterior, long: longitudinal, trans: transverse, FDL: m. flexor digitorum longus, PER: m. musculus peroneus longus + brevis, FHL: m. flexor hallucis longus. The units of measurement for the SEM and SDC are mm (thickness), mm^2 (CSA), or a percentage of the group mean muscle size (%SEM and %SDC). [a] indicates a non-normal distribution for the difference between the repeated measurements. [b] indicates the presence of heteroscedasticity. * indicates a significant difference ($P<0.05$) between age groups or ultrasound machines.

DISCUSSION

In this study, we assessed the intra-assessor reliability and measurement error for the morphology of selected foot muscles and PF derived from ultrasound images collected by a single operator using a tablet-based machine in older adults. We also compared the measurement error with that obtained in younger adults and examined the influence of the ultrasound machine that was used. The results showed that the morphology of most of the assessed muscles can be reliably assessed with acceptable measurement error in older adults when using a tablet-based device, although measurement errors were smaller for some muscles in younger adults. In general, using a mainframe machine did not improve the repeatability in younger adults. In fact, when the repeatability differed between the machines, the repeatability of muscle morphology measures was superior for the tablet-based machine.

The morphology of foot muscles could be assessed in older adults with an error ranging from 2.8% to 11.9%, equating to an SDC of 7.7% to 33.1%. When omitting the CSA of FDL, which showed an exceptionally large error, and selecting the most accurate morphology measure (i.e., CSA or thickness) for each muscle, the SDC was 15.7 % at its greatest extent in the older adult group using the table-based device. This means that, on an individual level, a change in foot muscle size beyond 15.7 % can be considered a real change [38]. In order to be a meaningful metric to measure a group mean change in muscle morphology, for example in a prospective intervention study, this change should exceed the SDC divided by the square root of the sample size [50]. A group change of this magnitude is realistic as an 8-week foot strengthening intervention in younger adults showed average foot muscle hypertrophy ranging from 5 to 15% [17] and, in general, older adults are expected to have a similar response to strength training [51]. Whether the morphological changes of foot muscles as a response to training in older adults indeed exceed the SDCs, needs to be investigated in future studies. Our range of SDCs corroborates well with the limits of agreement (LoA), a metric comparable with the SDC [52], reported by previous studies where the same muscles were examined in younger populations by operators with 8 years of ultrasound experience using more advanced machines [33,36]. Next to the measurement errors, the reliability of the muscle morphology measures in older adults was predominantly ‘excellent’ and at least ‘good’ (ICC: 0.75 to 0.96). This signifies that

overall the measurement error is small enough relative to the between-subject variance [38], enabling us to differentiate between older individuals.

Considering direct measures for toe flexor strength, previous research [21] revealed poorer reliability for toe flexor strength measures compared to ultrasound morphology (i.e., an indirect strength measure). In addition, a study in older adults [53] indicated a larger measurement error for toe flexor strength measurements than reported in the current study for foot muscle morphology. Together with the favorable ability of ultrasound to assess individual muscles, and although being an indirect strength measure, this supports its use to study the role of foot muscles in the older adult population. Future studies can use this methodology to investigate the effect of a foot strengthening program on foot muscle morphology in older adults. The latter also meets the requirement for a prospective study to approve the responsiveness of ultrasound to detect foot muscle hypertrophy in older adults.

For AbH and FDB, the cross-sectional area was measured with a slightly smaller error when compared to the thickness of the same muscle in older adults. The human error is assumed to affect the straightforward linear distance between the deeper and superficial epimysium (i.e., thickness) to a lesser degree than the demarcation of a muscle’s outline (i.e., CSA) [37]. Apparently, this advantage did not outweigh the larger image capturing variability associated with longitudinal imaging of these muscles with an oval-like cross-section. The superior repeatability for the CSA of AbH and FDB is auspicious as a two-dimensional quantity is better able to cover a non-uniform change in muscle morphology that may occur in response to exercise or muscle disuse [28]. The SDC for AbH’s CSA in the current study was substantially smaller than what was found using MRI (28 vs. 46.1 mm^2) and comparable for CSA of FDB (39 vs. 36.4 mm^2) [54]. The ability to accurately measure CSA of AbH and FDB in older adults is further promising as AbH and FDB are, together with QP, the intrinsic foot muscles most closely aligned with the medial longitudinal arch of the foot. Hence, these are key structures in the investigation of foot function [55,56].

In contrast to FDB and AbH, QP is a deeper located muscle and is, therefore, less accessible by ultrasound [57]. Indeed, the results show that QP’s CSA was measured with only small precision in older adults, the SDC being 26.8%. This SDC is three times worse than shown in a previous study in younger adults [33]. Apart from the contrasting study populations, the studies differ substantially at the level of experience of the operators (i.e., 10 months vs. 8 years) and the ultrasound machines used (tablet-based vs. mainframe). The post-processing delineating of the QP’s fascial borders, was experienced as extremely difficult by the researcher of the current study. Partially, this was due to the oblique orientation of the tissues adjacent to the medial aspect of the QP (e.g., plantar nerves, FDL tendon). This causes the ultrasound beam to reflect away from these tissues [57], resulting in an isoechoic appearance of QP and its surroundings. Together with the poor lateral resolution at this depth, this may have led to inaccuracy in the definition of the

muscle's envelope. In contrast to the SEM for the CSA, the SEM for the thickness of QP was reasonably low and presents, therefore, a better alternative to quantify the morphology of QP for operators with similar experience.

Three muscle morphology measures (CSA: FDB; thickness: AbH, FHL_{long}) showed superior repeatability in younger adults compared to older adults. This may be caused by an age-related decline in muscle quality, such as a higher degree of intramuscular adipose tissue [39], which indeed has been observed in the PIMs [58]. As a consequence, the ultrasound beam scatters and sound is largely absorbed before reaching the deeper epimysial border, preventing it to appear as a bright hyperechoic structure [57]. Further, muscle contractions, aimed to aid the offline muscle delineation, were not always accomplished in the older adults as they tended to fall asleep or the researcher observed difficulties to relax the muscle after contraction. Although the superior repeatability for some muscle morphology quantifications in the younger age group was in line with our expectations, the measurement errors for these morphology measures were extremely low in the younger adults (SEM: 1.4-3.6%) and acceptable in older adults (SEM: 3.7-7.0%). Surprisingly, TA_{trans} showed less measurement error in older adults (SEM: 3.2 vs. 5.9%) which could be explained by its more consistent shape in longitudinal direction compared to in younger adults.

Against our expectations, for the muscles showing dissimilar repeatability across the machines (i.e., thickness AbH and PER_{long}), the tablet-based device turned out to be advantageous. Apparently, for these muscles, the larger field of view owing to the larger footprint of the probe of the mainframe system and its expected superior image quality due to the use of advanced options were of insufficient benefit. The tabled-based device, instead, is equipped with a smaller probe and lighter cables, minimizing the chance for unintentional transducer manipulation that would be at the cost of the perpendicularity of the image captured and thus repeatability [57]. The similar performance across the machines indicates that for each muscle the image quality of the tablet-based machine was sufficient to delineate the epimysial borders, which has previously been demonstrated for the thickness and CSA of AbH using a laptop-based machine [37]. Likewise, another study observed invariant thickness of hip extensor muscles across two different ultrasound machines [59]. Our findings confirm the assumption from other authors that machines can be used interchangeably in the assessment of muscle morphology [41], except for FHB, which showed a systematic difference across the machines in our study. Hence, this implies that health care professionals are not contingent on the availability of a specific machine to monitor muscle morphological changes over time. It further indicates that measurements for foot muscles morphology are not restricted to well-equipped hospitals or research labs, but can easily take place at the home of aged or diseased populations. This is promising given the current implementation of transitioning care from hospital to peoples own home.

The relative SDCs for PF, a passive structure associated with foot posture [19], increased the more distal it was assessed, ranging from 16.5 to 22.2% in older adults. In younger adults the SDC was significantly smaller for the proximal and middle portion (PF_{prox}: 9.6%; PF_{mid}: 16.0%), resembling previously reported inter-assessor repeatability [34]. Callus may have interfered with image quality [43] in older adults more than in younger as this skin condition is more prevalent in that population [40] and especially manifested in the region of PF_{prox} and PF_{mid}. Changing to the mainframe machine improved the repeatability for the distal portion of PF to an SDC of 13.9% and is, as such, also in agreement with the literature [34]. This can be explained by the enhanced visibility of deeper tissues (e.g., 2nd metatarsal bone) through the advanced penetration of sound by the mainframe machine, aiding the correct probe position [30]. Whenever available, a mainframe machine is, therefore, recommended to measure the thickness of PF in the feet of older adults when callus is present.

The current study is the first to investigate the reliability and measurement error for a large selection of both intrinsic and extrinsic foot muscles, in addition to PF, in older adults. Accounting for the operator's proficiency and excluding measurements accordingly ensured a valid comparison of the measurement properties between older and younger adults. Nevertheless, the study was subjected to several limitations that need to be considered. Most importantly, this intra-assessor reliability study does not provide information on the validity of the ultrasound morphology measures. Although the operator was a novice scanner at the start of the training, she received intensive specific training in scanning the foot muscles according to a fixed protocol. In addition, detailed knowledge of the scanner and the triangulation during the training program further contributed to valid ultrasound measurements. Nevertheless, because of the uncertain accuracy of the morphology measures, a systematic error cannot be ruled out. A systematic error would influence the mean morphology measure itself and, as a consequence, the relative measurement properties (i.e., relative SEM and SDC), but not the absolute measurement properties. However, it is not expected that this has occurred substantially. In addition, the repeated measurements were sometimes only one or two days apart. Therefore, the image capturing at the second occasion may have been subjected to recall bias. Nevertheless, this bias is expected to be marginal, considering the straightforward scan protocol. Further, the measurement properties were estimated from samples consisting of 10 to 18 participants, believed to be relatively small [60]. However, the sample size of the older adult group exceeded that of other ultrasound reliability studies with this amount of tissues [33,34]. Another limitation is that the comparison between machines only pertains to younger adults, as we decided to extend the protocol after the data collection was completed in older adults. Whilst it is unclear how a change of machine affects the repeatability in older adults, the measurement properties for the tablet-based device were already promising for its future use. The results are, however, limited to a subset of tissue morphology measures determined

from pilot testing with the tablet-based device. Hence, the applicability of the mainframe machine in the assessment of, in particular, the CSA of muscles such as QP, FHB and AbDM remains elusive. Lastly, only a single operator was involved in this study which means that the measurement properties cannot simply be generalized to any other operator [60]. This is because not only is the quality and consistency of the acquired images determined by the ultrasound experience and the background of the operator, but also does the post-processing delineation or identification of muscle borders rely heavily on the anatomical knowledge of the rater [61]. Nevertheless, a 10-month period of intense specific training, during which a specific foot muscle scan protocol was used, appeared to be sufficient to obtain good to excellent reliability and measurement error, but only when a single operator performs the measurements.

CONCLUSION

The results of this intra-assessor reliability study showed that a tablet-based ultrasound machine can be reliably used to assess the morphology of selected foot muscles in older adults, with the exception of plantar fascia thickness. This supports the use of this instrument in future studies to gain understanding of the role of these foot muscles in foot function. Although the measurement errors were smaller in younger adults for some muscle morphology measures, they seem adequate in older adults to detect hypertrophy as a response to training on a group level. The use of a tablet-based device seems to be a good alternative to a mainframe system, but how its superior repeatability applies to older adults needs to be further investigated. Nevertheless, our findings advocate the use of ultrasound in future studies or in clinical practice when foot muscle morphology is the outcome of interest, without being restricted to expensive ultrasound machines that often have limited access. In addition, the use of a tablet-based device enables the researcher or clinician to perform the ultrasound measurements at any location, even at the home of the older adults.

LIST OF ABBREVIATIONS

PIM: plantar intrinsic foot muscle; MRI: magnetic resonance imaging; CSA: cross-sectional area; ICC: intra-class correlation coefficient; CI: confidence interval; TA: tibialis anterior muscle; PER: peroneus muscle; FDL: flexor digitorum longus muscle; AbH: abductor hallucis muscle; FHL: flexor hallucis longus muscle; FDB: flexor digitorum brevis muscle; QP: quadratus plantae muscle; FHB: flexor hallucis brevis muscle; AbDM: abductor digiti minimi muscle; PF: plantar fascia; SEM: standard error of measurement; SDC: smallest detectable change; Prox: proximal portion; Mid: middle portion; Dist: distal portion; Long: longitudinal; Trans: transverse; LoA: limits of agreement.

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DECLARATIONS

Ethics approval and consent to participate

The medical ethical committee of Maxima MC declared that ethical approval was not required for this study protocol (N19.105). Written informed consent was obtained before the start of data collection.

Availability of data and materials

The dataset supporting the conclusions of this article is available on request in the DataverseNL repository, https://doi.org/10.34894/XNLROB .

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

Each author was involved in the conception and design of the study. LW collected, analyzed, interpreted and managed the data. LW drafted the manuscript which was reviewed by EW, MP and BV. All research activities were supervised by EW, MP and BV. All authors read and approved the final manuscript.

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SUPPLEMENTARY MATERIALS

Supplementary Material 2A: Protocol for imaging the foot tissues

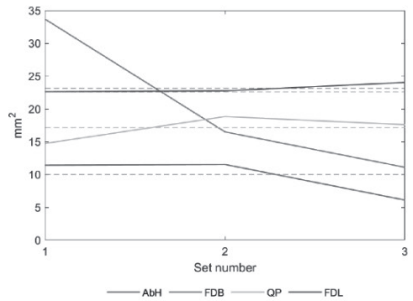
Location	Transverse plane	Longitudinal plane
The **extrinsic foot muscles** were first imaged on the short axis in the extension of the drawing line and then on the long axis by rotating the probe 90°.		
TA was imaged at 25% of LLLL, lateral to the anterior border of the tibia.	The interosseous membrane was kept as horizontal as achievable.	Attempts were made to image the aponeurosis in the middle of the muscle belly.
PER was imaged at 50% of LLLL, such that the muscle was imaged on top of the fibula.		
FDL was imaged on the short axis only at 50% of MLLL	The position and orientation of the probe was adjusted in a way the muscle was least obscured by the tibia.	
FHL was imaged at 80% of MLLL.		The myotendinous junction of the soleus muscle could often be observed.
The **intrinsic foot muscles** were first imaged on the long axis and then on the short axis.		
Location	**Transverse plane**	**Longitudinal plane**
AbH	The scan was made on a line directly anterior to the medial malleolus and perpendicular to the long axis of the foot.	The probe was placed at the muscle's origin on the medial process of the calcaneal tuberosity, moving towards just inferior to the navicular tuberosity until the thickest part of the muscle belly was captured.
FDB	At the thickest point, the probe was rotated 90° for the transverse image.	A scan was made on the drawing between the medial process of the calcaneal tuberosity and the third ray where the muscle showed its thickest part.
QP	At the QP's thickest portion, the probe was rotated 90° to capture the muscle's cross section.	The spring ligament was used as an internal landmark and located by placing the probe at the medial plantar side of the foot.
FHB		The probe was placed along the shaft of the first metatarsal bone on a line joining the medial process of the calcaneal tuberosity and the first metatarsophalangeal joint.
AbDM		An image was captured where the muscle showed its thickest part on a line between its origin to the lateral tuberosity and the fifth metatarsal head.

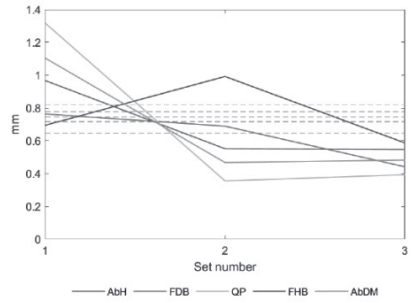
Supplementary Material 2A: Continued

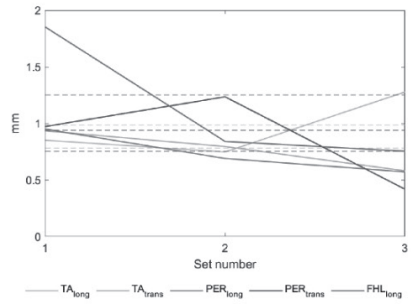
Location	Transverse plane	Longitudinal plane
The **PF** was imaged at three locations on a line between its attachment to the medial process of the calcaneal tuberosity and the second ray.		The proximal fascia (PF_{prox}) was imaged distal to its attachment to the calcaneus, where the visibility of the PF was not obstructed by anisotropy. Moving the probe along the scan line, the middle fascia (PF_{mid}) was located halfway its slope adjacent to the fat path and the distal fascia (PF_{dist}) halfway the base and the head of the second metatarsal bone.

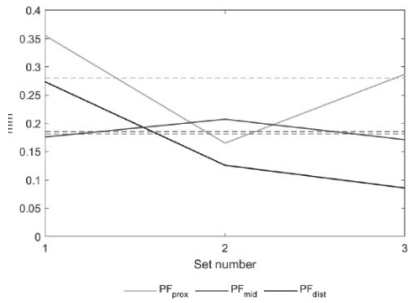
MLLL: medial lower leg length - the distance between the fibular head and the inferior border of the lateral malleolus.
LLLL: laterally lower leg length - the distance between the medial knee joint and the inferior border of the medial malleolus.

Supplementary Material 2B: Learning curves in ultrasound assessment of foot tissues showing the standard error of measurement for consecutive sets of participating older adults









AbH: m. abductor hallucis, FDB: m. flexor digitorum brevis, QP: m. quadratus plantae, FHB: m. flexor hallucis brevis, AbDM: m. abductor digiti minimi, PF: plantar fascia, prox: proximal, mid: middle, dist: distal, TA: m. tibialis anterior, long: longitudinal, trans: transverse, FDL: m. flexor digitorum longus, PER: m. musculus peroneus, FHL: m. flexor hallucis longus. Dotted lines indicate the standard error of measurement when all participants are included.

Supplementary Material 2C: Extended tables presenting the intra-assessor measurement properties for ultrasound morphology of selected foot muscles and plantar fascia in older and younger adults

Table 4. intra-assessor measurement properties for ultrasound morphology of selected foot muscles and plantar fascia in older adults.

		n	ICC	CI -	CI +	SEM	p	CI -	CI +	%SEM	SDC	CI -	CI +	%SDC
AbH	CSA	18	0.96	0.90	0.99	10	0.2587	7	14	5.0	28	20	38	13.9
	Th	18	0.87	0.68	0.95	0.7	0.0001	0.5	1.0	7.0	2.0	1.4	2.8	19.3
FDB	CSA	18	0.88	0.70	0.95	23	0.0011	16	31	9.4	63	45	87	26.0
		12	0.96	0.88	0.99	14.1	0.0368	9.4	21.0	5.7	39.0	26.1	58.1	15.7
	Th	18	0.91	0.77	0.96	0.7	0.1995	0.5	0.9	6.3	1.8	1.3	2.5	17.4
QP	CSA	18[a]	0.75	0.44	0.90	17	0.5241	12	24	9.7	47	34	66	26.8
	Th	18	0.60	0.19	0.83	0.8	0.0007	0.6	1.1	9.2	2.3	1.6	3.2	25.5
		12	0.92	0.70	0.98	0.4	0.1464	0.3	0.6	4.2	1.0	0.7	1.5	11.6
FHB	Th	18	0.78	0.50	0.91	0.8	0.1752	0.6	1.1	5.7	2.2	1.6	3.0	15.7
AbDM	Th	18[a]	0.76	0.45	0.90	0.8	0.0346	0.5	1.0	8.1	2.1	1.5	2.9	22.5
		12	0.89	0.41	0.97	0.5	0.3267	0.3	0.7	5.2	1.3	0.9	2.0	14.3
PF_{prox}	Th	18[a]	0.87	0.69	0.95	0.28	0.0071	0.20	0.39	7.2	0.78	0.56	1.08	19.9
		12[b]	0.94	0.80	0.98	0.23	0.0284	0.2	0.3	6.0	0.65	0.43	0.97	16.5
PF_{mid}	Th	18	0.70	0.35	0.88	0.19	0.0988	0.13	0.26	7.7	0.51	0.37	0.71	21.4
PF_{dist}	Th	18	0.44	0.01	0.74	0.18	0.1706	0.13	0.25	13.9	0.50	0.36	0.70	38.6
		12	0.57	0.06	0.85	0.11	0.2607	0.1	0.2	8.0	0.30	0.20	0.45	22.2
TA_{long}	Th	18[a]	0.92	0.79	0.97	1.0	0.0851	0.7	1.4	3.9	2.7	2.0	3.8	10.8
TA_{trans}	Th	18	0.94	0.85	0.98	0.8	0.0383	0.6	1.1	3.2	2.2	1.6	3.0	8.9
FDL	Th	18	0.79	0.53	0.92	23	0.0942	17	32	11.9	64	46	89	33.1
PER_{long}	Th	18	0.88	0.69	0.95	0.8	0.3602	0.5	1.0	5.3	2.1	1.5	2.9	14.6
PER_{trans}	Th	18	0.84	0.43	0.95	0.9	0.0947	0.7	1.3	6.8	2.6	1.9	3.6	18.9
FHL_{long}	Th	18	0.81	0.57	0.92	1.3	0.0010	0.9	1.7	5.0	3.5	2.5	4.8	13.9
		12	0.94	0.81	0.98	0.8	0.0173	0.5	1.2	3.2	2.2	1.5	3.3	8.8
FHL_{trans}	Th	7	0.97	0.86	1.00	0.7	0.3931	0.4	1.2	2.8	1.9	1.1	3.2	7.7

ICC: intra-class correlation coefficient, SEM: standard error of measurement, SDC: smallest detectable change, CI- and CI+: lower and upper limit of the 95% confidence interval, CSA: cross-sectional area, th: thickness, AbH: m. abductor hallucis, FDB: m. flexor digitorum brevis, QP: m. quadratus plantae, FHB: m. flexor hallucis brevis, AbDM: m. abductor digiti minimi, PF: plantar fascia, prox: proximal, mid: middle, dist: distal, TA: m. tibialis anterior, long: longitudinal, trans: transversal, FDL: m. flexor digitorum longus, PER: m. musculus peroneus, FHL: m. flexor hallucis longus. The units of measurement of the SEM and SDC are mm (thickness), mm^2 (CSA), or a percentage of the group mean muscle size (%SEM and %SDC). [a] indicates a non-normal distribution of the difference between the repeated measurements. [b] indicates the presence of heteroscedasticity. p-value is presented for the comparison across age groups.

Table 5. intra-assessor measurement properties for ultrasound morphology of selected foot muscles and plantar fascia in younger adults using a tablet-based machine.

		n	ICC	CI -	CI +	SEM	CI -	CI +	%SEM	SDC	CI -	CI +	%SDC
AbH	CSA	10	0.98	0.93	1.00	8	5	12	4.2	22	14	35	11.6
	Th	10	0.99	0.98	1.00	0.2	0.1	0.3	1.6	0.5	0.3	0.8	4.5
FDB	CSA	10	0.98	0.91	0.99	8	5	12	3.6	21	14	33	10.0
	Th	10	0.87	0.58	0.97	0.8	0.5	1.3	7.6	2.3	1.5	3.5	21.0
QP	Th	10	0.93	0.77	0.98	0.3	0.2	0.4	2.6	0.7	0.5	1.1	7.3
FHB	Th	10	0.93	0.75	0.98	0.6	0.4	0.9	4.0	1.6	1.0	2.5	11.2
AbDM	Th	10[a]	0.96	0.85	0.99	0.4	0.3	0.6	3.7	1.1	0.7	1.8	10.2
PF_{prox}	Th	10	0.96	0.87	0.99	0.12	0.08	0.19	3.5	0.34	0.22	0.52	9.6
PF_{mid}	Th	10	0.88	0.60	0.97	0.12	0.08	0.19	5.8	0.34	0.22	0.52	16.0
PF_{dist}	Th	10	0.44	-0.18	0.82	0.13	0.09	0.21	11.0	0.37	0.24	0.57	30.6
TA_{long}	Th	10	0.62	0.02	0.89	1.4	0.9	2.2	6.4	4.0	2.6	6.2	17.7
TA_{trans}	Th	10	0.67	0.08	0.91	1.3	0.8	2.0	5.9	3.6	2.3	5.5	16.2
FDL	Th	10	0.94	0.39	0.99	15	10	23	10.3	42	27	65	28.5
PER_{long}	Th	10	0.90	0.67	0.97	0.7	0.4	1.0	5.0	1.8	1.2	2.9	13.7
PER_{trans}	Th	10	0.93	0.76	0.98	0.6	0.4	1.0	4.5	1.7	1.1	2.6	12.4
FHL_{long}	Th	8	0.98	0.92	1.00	0.3	0.2	0.6	1.4	1.0	0.6	1.6	3.9
FHL_{trans}	Th	10	0.96	0.87	0.99	0.6	0.4	1.0	2.8	1.8	1.1	2.7	7.7

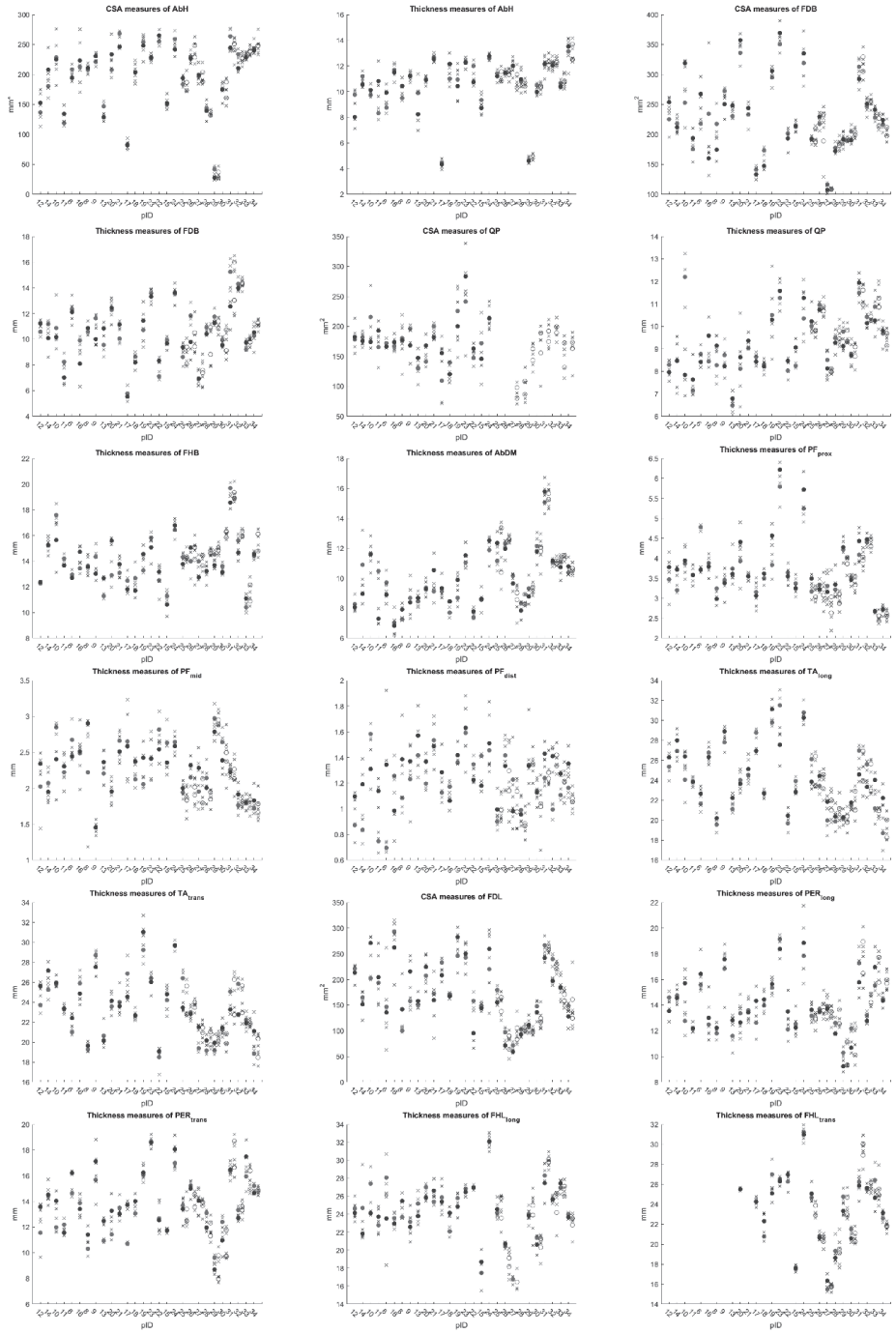
ICC: intra-class correlation coefficient, SEM: standard error of measurement, SDC: smallest detectable change, CI- and CI+: lower and upper limit of the 95% confidence interval, CSA: cross-sectional area, th: thickness, AbH: m. abductor hallucis, FDB: m. flexor digitorum brevis, QP: m. quadratus plantae, FHB: m. flexor hallucis brevis, AbDM: m. abductor digiti minimi, PF: plantar fascia, prox: proximal, mid: middle, dist: distal, TA: m. tibialis anterior, long: longitudinal, trans: transversal, FDL: m. flexor digitorum longus, PER: m. musculus peroneus, FHL: m. flexor hallucis longus. The units of measurement of the SEM and SDC are mm (thickness), mm^2 (CSA), or a percentage of the group mean muscle size (%SEM and %SDC). [a] indicates a non-normal distribution of the difference between the repeated measurements.

Table 6. intra-assessor measurement properties for ultrasound morphology of selected foot muscles and plantar fascia in younger adults using a mainframe machine.

		n	ICC	CI -	CI +	SEM	p	CI -	CI +	%SEM	SDC	CI -	CI +	%SDC
AbH	CSA	10	0.98	0.93	1.00	9	0.4039	6	15	4.9	26	17	40	13.6
	Th	10	0.97	0.84	0.99	0.4	0.0363	0.3	0.6	3.7	1.1	0.7	1.7	10.3
FDB	CSA	10	0.94	0.77	0.99	13	0.0670	9	21	6.3	37	24	57	17.6
	Th	10	0.82	0.47	0.95	1.0	0.5055	0.6	1.5	9.2	2.7	1.8	4.2	25.4
QP	Th	10	0.93	0.73	0.98	0.3	0.4396	0.2	0.4	2.8	0.8	0.5	1.2	7.8
FHB	Th	10	0.93	0.74	0.98	0.5	0.7141	0.3	0.8	3.5	1.5	0.9	2.3	9.7
AbDM	Th	10[a]	0.89	0.64	0.97	0.7	0.1155	0.5	1.1	6.3	2.0	1.3	3.0	17.4
PF_{prox}	Th	10	0.95	0.80	0.99	0.14	0.8014	0.09	0.22	4.3	0.40	0.26	0.62	12.0
PF_{mid}	Th	10	0.93	0.75	0.98	0.10	0.5877	0.06	0.16	4.8	0.28	0.18	0.43	13.2
PF_{dist}	Th	10	0.89	0.65	0.97	0.06	0.0008	0.04	0.09	5.0	0.15	0.10	0.24	13.9
TA_{long}	Th	10	0.68	0.17	0.91	1.3	0.5427	0.9	2.1	6.0	3.7	2.4	5.8	16.7
TA_{trans}	Th	10	0.63	0.09	0.89	1.3	0.8661	0.9	2.0	6.0	3.7	2.4	5.7	16.6
FDL	Th	10	0.95	0.82	0.99	13	0.3156	9	21	9.3	37	24	58	25.9
PER_{long}	Th	10	0.84	0.49	0.96	1.0	0.0050	0.6	1.6	7.2	2.8	1.8	4.3	19.9
PER_{trans}	Th	10	0.87	0.59	0.97	0.9	0.1538	0.6	1.4	6.9	2.6	1.6	4.0	19.0
FHL_{long}	Th	8	0.93	0.61	0.99	1.0	0.0501	0.6	1.6	3.9	2.6	1.6	4.3	10.8
FHL_{trans}	Th	10	0.98	0.91	0.99	0.6	0.9434	0.4	0.9	2.7	1.7	1.1	2.6	7.3

ICC: intra-class correlation coefficient, SEM: standard error of measurement, SDC: smallest detectable change, CI- and CI+: lower and upper limit of the 95% confidence interval, CSA: cross-sectional area, th: thickness, AbH: m. abductor hallucis, FDB: m. flexor digitorum brevis, QP: m. quadratus plantae, FHB: m. flexor hallucis brevis, AbDM: m. abductor digiti minimi, PF: plantar fascia, prox: proximal, mid: middle, dist: distal, TA: m. tibialis anterior, long: longitudinal, trans: transversal, FDL: m. flexor digitorum longus, PER: m. musculus peroneus, FHL: m. flexor hallucis longus. The units of measurement of the SEM and SDC are mm (thickness), mm^2 (CSA), or a percentage of the group mean muscle size (%SEM and %SDC). [a] indicates a non-normal distribution of the difference between the repeated measurements. p-value is presented for the comparison across machines.

Supplementary Material 2D: Graphical presentation of the raw data on which the measurement properties are based



CSA: cross-sectional area; AbH: m. abductor hallucis, FDB: m. flexor digitorum brevis, QP: m. quadratus plantae, FHB: m. flexor hallucis brevis, AbDM: m. abductor digiti minimi, PF: plantar fascia, prox: proximal, mid: middle, dist: distal, TA: m. tibialis anterior, long: longitudinal, trans: transversal, FDL: m. flexor digitorum longus, PER: m. musculus peroneus, FHL: m. flexor hallucis longus, red: occasion 1, blue: occasion 2; cross markers: trials, circle markers: average morphology measure per participant, filled markers: tablet-based machine, non-filled markers: mainframe machine.

The effect of interventions anticipated to improve plantar intrinsic foot muscle strength on fall-related dynamic function in adults: a systematic review (study 2)

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3

ABSTRACT

Background: the plantar intrinsic foot muscles (PIMs) have a role in dynamic functions, such as balance and propulsion, which are vital to walking. These muscles atrophy in older adults and therefore this population, which is at high risk of falling, may benefit from strengthening these muscles in order to improve or retain their gait performance. Therefore, the aim was to provide insight in the evidence for the effect of interventions anticipated to improve PIM strength on dynamic balance control and foot function during gait in adults.

Methods: a systematic literature search was performed in five electronic databases. The eligibility of peer-reviewed papers, published between January 1, 2010 and July 8, 2020, reporting controlled trials and pre-post interventional studies was assessed by two reviewers independently. Results from moderate- and high-quality studies were extracted for data synthesis by summarizing the standardized mean differences (SMD). The GRADE approach was used to assess the certainty of evidence.

Results: screening of 9199 records resulted in the inclusion of eleven articles of which five were included for data synthesis. Included studies were mainly performed in younger populations. Low-certainty evidence revealed the beneficial effect of PIM strengthening exercises on vertical ground reaction force (SMD: -0.31-0.37). Very low-certainty evidence showed that PIM strength training improved the performance on dynamic balance testing (SMD: 0.41-1.43). There was no evidence for the effect of PIM strengthening exercises on medial longitudinal foot arch kinematics.

Conclusions: this review revealed at best low-certainty evidence that PIM strengthening exercises improve foot function during gait and very low-certainty evidence for its favorable effect on dynamic balance control. There is a need for high-quality studies that aim to investigate the effect of functional PIM strengthening exercises in large samples of older adults. The outcome measures should be related to both fall risk and the role of the PIMs such as propulsive forces and balance during locomotion in addition to PIM strength measures.

BACKGROUND

Annually, approximately one third of the adults aged over 65 year fall at least once and this number increases with advancing age [1]. One third of all falls result in serious injury [2]. These injuries eventually lead to hospitalization, institutionalization, or mortality in a substantial number of events [3]. Since the rate of serious injuries as a consequence of a fall in older adults increases over the years and because of its financial and societal consequences, there is an urgent need for improving the prevention of falling in this specific population.

Altered gait and related balance deficits are strong determinants of falling [2,4,5] and very common [4,6,7] in older adults. A wide range of biological factors can be related to these age-related changes. However, there is rational to believe that the decreased force-producing capacity of the plantar intrinsic foot muscles (PIMs), as observed in older adults [8], may have a role in at least two aspects of the functional decline that make them more likely to fall. These comprise of diminished balance control in dynamic circumstances and reduced generation of propulsive power.

Older adults experience difficulties to control their balance during gait, particularly in the frontal plane [9,10]. Mechanically, this can be explained by the narrowed mediolateral stability margins in comparison with younger adults resulting from increased sway of the body's center of mass in this direction [9] in conjunction with the more medially directed progression of the center of pressure (CoP) throughout the loading phase of gait in older adults [11]. This medial shift of the CoP has been associated with a lower medial longitudinal foot arch (MLA) [12], which is typical of the aging foot [13,14]. A flatter foot might also negatively impact dynamic balance as this causes increased motion of the forefoot, reflecting reduced stiffness of the foot [15]. This lack of a high arched stiff foot resulting in a less stable base of support might be due to insufficient force produced by the PIMs [16–18]. In addition to this role in dynamic balance during gait, the PIMs also play a role in static postural balance, especially in the frontal plane or when the postural demand of the task is increased [19,20]. Hence, it is likely that the observed atrophy of the PIMs in older adults interferes with the capability of the postural system to remain balanced during gait.

Not only decreased control of balance is typical for older adults' gait, but also reduced generation of propulsive power [7,21]. A reduced push-off may result in smaller steps [22], slower walking speed [7] and increased stance time [21]. These spatiotemporal gait parameters are all associated with an increased risk of falling [23]. The reduced propulsive power has been previously attributed to the decreased capacity of the ankle plantar flexors to generate power at the ankle joint [22,24]. However, since the foot is simply modelled as one rigid body in these studies, it remains unclear to which extent the foot contributed to the estimated ankle joint power [25]. Instead, a recent study, using a multi-segment foot model [26], showed that normal push-off was jeopardized when the PIMs

were unable to contract. This implies that effective force transmission to the ground may be hindered by the diminished force capacity of the PIMs in older adults.

Thus, for older adults, PIMs that function properly (e.g., have sufficient strength and endurance) seem to be important to walking safely. This is further supported by the finding that toe flexion strength, both credited to the PIMs and the extrinsic foot muscles [27], is an independent predictor of dynamic balance performance in older adults [28]. Furthermore, older adults with less toe flexion strength were more likely to fall and this variable was more discriminative than a combination of other intrinsic factors, such as proprioception and quadriceps muscle strength [29]. Assuming that a loss of muscle strength is a reversible process in older adults [30], older adults may benefit from strengthening the PIMs in order to improve or retain their gait performance and decrease the risk of falling.

Despite the potential of strengthening the PIMs, only a few studies investigated the effect of strengthening exercises for the foot muscles in older adults, with no attempts made to distinguish between the contribution of intrinsic and extrinsic foot muscles. These studies revealed consistent results: increased toe plantar flexion strength [31–33] and improved balance performance [31,32], while gait speed remained unchanged [32,33]. Additionally, a systematic review [34] and a randomized controlled trial (RCT) [35] evaluating programs consisting of both foot and ankle exercises, not limited to strengthening exercises, concluded these programs to be beneficial for static balance [34,35] and reducing the number of falls [35]. However, to the extent of our knowledge, no studies investigated the effect of strength training directed specifically at the PIMs on fall risk related outcomes in older adults. Therefore, the preventative effect of strengthening the PIMs in this population at high risk to falling remains unclear. Nevertheless, evidence regarding the effect of such interventions in adults of all ages on parameters associated with a higher fall risk in older adults would enhance our comprehension of its potential in older adults.

A recent (2017) systematic review by Huffer et al. [36] investigated if plantar foot strength training interventions were effective in the treatment or prevention of plantar fasciitis and in improving intrinsic foot muscle strength. Based on primarily healthy study populations not expected to be at increased risk of plantar fasciitis, the authors could not draw a convincing conclusion on the effect of PIM strength training on functional performance due to the diverging outcome measures used in the included studies. Since this systematic review, numerous studies emerged in which the effect of interventions aimed to improve PIM strength was investigated. These studies demonstrated a beneficial effect pertaining to PIM strength and hypertrophy [37–41]. However, it is not clear to what extent this reflects improved dynamic function. As PIMs are primarily engaged in dynamic functions and these are vital to walking in older adults, insight in the effect of PIM strengthening interventions on these locomotor functions would be helpful in optimizing fall prevention programs. Therefore, the aim of the current systematic literature review was to provide

insight in the evidence for the effect of interventions anticipated to improve PIM strength on dynamic balance control and foot function during gait in adults.

METHODS

This systematic review has been reported according to the PRISMA statement [42]. The protocol is registered and accessible in the PROSPERO database under the number CRD42020197788.

Search strategy

PubMed, CINAHL Plus with full text, SPORTSDiscus with full text, PEDRO and Web of Science were used to search the literature for peer-reviewed articles. Because no intervention studies concerning PIM strength training were expected to be published before 2010 based on the review of Huffer et al. [36], the search was limited to publications between January 1, 2010 and July 8, 2020. The search strategy applied in PubMed is shown in Table 1 and the equivalent strategies for the other databases can be found in Supplementary Material 3A. The search string was built from three sets of terms related to 1) the type of intervention, 2) the target of the intervention and 3) outcome measures. A fourth set was added to exclude articles concerning neurological pathologies known to cause gait impairment. Available MeSH terms or subject headings that relate to “strength training” or “exercise therapy” were explored and included in the search string whenever applicable. A library information specialist was involved in establishing the search string. If allowed by the search engine, the search was restricted to full text articles written in English or Dutch, languages that the researchers can read and interpret at a proficient level, and reporting studies on human subjects. Additional records were either found by checking the reference lists of included articles or by forward citation tracking of the same articles using Google Scholar on September 1, 2020. All five databases were checked for relevant articles published afterwards on April 26, 2021. These additional searches were performed by a single investigator (LW).

Table 1: Search strategy as applied in PubMed.

Type of intervention:	AND	“exercise therapy” [MeSH Terms] OR “resistance training” [MeSH Terms] OR exercise OR strengthening OR shoes OR footwear OR barefoot OR foot ortho* OR insole* OR inlay*
Target of intervention:	AND	doming OR “short foot” OR “foot core” OR foot musc* OR intrinsic foot OR plantar musc* OR toe musc* OR hallu* muscle
Outcome measure:	AND	postur* balance OR postur* stability OR postur* control OR stance balance OR stance stability OR stance control OR dynamic* OR function* OR gait OR walking OR locomotion OR running
Pathologies:	NOT	stroke OR “multiple sclerosis” OR “cerebral palsy”

Selection criteria

Studies were included if characterized by:

- a study **population** consisting of adults of all ages in the absence of a neuromuscular or neurological condition affecting lower extremity function severely and without any painful musculoskeletal complaints in the lower extremity. The latter is expected to interfere with exercise performance and is negatively associated with adherence [43];
- studying the effect of noninvasive **interventions** anticipated to improve PIM strength. As the focus is on strength, as opposed to neuromuscular adaptations, interventions had to last at least 4 weeks [38,44]. These interventions include, for example but were not restricted to, 1) muscle strengthening programs composed of 'short foot' or 'foot doming' exercises or exercises requiring toe flexion muscle force (e.g., toe plantar flexion, towel curl exercise, marble pick up, heel raises) or toe ab-/adduction muscle force (e.g., toe spread out), 2) a transition from conventional to minimal shoe or barefoot condition;
- reporting **outcome measures**, at least assessed at baseline and directly post intervention, that are related to the locomotor system's function on balance control and propulsion. These measures should originate from the following domains: 1) dynamic balance (e.g., star excursion balance test), 2) foot and ankle biomechanics during gait or running (e.g., MLA kinematics, kinetics, plantar pressure, propulsive power of foot and ankle joints), 3) anterior and vertical ground reaction force (GRF) peak and impulse at push-off phase during gait or running and 4) spatiotemporal gait or running parameters.
- In addition, if the intervention targeted other muscles additional to the PIMs (e.g., heel raises, foot and ankle exercise program, transition to minimal shoe or barefoot condition), then at least the outcome of one measure of purely PIM strength (e.g., size or doming strength) should be reported, in order to be able to associate changes in dynamic outcome measures to changes in PIM strength.
- one of the following **study designs**: 1) a controlled trial in which one of the above mentioned interventions was the contrast between the trial arms (i.e., intervention A compared to intervention A + intervention of interest) or was compared with 'no intervention'/ 'placebo' (e.g. stretching)/ 'usual care' (e.g., usual training regime), 2) a controlled trial in which at least one group received only the intervention of interest, but without an adequate control group as described in 1. This was considered as a pre-post interventional study in further analysis, and 3) a pre-post interventional study in which the study population received only the intervention of interest.
- Articles were excluded when the intervention was described as 1) an exercise intervention not only focusing on toe, foot or ankle muscles, (e.g., fall prevention programs, rehabilitation therapy), 2) balance or proprioceptive training, 3) running training or walking program without a transition to minimal shoe or barefoot condition, or 4) post-operative therapy.

Selection process

Subsequent to automatic duplicate removal (Covidence systematic review software, Veritas Health Innovation, Melbourne, Australia. Available at www.covidence.org), the titles and abstracts were screened for possible eligible studies by two reviewers (LW, HB) independently. After reaching consensus, the full text of these remaining records was evaluated according to the selection criteria, by the same reviewers blinded to each other's decision. Any decisional inconsistency regarding inclusion or the reason for exclusion were resolved through discussion. A third reviewer (BV) was available during the process to resolve any remaining conflict.

Data extraction

Predefined data sheets were customized to extract sample characteristics, description of intervention, methodology used to assess outcomes, results on outcome measures of interest (including PIM strength if reported) at baseline and directly post-intervention for each outcome domain and the statistical significance of comparisons (i.e., group x time interaction effect for controlled trials and time effect for pre-post interventional studies). In case an article reported multiple outcomes within the same outcome domain, the outcome measure that is advocated by the literature as most closely related to the role of the PIMs was selected for further synthesis [45,46]. If equally related, further decisions were first made based on the availability of data, second on statistical significance and last on the effect size. Extraction was performed by a single reviewer (LW) and checked for correctness by the other reviewer (HB). The data were tabulated for presentation purposes.

METHODOLOGICAL QUALITY ASSESSMENT

The Downs & Black checklist [47] was used to assess the methodological quality of the included articles independently by two reviewers (LW, HB). The checklist contains 27 questions addressing clarity and completeness of reporting (10 items), external validity (3 items), internal validity (13 items) and power (1 item). This checklist has been used previously in systematic reviews and is applicable to evaluate various study designs [36,48,49]. Items 23 and 24 are not applicable to non-randomized studies and additional to these items, item 5, 21, 22, 25 do not apply to pre-post interventional studies. These items were therefore scored 'unable to determine' in these cases. As such, a pre-post interventional study is inherently classified as being of less quality compared to an RCT. Item 27, concerning the power of the study, was transformed into a dichotomous scale indicating whether or not a sample size calculation was reported [36]. The checklist as it was used in the current review is provided in Supplementary Material 3B. In case no consensus was reached on an item, a third reviewer (BV) was available for a final decision. Only the total score on the construct 'internal validity' was used to determine the methodological quality of the study. A study with a score on 'internal validity' between

0 and 4 was designated as of 'low quality', a score between 5 and 8 as of 'moderate quality' and between 9 and 13 as of 'high quality' [49].

Data analysis

Effect sizes of comparisons were expressed in standardized mean differences (SMD) and calculated according to the formulas proposed by Lakens et al. [50]. The standardized mean difference between groups in change from baseline for the sample was given by Cohen's d_s:

$$d_s = \frac{\overline{X_{I,diff}} - \overline{X_{C,diff}}}{\sqrt{\frac{(n_I - 1)SD_I^2 + (n_C - 1)SD_C^2}{n_I + n_C - 2}}} \quad (1)$$

where *C* and *I* indicate the control group and intervention group, respectively. $\overline{X_{I,diff}} - \overline{X_{C,diff}}$ is the difference in the change from baseline between the control group and the intervention group. This numerator was preferred over the between-groups post-intervention difference. This was because baseline measures tended to differ between groups and therefore, the between-groups post-intervention difference may not represent an intervention effect adequately. The pooled pre-intervention standard deviation was used as the denominator in Formula 1 as an alternative to the standard deviation of the changes from baseline, because there was not enough information available to determine the latter for the majority of studies. For the same reason, it was impossible to determine the confidence interval of the SMD.

In order to be able to interpret the SMD across study designs (i.e., between-group and within-group designs), the SMD for within group differences was given by Cohen's d_{av}:

$$d_{av} = \frac{M_{t_1 - t_0}}{\frac{SD_{t_0} + SD_{t_1}}{2}} \quad (2)$$

where t_0 and t_1 indicate the baseline and post-intervention measurement, respectively and $M_{t_1 - t_0}$ is the mean change from baseline.

The SMDs (i.e., d_s and d_{av}) were corrected in case of a small sample size (n<20) [50] resulting in Hedges's g_s and g_{av}:

$$g_s = d_s \times \left(1 - \frac{3}{4(n_I + n_C) - 9}\right) \quad (3)$$

$$g_{av} = d_{av} \times \left(1 - \frac{3}{4(2n) - 9}\right) \quad (4)$$

The SMD values were transformed in a way that positive values indicate an improvement in the outcome measure favoring the intervention. An SMD < 0.5 was interpreted as a small effect, between 0.5 and 0.8 as a moderate effect, and ≥ 0.8 as a large effect [51].

Data synthesis

A meta-analysis was not undertaken because the unknown variance of the change from baseline impeded adequate calculation of confidence intervals around the effect estimates [52]. In spite of efforts to request the required data from the authors of included articles, only one author provided these data. Therefore, the method of 'summarizing effect estimates' was applied instead [52]. Only studies of moderate and high methodological quality were used in the synthesis [52].

The GRADE approach [53] was used to assess the certainty of evidence for each outcome domain for which at least one moderate or high quality study was included and only by taking the moderate and high quality studies into account [52]. Starting with an initial 'high' score, the quality of evidence was subsequently downgraded by one or two levels based on concerns on these five factors:

1. Risk of bias
2. Inconsistency of results
3. Indirectness of evidence
4. Imprecision of results
5. Probability of publication bias

The final grade was 'high', 'moderate', 'low' or 'very low' and reflects the certainty of the true effect for each outcome domain.

A sensitivity analysis was performed to assess the robustness of the level of evidence by modifying the lower boundary for classifying the studies as being of moderate methodological quality (i.e., ≥ 4 or ≥ 6, rather than ≥ 5).

RESULTS

Study selection

The process of study selection is shown in Identification 1. In the databases and through forward and backward citation tracking, 9198 unique records were identified. One extra article was added as a result of the additional search in the most recent literature. Among these records, 78 articles were deemed relevant based on title and abstract. The screening of the full texts resulted in inclusion of eleven studies that met the selection criteria. Among the excluded studies were the studies of Spink et al. [35] and Okamura et al. [41], because the interventions incorporated more than only toe, foot and ankle strengthening exercises in combination with the fact that isolated intrinsic foot muscle strength or strength capacity was not evaluated.

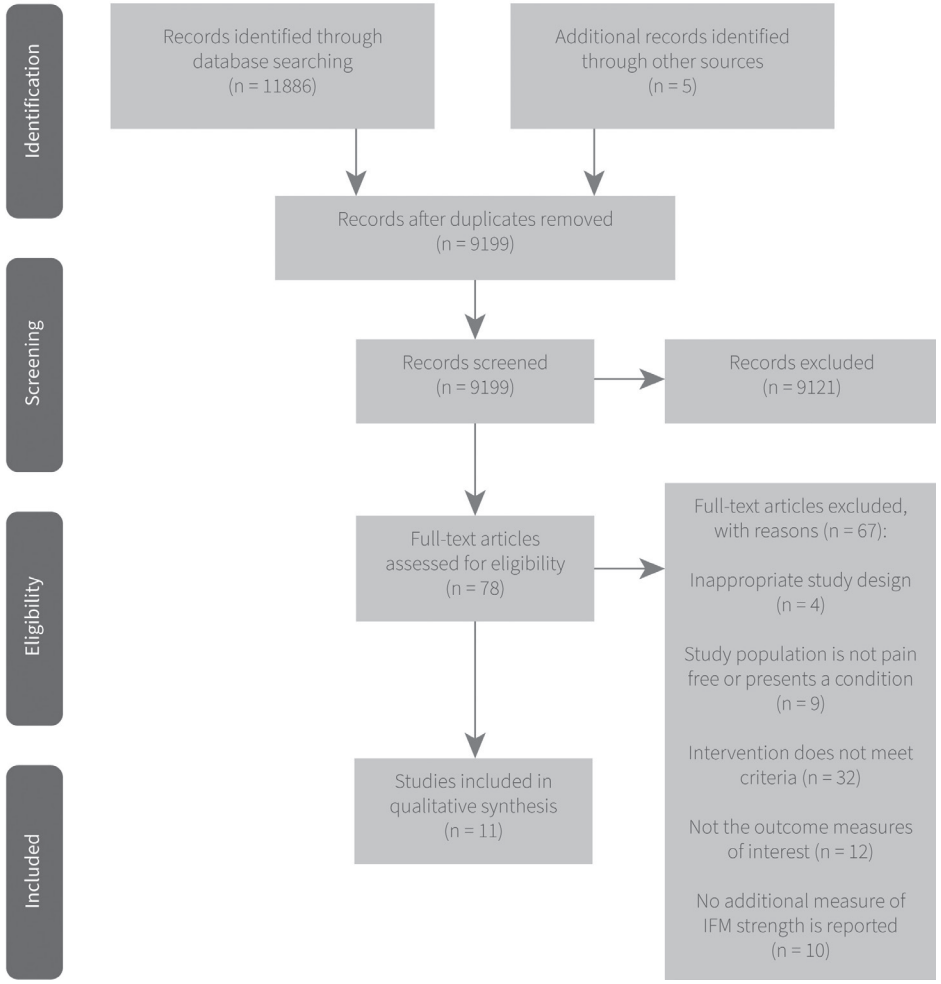

Figure 1: PRISMA flow chart [42] of applied selection process.

Characteristics of included studies

The characteristics of the included studies are summarized in Table 2. These studies consist of four RCTs [39,40,54,55], one nonrandomized controlled trial [56] and six pre-post interventional studies or RCTs that are considered as pre-post interventional (i.e., no adequate control group) [57–62].

The total number of participants was 226 (range: 7-40) with a mean age of 23.3 years. One study included older participants (> 60 yr) and these were diagnosed with diabetes [56]. Other study populations were characterized by chronic ankle instability [55,58,62], pronated foot posture [40,60,61], or long-distance runners [39]. The three remaining studies [54,57,59] included participants without any of such notable common characteristics.

All included studies investigated the effect of a strength exercise program with a duration of four to eight weeks. In nine studies [40,54,56–62], the effect of only short foot exercises was investigated. In the two other studies the exercise program was composed of either various intrinsic foot muscle exercises [55] or foot and ankle exercises [39]. The number of prescribed exercise sessions in a week ranged from a minimum of three sessions to daily practice. Half of the programs commenced with an instructional training session [40,54,57,59,60]. In two studies all sessions were supervised [60,62]. One out of four weekly sessions was supervised in two other studies [39,40]. The remainder of the sessions in these and other studies were unsupervised or supervision was not specified. Sometimes a weekly phone consult [54] or an extra instructional training session mid-way was added to the program [54]. The session duration varied from a few to 30 minutes. Most programs were progressive in the level of difficulty, either fixed or customized. Adherence (i.e., the proportion of the prescribed unsupervised sessions that is accomplished) was not reported in six studies [39,54–56,58,61]. In the three other studies that comprised of unsupervised sessions [40,57,59], 67.2 – 102.1% of the prescribed unsupervised sessions were completed. Attendance (i.e., the proportion of the scheduled supervised sessions that is attended) was reported to be 77.5 [40] and 80.4 % [39] or was not reported [54,60,62].

Dynamic balance performance was the outcome measure in eight studies, using either the star excursion balance test (SEBT) [56,57], the Y balance test (YBT) [54,55,60–62] or a test with a moving platform [58]. Three studies did a gait [40,59] or running [39] analysis to evaluate the effect of the intervention using various parameters for foot biomechanics [39,40,59], GRF [39,40] and spatiotemporal characteristics [40,59]. The last column of Table 2 shows the selected outcome measures per domain, based on the predefined prioritization, for further analysis.

Table 2: characteristics of included studies, sorted by outcome domain and in descending order according to methodological quality.

			Intervention				Outcomes		
Study/ Design	**Methodo-logical quality**	**Study population gender: (male/ female) age: mean ± sd**	**Type**	**Volume**	**Progression**	**Supervision**	**Adherence/ attendance**	**Domain**	**Instruments and measures**
Taddei et al. [39] Randomized controlled trial	High	Long distance runners IG (n=14) Gender: 5/9 Age: 41.9 ± 7.4 yr CG (n=14) Gender: 9/5 Age: 41.6 ± 6.0 yr	I: Foot and ankle strength exercise program C: stretching program	8 weeks 4 sessions 20-30 minutes	Customized, 3 levels (sitting, double leg, single leg stance)	Weekly supervised session	80.4% supervised sessions attended		Barefoot running analysis with 3D motion capture system and force plates:
								Foot and ankle biomechanics	MLA ROM[b] and stiffness;
								Ground reaction forces	GRF vertical[a] and AP impulse at push-off.
Okamura et al. [40] Randomized controlled trial	High	Pronated foot posture IG (n=10) Gender: 1/9 Age: 19.7 ± 0.9 yr CG (n=10) Gender: 2/8 Age: 20.2 ± 1.5 yr	I: Short-foot exercise program supported by electrical stimulation and EMG biofeedback C: No intervention	8 weeks 3 sessions 3 sets 10 reps 5s contraction 45s rest between sets	Customized, 3 levels (sitting, double leg, single leg stance)	Initial 20-minute training session, weekly supervised session	102.1% unsupervised sessions accomplished; 77.5% supervised sessions attended		Barefoot gait analysis with 3D motion capture system and force plates:
								Foot and ankle biomechanics	Navicular drop[a] and corresponding moment in time;
								Ground reaction forces	GRF (anterior, medial, vertical[c]) in second half of stance;
								Spatiotemporal parameters	Stance phase duration.
Matsumoto et al. [59] Pre-post intervention study	Low	n=20 Gender: 10/10 Age: 20.0 ± 2.4 yr	I: Short-foot exercise program	4 weeks # sessions NR 30 reps 5s contraction	Fixed, 3 levels: wk 1 – sitting wk 2 – double leg stance wk 3 to 4 – single leg stance	Initial 30-min training session	67.2% sessions accomplished		Barfoot gait analysis with 3D motion capture system and pressure plate:
								Foot and ankle biomechanics	MLA compression[a], peak pressure per foot region, total plantar contact area;
								Spatiotemporal parameters	Gait speed.
Lynn et al. [54] Randomized controlled trial	High	IG (n=8) Gender: 3/5 Age: 23.7 ± 2.1 CG (n=8) Gender: 3/5 Age: 22.6 ± 1.7 yr	I: Short-foot exercise program C: No intervention	4 weeks daily 100 reps 5s contraction	Fixed, 2 levels: week 1,2 – sitting week 3,4 – double leg stance	Initial training session, weekly phone consult, extra instructional training session before week 3	NR	Dynamic balance	YBT mediolateral CoP excursion for dominant and non-dominant[c] stance leg

Table 2: Continued

			Intervention				Outcomes		
Study/ Design	**Methodological quality**	**Study population gender: (male/female) age: mean ± sd**	**Type**	**Volume**	**Progression**	**Supervision**	**Adherence/ attendance**	**Domain**	**Instruments and measures**
Lee and Choi [55] Randomized controlled trial	Moderate	Chronic ankle instability IG (n=15) Gender: 5/10 Age: 20.9 ± 1.1 yr CG (n=15) Gender: 5/10 Age: 20.8 ± 0.9 yr	I: IFM strength exercise program C: no intervention	6 weeks 3 sessions 3 blocks 4 sets 3-15 reps 3-20s contraction	Fixed, 3 levels: week 1,2 – sitting week 3,4 – double leg stance week 5,6 – single leg stance	Supervision, but not specified	NR	Dynamic balance	YBT composite reach distance normalized to leg length
Mulligan et al. [57] Pre-post intervention study	Moderate	n=21 Gender: 3/18 Age: 26.1 ± 3.7	Short-foot exercise program	4 weeks daily 3 min 5s contraction	Customized, 3 levels (sitting, double leg, single leg stance) + variations (vision, surface stability)	Initial 1-hour training session	85.7% sessions accomplished	Dynamic balance	SEBT reach distance in five directions, among which medial[a]
Tudpor et al. [56] Non-randomized controlled trial	Low	Diabetes IG (n=8) Gender: 4/4 Age: 62.6 ± 0.4 yr CG (n=7) Gender: 3/4 Age: 67.4 ± 0.5 yr	I: foot strength exercises + short-foot exercises C: foot strength exercises	8 weeks daily IG 30 reps of foot exercises + 30 min SFE CG 30 reps of foot exercises	No progression, sitting position		NR	Dynamic balance	SEBT reach distance normalized to leg length in eight directions, among which lateral[a]
Lee et al. [58] Pre-post intervention study	Low	Chronic ankle instability (n=15) Gender: 7/8 Age: 21.5 ± 2.5 yr	Short-foot exercise program	8 weeks 3 sessions 3 sets 12 reps 5s contraction	2 levels, fixed: week 1 to 4 – sitting weeks 5 to 8 – single leg stance		NR	Dynamic balance	Moving platform: overall and medio-lateral[a] center of gravity displacement index score
Ma et al. [62] Pre-post intervention study	Low	Chronic ankle instability (n=14) Gender: 6/8 Age: 20.3 ± 1.5 yr	Short-foot exercise program + sham transcranial direct current stimulation	4 weeks 3 sessions 20 minutes 4 sets	3 levels (sitting, double leg, single leg stance)	All sessions were supervised	NR	Dynamic balance	YBT composite reach distance normalized to leg length
Kim et al. [60] Pre-post intervention study	Low	Pronated foot function (n=7) Gender: 6/1 Age: 24.0 ± 1.9 yr	Short-foot exercise program	5 weeks 3 sessions 30 min	No progression, sitting position	Initial training session, all sessions were supervised	NR	Dynamic balance	YBT composite reach distance normalized to leg length
Pisal et al. [61] Pre-post intervention study	Low	Pronated foot posture (n=40) Gender: NR Age: NR	Short-foot exercise program	4 weeks daily 100 reps 5s contraction			NR	Dynamic balance	YBT reach distance of both legs in three directions, among which posterolateral with the right leg[d]

IG: intervention group, CG: control group, I: intervention, C: control, PIM: plantar intrinsic foot muscle, MLA: medial longitudinal arch, ROM: range of motion, GRF: ground reaction force, CoP: center of pressure, AP: anteroposterior, CSA: cross-sectional area, US: ultrasound, YBT: Y-balance test, SEBT: star excursion balance test, NR: not reported.

[a,b,c,d]: indicates the selected outcome measure when multiple measures were reported within the same outcome domain, based on the prioritization: relation with the role of the PIMs ([a]), availability of data ([b]), statistical significance ([c]), and effect size ([d]). For example, indication '[d]' means that several outcome measure were considered equally related to the role of the PIMs, the data to determine the SMD was available for more than one of these measures and more than one was statistically significant, of which the measure with the largest effect size was selected for further analysis.

Quality assessment

The results of the quality assessment for 'reporting' and 'internal validity' are shown in Table 3. The median score for 'reporting' was 6 out of 13 (range: 3-11). Three studies [59–61] attained less than half of the points for this category. Almost half of the studies failed to describe the intervention clearly enough and/or lacked to report the losses of patients to follow-up. None of the items for 'external validity' (not displayed in Table 3) could be graded due to the lack of detailed information concerning recruitment procedures and the non-medical setting in which the program took place.

The total score for the category 'internal validity' ranged from 2-12. More than half of the studies was classified as being of 'low' quality [56,58–61], leaving two moderate-quality studies [55,57] and three high-quality RCTs [39,40,54] for data synthesis and quality of evidence assessment. The moderate quality studies consisted of one pre-post interventional study [57] that attained the nearly maximum grade for its design and one RCT [55]. Compared to the high-quality RCTs, the moderate-quality RCT [55] did not clearly describe confounders and the loss of subjects to follow-up. Therefore, the raters were unable to determine if items 25 (i.e., adjustment for confounding) en 26 (i.e., accounting for losses to follow-up) were met by the study, resulting in a zero score on these items. Two RCTs of moderate- [55] and high-quality [54] neither described the degree of adherence or attendance nor the measures taken to promote this behavior. The same two studies did not address blinding of the assessors to the allocated intervention. These studies were the only RCTs that assessed dynamic balance as the outcome of the intervention.

Data synthesis

Five studies were eligible to be included for data synthesis and quality of evidence assessment. Two high quality RCT's [39,40] investigated foot function during gait, whereas dynamic balance was the outcome measure in one high-quality RCT [54], one moderate-quality RCT [55] and one moderate-quality pre-post intervention study [57]. The effects of the interventions on the selected outcome measures are presented in Table 4. The effects of the interventions on other outcomes can be found in Additional file 3 of the online Supplementary Materials.

Table 3: Quality assessment scores on the items of reporting and internal validity.

		Taddei et al. [39]	Okamura et al. [40]	Lynn et al. [54]	Lee and Choi [55]	Mulligan et al. [57]	Tudpor et al. [56]	Lee et al. [58]	Ma et al. [62]	Matsumoto et al. [59]	Kim et al. [60]	Pisal et al. [61]
Reporting	1. Objective	1	1	1	1	1	1	0	1	0	0	0
	2. Main outcomes	1	1	1	1	1	1	1	1	1	1	0
	3. Sample characteristics	1	1	1	1	1	0	0	1	0	1	0
	4. Intervention	1	1	1	0	1	0	0	1	0	0	0
	5. Confounders	2	2	2	0	0	1	0	0	0	0	0
	6. Main findings	1	1	1	1	1	1	1	0	1	1	1
	7. Random variability	1	1	1	1	1	1	0	1	1	0	1
	8. Adverse events	0	0	0	0	0	0	0	1	0	0	0
	9. Lost to follow up	1	1	1	0	1	0	1	1	0	0	0
	10. Actual p-values	1	1	0	0	1	0	1	1	1	0	1
	27. Sample size calculation	0	1	0	0	0	0	1	1	0	0	1
	Total reporting (max. 12)	**10**	**11**	**9**	**6**	**8**	**6**	**6**	**9**	**5**	**3**	**4**
Internal validity	14. Blinding subjects	0	1	0	0	0	0	0	0	0	0	0
	15. Blinding assessors	1	1	0	0	0	0	0	0	0	0	0
	16. Data dredging	1	1	1	1	1	1	1	1	1	1	1
	17. Different lengths of follow-up	0	1	0	1	0	1	0	0	1	0	0
	18. Statistical tests	1	1	1	1	1	1	1	1	1	1	0[a]
	19. Compliance	1	1	0[a]	0[a]	1	0[a]	0[a]	0[a]	0[a]	0[a]	0[a]
	20. Accurate outcome measures	1	1	1	1	1	1	1	1	1	1	1
	21. Same origin of sample	1	1	1	1	0	1	0	0	0	0	0
	22. Same recruitment period	1	1	1	1	0	1	0	0	0	0	0
	23. Randomization	1	1	1	1	0	0	0	0	0	0	0
	24. Concealed assignment	1	1	0	0	0	0	0	0	0	0	0
	25. Confounding	1	1	1	0	0	0	0	0	0	0	0
	26. Lost to follow up	1	1	1	0	0	0	0	0	0	0	0
	Total Internal validity (max. 13)	**12**	**11**	**9**	**7**	**5**	**4**	**4**	**4**	**3**	**3**	**2**

[a] unable to determine. Studies are presented in descending order according to the score on internal validity. Gray shaded cells indicate that items were not applicable to the respective study design.

Table 4: Intervention effects on foot function during gait and running and dynamic balance.

				Intervention group				Control group		Intervention vs. control group		
Study/ Design	**Methodo-logical quality**	**Outcome domain**	**Selected outcome Measure**	**Baseline Mean ± sd**	**Follow-up Mean ± sd**	**Within group mean difference**	**Within group SMD**	**Baseline Mean ± sd**	**Follow-up Mean ± sd**	**Between group difference in change from baseline**	**Between group SMD in change from baseline [c]**	**Narrative summary of findings on PIM strength**
Taddei et al. [39] Randomized controlled trial	High	Foot and ankle biomechanics	MLA ROM (°)	4.2 ± 2.4	3.6 ± 2.3	-0.6	0.26	4.6 ± 2.2	4.6 ± 1.8	-0.6	0.26	MRI assessed PIM volume was significantly increased in IG as opposed to CG, whereas CSA and toe plantar flexion strength remained unchanged
		Ground reaction forces	GRF vertical impulse in second half of stance (N·s)	65.9 ± 7.9	67.9 ± 6.5	2.0	0.28[NR]	74.3 ± 7.0	73.5 ± 6.5	2.8	0.37[†]	
Okamura et al. [40] Randomized controlled trial	High	Foot and ankle biomechanics	Navicular drop (mm)	6.2 ± 1.7	6.2 ± 1.5	0.0	0.00	5.9 ± 2.6	5.4 ± 2.5	0.5	-0.23	US assessed PIM thickness in IG and CG remained unchanged
		Ground reaction forces	GRF vertical in second half of stance (% BW)	109.1 ± 4.5	108.3 ± 5.7	-0.8	-0.16	107.5 ± 6.2	108.4 ± 6.5	-1.7	-0.31	
		Spatiotemporal parameters	Stance phase duration (ms)	610.1 ± 36.8	600.4 ± 34.5	-9.7	0.27	623.6 ± 36.8	618.8 ± 47.1	-4.9	0.13	
Matsumoto et al. [59] Pre-post intervention study	Low	Foot and ankle biomechanics	MLA compression (°)	3.72 ± 6.8	3.65 ± 9.8	-0.07	0.01	n/a	n/a	n/a	n/a	Toe grip strength in IG was significantly increased
		Spatiotemporal parameters	Gait speed (m/s)	0.33 ± 0.02	0.33 ± 0.04	0.00	0.00	n/a	n/a	n/a	n/a	
Lynn et al. [54] Randomized controlled trial	High	Dynamic balance	YBT mediolateral CoP excursion for non-dominant stance leg (mm)	52.4 ± 4.5	43.1 ± 5.1	-9.3	1.83*	47.8 ± 7.8	48.1 ± 5.5	-9.6	1.43[†]	n/a
Lee and Choi [55] Randomized controlled trial	Moderate	Dynamic balance	YBT composite reach distance (% leg length)	66.8 ± 9.6	70.9 ± 8.7	6.1[b]	0.66*	65.4 ± 8.7	66.7 ± 9.1	3.8[b]	0.41[†]	n/a
Mulligan et al. [57] Pre-post intervention study	Moderate	Dynamic balance	SEBT reach distance in medial direction (cm)	57.8 ± 7.4	61.6 ± 6.6	3.8	0.54*	n/a	n/a	n/a	n/a	n/a

Table 4: Continued

Study/ Design	Methodo-logical quality	Outcome domain	Selected outcome Measure	Intervention group				Control group		Intervention vs. control group		Narrative summary of findings on PIM strength
				Baseline Mean ± sd	Follow-up Mean ± sd	Within group mean difference	Within group SMD	Baseline Mean ± sd	Follow-up Mean ± sd	Between group difference in change from baseline	Between group SMD in change from baseline [c]	
Tudpor et al. [56] Non-randomized controlled trial	Low	Dynamic balance	SEBT reach distance in the lateral direction (% leg length)	54.8 ± 5.4[a]	53.6 ± 9.6[a]	-1.2	-0.15	59.0 ± 9.5[a]	55.6 ± 6.9[a]	2.2	0.27	n/a
Lee et al. [58] Pre-post intervention study	Low	Dynamic balance	Medio-lateral center of gravity displacement index score as a response to a moving platform	3.4 ± 1.0	1.5 ± 0.8	-1.9	1.98[NR]	n/a	n/a	n/a	n/a	n/a
Ma et al. [62] Pre-post intervention study	Low	Dynamic balance	YBT composite reach distance (% leg length)	97.0[d] ± 7.5[a,d]	96.0[d] ± 7.5[a,d]	-1.0	-0.13	n/a	n/a	n/a	n/a	n/a
Kim et al. [60] Pre-post intervention study	Low	Dynamic balance	YBT composite reach distance (% leg length)	74.3 ± 8.3	82.4 ± 7.4	8.1	0.97*	n/a	n/a	n/a	n/a	n/a
Pisal et al. [61] Pre-post intervention study	Low	Dynamic balance	YBT reach distance of right leg in posterolateral direction	61.1 ± 5.2	65.1 ± 5.1	4.0	0.78*	n/a	n/a	n/a	n/a	n/a

Studies are sorted by outcome domain and in descending order according to methodological quality. Grey-shaded studies were not included in the data synthesis. † significant group x time interaction effect, * significant effect for time in the intervention group, [NR] significance not reported, sd: standard deviation, SMD: standardized mean difference, PIM: plantar intrinsic foot muscles, MLA: medial longitudinal arch, ROM: range of motion, CoP: center of pressure,

IG: intervention group, CG: control group, CSA: cross-sectional area, GRF: ground reaction force, BW: body weight, US: ultrasound, YBT: Y-balance test, SEBT: star excursion balance test . [a] sd derived from the reported standard error of the mean (SEM) according to the formula: SEM * $\sqrt{n}$, [b] value adopted from the article, [c] positive values indicate an improvement in the outcome measure favoring the intervention and vice versa, [d] value estimated from graph.

Foot function during gait and running

The effect of PIM strengthening exercises on foot function during gait and running was investigated by an 8-week short-foot exercise program in individuals with a pronated foot posture [40] and by a foot and ankle exercise program of the same duration in younger to middle-aged long-distance runners [39].

The results on foot and ankle biomechanics were limited to the effect on MLA motion. Non-significant changes were found in either the navicular drop during gait in healthy young adults with pronated foot posture (SMD: -0.23) [40] or the range of motion in the mid foot joint during running in long-distance runners (SMD: 0.26) [39]. Consequently, there is no evidence supporting the effect of PIM strengthening exercises on MLA kinematics.

Deviating results were found concerning the effect of PIM strengthening exercises on GRF in the late stance phase. Vertical GRF impulse during running push-off was significantly increased in long-distance runners that participated in a foot and ankle exercise program (SMD: 0.37) [39], whereas vertical peak GRF during gait remained unchanged in younger adults with pronated foot posture that were involved in a short-foot exercise program (SMD: -0.31) [40]. The beneficial effect that was found for the foot and ankle exercise intervention was accompanied by an increase in PIM volume [39]. The certainty of evidence for the effect of PIM strengthening exercises on vertical GRF was graded ‘low’ due to the inconsistency in findings and the imprecision of the data (i.e., small sample sizes).

Stance phase duration of gait was the only spatiotemporal parameter eligible for the synthesis and investigated by one study [40]. No effect of the short-foot exercise program was found on this outcome measure (SMD: 0.13) [40].

Dynamic balance control

Both studies that investigated the effect of a 4-week short foot exercise program [54,57] as well as the study in which participants were enrolled in a more comprehensive 6-week PIM exercise program [55] showed a significant improvement in performance on a dynamic balance test in the intervention group (SMD: 0.54-1.83) that was not present in the control group of the RCTs [54,55]. When the statistical non-significant change from baseline on balance performance of the control group was taken into account, the controlled trials [54,55] further demonstrated an SMD of 0.41 for composite reach distance on the Y-balance test in individuals with chronic ankle instability [55] and an SMD of 1.43 for mediolateral displacement of the CoP while performing the SEBT in healthy young adults [54]. These SMDs of the change from baseline between the groups was 9% [55] and 18% [54] lower than the within group SMD of the intervention group for the same studies.

Based on the finding that the one high-quality study [54] also had some methodological shortcomings (e.g., no description of adherence/attendance and blinding of assessor) that led to concerns on the risk of bias, the certainty of evidence was downgraded by two levels. Due to the imprecision of the results (i.e., small sample sizes), the level of evidence for the effect of PIM strengthening intervention on improving dynamic balance was further downgraded to a final grade of 'very low'.

The sensitivity analyses only pertained to studies on the outcome domain of dynamic balance. The level of evidence was not affected by a more progressive or conservative cut-off value for moderate-quality studies.

DISCUSSION

The aim of the study was to provide insight in the evidence for the effect of interventions anticipated to improve PIM strength on dynamic balance control and foot function during gait in adults. Only five studies with small sample sizes were of sufficient methodological quality to be included for data synthesis. This indicates that little is known about the effect of PIM strengthening interventions on fall-related dynamic function. The results were limited to the effects of only strength training interventions in a primarily younger population. Low-certainty evidence revealed the beneficial effect of PIM strengthening exercises on vertical GRF. Very low-certainty evidence showed that PIM strength training improved dynamic balance control. Additionally, there was a lack of evidence for the effect of PIM strengthening exercises on MLA kinematics.

The low-certainty evidence for the beneficial effect of PIM strengthening exercises on vertical GRF impulse was based on the small improvement of this parameter during

running as a result of the intervention in a high-quality proof-of-principle RCT. This improvement was not only accompanied, but also associated, with hypertrophy of the PIMs [39]. Therefore, the effect could be carefully ascribed specifically to the PIM exercises as part of the comprehensive foot and ankle exercise program. PIMs are known to facilitate stiffening the foot during late stance enabling efficient force transmission [26], which could be the mechanisms supporting the finding on increased vertical GRF impulse in healthy long-distance runners [39]. Although the authors did not clarify if the enhanced impulse was the result of increased vertical GRF or an unfavorable prolonged push-off phase, they interpreted the enhanced impulse as less energy consuming and therefore increased amount of GRF is more plausible.

For dynamic balance control, very low-certainty evidence showed improvement after a PIM strengthening program. Although the diverse studies consistently demonstrated an improvement after the intervention, there were not only major concerns on the risk of bias, but also on the instruments and the measures that were used. It is remarkable that a large effect (SMD: 1.43) was only demonstrated by the study with the least concern on all of these aspects [54]. This high-quality study assessed the mediolateral direction of balance, which is most relevant from the perspective of the PIMs. This was also the only study that used highly accurate instrumented equipment (i.e., a force plate) to assess balance during the performance of a leg reach test. In contrast, the other two studies [55,57] manually measured the distance reached by the leg which is merely the result of a movement measured at one instance in time, rather than being a measure of balance control while reaching [63]. This makes it disputable how the reach performance on a dynamic balance test (e.g. SEBT, YBT), which is also predominantly applicable to physically active individuals [64], relates to balance control during gait [65] which is the topic of interest when it comes to the risk of falling.

Whilst the studies that evaluated balance as the outcome of the intervention all applied isolated PIM exercises (e.g., short-foot exercise), none of them additionally assessed PIM strength. This implies that the improvement was not the result of stronger extrinsic foot muscles, nor can it be ascribed to stronger intrinsic foot muscles with certainty. Other mechanisms than strength gains could have mediated the intervention effect, such as improved neuromuscular control [55], proprioception, or plantar sensation [66]. A learning effect also could have occurred as the SMDs of the changes from baseline between groups were only a maximum of 18% smaller than the within group SMDs of the same studies [54,55].

The lack of evidence for the effect of PIM strengthening exercises on MLA kinematics may be explained by the study population in combination with the investigated activities (i.e., gait [40,59] and running [39]). Firstly, there was no indication of abnormal dynamic MLA motion in the selected samples. This also applies to the study of Okamura et al. [40] including participants with pes planus alignment, as a statically assessed foot posture does

not correlate well with the dynamic behavior of the MLA [67]. Secondly, the PIMs seem to contribute only marginally to MLA motion control during loading in gait and running in healthy younger adults [26]. Both of these explanations may have mitigated the effect of the observed gain in toe plantar flexion force [59] or PIM force capacity [39] on MLA motion.

Only one study that met our selection criteria [56] was characterized by a study sample consisting of older adults. However, due to the poor methodological quality it was not included in the synthesis. We revisited the excluded records and found that the limited number of eligible studies in older adults could not be attributed to the criterion to exclude studies in participants presented with pain. The scarcity of studies in older adults is remarkable as this population is known to have diminished PIM force producing capacity [8] and concomitant gait deficiencies that are related to the role of the PIMs. Older adults seem to be as responsive to PIM strength training as younger adults with respect to neural and muscular adaptation [30], but they may potentially benefit more with respect to functional improvements. Whereas younger adults may not use the full capacity of PIM strength during gait, older adults' gait may be more demanding. Stronger PIMs could then sooner result in a corresponding improvement in their gait, which is expected to decrease the risk of falling [5]. Therefore, studies with older adults are merited to build on the evidence for the effect of PIM strengthening exercises on dynamic function in this specific population. Based on the forgoing discussion on the body of evidence, these studies should be of high quality and are recommended to assess meaningful fall-related parameters such as balance capabilities during gait and propulsive force generation.

Strength training for older adults targeting the PIMs involves some additional aspects that need to be taken into account when investigating interventions in this specific population. First, plantar cutaneous somatosensation and proprioception, predominantly in the distal joints, declines with aging [68]. As a consequence, decreased awareness of plantar loading and diminished joint position and motion sense may be encountered. This may encumber the ability to properly execute the required exercise movements and therefore may hamper the effectiveness of training. Second, the motor control of primarily complex tasks is affected in older adults [30]. PIM exercises are complex in nature, illustrated by the learning curve in motor performance of the task [69] and the inability to perform these exercises even by younger adults [70]. Both the diminished afferent information and reduced motor control in combination with the complex nature of PIM exercises underpin the disputability of purely PIM training for strengthening the PIMs in older adults. Enhancing sensory afferent information [70] and providing biofeedback from muscle activity and plantar pressure [41,71] have been suggested for PIM training to overcome these deficits. However, the execution of PIM exercises (e.g., the short-foot exercise) requires a voluntary contraction of the PIMs that is very dissimilar to everyday activities such as walking, adding another challenge regarding the suitability of PIM exercises aiming to improve gait in older adults.

The one study with a significant beneficial effect on gait function [39] consisted of a comprehensive foot and ankle exercise program including heel raising. Such exercises are characteristic for balance and functional training that has been advocated to be the primary kind of training within fall prevention interventions, rather than only resistance training [72]. Indeed, heel raising is a common aspect of fall prevention programs [73–75]. Moreover, older adults who participated in a multifaceted podiatry intervention exhibited a reduced number of falls, and this was predominantly attributed to the foot and ankle exercises [35]. Primarily intended to strengthen the ankle plantar flexor muscles [76], raising the heel off the ground also requires the foot to act as a rigid lever. This may require PIMs to be active in a similar way as compared to when they contribute to foot stiffening for push-off during gait [18,26]. Although common within fall preventions programs, only few studies [32,39,77] investigated the effect of foot and ankle strengthening exercises on fall-related dynamic balance and gait parameters and one study [39] assessed a measure of PIM strength simultaneously. In order to better understand the role of the PIMs in the benefits of functional foot and ankle exercises as components of fall prevention programs and to formulate related recommendations, future studies should evaluate changes in PIM strength or strength capacity next to outcome measures related to dynamic foot function and balance control.

Several limitations of the study need to be taken into account. Most importantly, there was heterogeneity in study populations, interventions and the investigated activities within outcome domains (e.g. walking vs. running). The extent to which studies were similar enough to be grouped together may be questionable. Therefore, the results of this study must be interpreted with caution. However, the diversity in study populations is not expected to have confounded the results to a large extent. The execution of and adherence to the exercises, and thus the intervention effects, is not likely to be influenced by the characteristics of most study populations (e.g., pronated foot posture). On the other hand, it is questionable how this applies to a population of individuals with chronic ankle instability. The one study with this population that was included in the synthesis still showed a significant intervention effect [55]. Regarding the variety of activities of interest, the single significant effect of PIM strengthening exercises on vertical GRF impulse was found for running only [39]. It remains elusive how this can be generalized to walking due to the limited existence of similar studies for walking. Another limitation is that a meta-analysis was not possible due to the unknown variance of changes from baseline for the majority of studies. Therefore, the effect estimates were summarized rather than providing a combined estimate of the average treatment effect. The accompanying drawback of this method is that it does not account for the differences in sample sizes across the studies. This only applied to the outcome domain of dynamic balance, since the sample size of the respective studies varied. Lastly, the pooled pre-intervention standard deviation was chosen as an alternative for the denominator in the SMD calculation of the changes from baseline. However, it is expected that this standard deviation is smaller than that of the

change from baseline, as was apparent in the study of Lee and Choi [55]. Therefore, it is likely that the reported SMDs underestimated the true SMDs.

CONCLUSION

This review revealed at best low-certainty evidence that PIM strengthening exercises improve foot function during gait and very low-certainty evidence for its favorable effect on dynamic balance control. This was based on the findings from a limited number of high-quality studies with small samples of primarily healthy younger adults. In order to build on the body of evidence for strengthening the PIMs from the perspective of the prevention of falling, there is a need for high-quality studies that aim to investigate the effect of functional strengthening exercises targeting the PIMs in large samples of older adults. The outcome measures should be related to either fall risk and the role of the PIMs such as propulsive forces or balance during walking in conjunction with PIM strength measures.

LIST OF ABBREVIATIONS

PIM: plantar intrinsic foot muscle; CoP: center of pressure; MLA: medial longitudinal foot arch; RCT: randomized controlled trial; GRF: ground reaction force; SMD: standardized mean difference; diff: difference; SEBT: star excursion balance test; YBT: Y balance test.

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DECLARATIONS

Availability of data and materials

All data generated or analyzed during this study are included in this published article and its additional files.

Competing interest

The authors declare that they have no competing interests.

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Authors' contribution

LW, EW, MP and BV conceptualized the study, designed the methodology and acquired the funding. LW en HB collected the data. LW performed the data analysis and managed the data. LW wrote the initial draft, which was reviewed and edited by EW, HB, MP and BV. All research activities were supervised by EW, MP and BV.

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SUPPLEMENTARY MATERIALS

Supplementary Material 3A: Search strategies for each database

Pubmed

#1 "exercise therapy" [MeSH Terms] OR "resistance training" [MeSH Terms] OR exercise OR strengthening OR shoes OR footwear OR barefoot OR foot ortho* OR insole* OR inlay*

#2 doming OR "short foot" OR "foot core" OR foot musc* OR intrinsic foot OR plantar musc* OR toe musc* OR hallu* muscle

#3 postur* balance OR postur* stability OR postur* control OR stance balance OR stance stability OR stance control OR dynamic* OR function* OR gait OR walking OR locomotion OR running

#4 #1 AND #2 AND #3

#5 stroke OR "multiple sclerosis" OR "cerebral palsy"

#6 #4 NOT #5, "Humans, Dutch, English, from 2010-2020"

CINAHL Plus with Full Text (EBSCOhost interface)

#1 MH "Muscle Strengthening+" OR exercise OR strengthening OR shoes OR footwear OR barefoot OR foot ortho* OR insole* OR inlay*

#2 doming OR "short foot" OR "foot core" OR foot musc* OR intrinsic foot OR plantar musc* OR toe musc* OR hallu* muscle

#3 postur* balance OR postur* stability OR postur* control OR stance balance OR stance stability OR stance control OR dynamic* OR function* OR gait OR walking OR locomotion OR running

#4 #1 AND #2 AND #3

#5 stroke OR "multiple sclerosis" OR "cerebral palsy"

#6 #4 NOT #5, Limiters - Published Date: 20100101-20200731; Peer Reviewed; English Language; Expanders – Apply related words; Also search within the full text of the articles; Apply equivalent subjects Search modes - Boolean/Phrase

SPORTDiscus with Full Text (EBSCOhost interface)

#1 DE "STRENGTH training" OR DE "EXERCISE therapy" OR DE "RESISTANCE training" OR exercise OR strengthening OR shoes OR footwear OR barefoot OR foot ortho* OR insole* OR inlay*

#2 doming OR "short foot" OR "foot core" OR foot musc* OR intrinsic foot OR plantar musc* OR toe musc* OR hallu* muscle

#3 postur* balance OR postur* stability OR postur* control OR stance balance OR stance stability OR stance control OR dynamic* OR function* OR gait OR walking OR locomotion OR running

#4 #1 AND #2 AND #3

#5 stroke OR "multiple sclerosis" OR "cerebral palsy"

#6 #4 NOT #5, Limiters - Published Date: 20100101-20200731; Peer Reviewed; Language: English; Publication Type: Academic Journal; Document Type: Article, Expanders – Apply related words; Also search within the full text of the articles; Apply equivalent subjects Search modes - Boolean/Phrase

PEDro

Abstract & Title: foot

Therapy: strength training; orthoses, taping, splinting

Body Part: foot or ankle

Subdiscipline: musculoskeletal

Web of Science

#1 TS="resistance training" OR TS=exercise OR TS=strengthening OR TS=shoes OR TS=footwear OR TS=barefoot OR TS=foot ortho* OR TS=insole* OR TS=inlay*

#2 TS=doming OR TS= "short foot" OR TS= "foot core" OR TS=foot musc* OR TS=intrinsic foot OR TS=plantar musc* OR TS=toe musc* OR TS=hallu* muscle

#3 TS=postur* balance OR TS=postur* stability OR TS=postur* control OR TS=stance balance OR TS=stance stability OR TS=stance control OR TS=dynamic* OR TS=function* OR TS=gait OR TS=walking OR TS=locomotion OR TS=running

#4 #1 AND #2 AND #3

#5 TS=stroke OR TS= "multiple sclerosis" OR TS= "cerebral palsy"

#6 #4 NOT #5

#7 #6 *AND* LANGUAGE: (English OR Dutch) *AND* DOCUMENT TYPES: (Article)

Supplementary Material 3B: Modified Downs & Black checklist as it was used to assess the quality of the studies included in the review

REPORTING: "Yes=1," "No=0"; maximum score: 12	Instructions from the Downs & Black checklist	Additional instructions for how the items were applied in the current review to:	
		RCTs	Pre-post intervention studies
1. Is the hypothesis / aim / objective of the study clearly described?			
2. Are the main outcomes to be measured clearly described in the Introduction or Methods section	If the main outcomes are first mentioned in the Results section, the question should be answered no.		
3. Are the characteristics of the patients / samples included in the study clearly described?	In cohort studies and trials, inclusion and/or exclusion criteria should be given.		
4. Are the interventions of interest clearly described?	Treatments and placebo (where relevant) that are to be compared should be clearly described.		
5. Are the distributions of principal confounders in each group of subjects to be compared clearly described? "Yes=2," "Partially=1," "No=0"	A list of principal confounders is provided.	'partially' when it is not clear if confounding characteristics were statistically different between groups	n/a
6. Are the main findings of the study clearly described?	Simple outcome data (including denominators and numerators) should be reported for all major findings so that the reader can check the major analyses and conclusions. (This question does not cover statistical tests which are considered below).		

Supplementary Material 3B: Continued

REPORTING: "Yes=1," "No=0"; maximum score: 12	Instructions from the Downs & Black checklist	Additional instructions for how the items were applied in the current review to:	
		RCTs	Pre-post intervention studies
7. Does the study provide estimates of the random variability in the data for the main outcomes?	In non-normally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered yes.	Main outcomes were seen as the baseline and post-intervention measures for both groups	Main outcomes were seen as the baseline and post-intervention measures
8. Have all important adverse events that may be a consequence of the intervention been reported?	This should be answered yes if the study demonstrates that there was a comprehensive attempt to measure adverse events. (A list of possible adverse events is provided).	e.g., discomfort, convulsion, injury 'yes' if stated that no adverse events occurred	idem
9. Have the characteristics of patients lost to follow-up been described?	This should be answered yes where there were no losses to follow-up or where losses to follow-up were so small that findings would be unaffected by their inclusion. This should be answered 'no' where a study does not report the number of patients lost to follow-up.	'no' when losses to follow-up were not reported	idem
10. Have actual probability values been reported (e.g., 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?		Applies to the main outcomes of the study as opposed to the outcomes relevant to our review 'yes' when at least two decimals are presented	idem
27. Is the sample size calculation reported?			

Supplementary Material 3B: Continued

EXTERNAL VALIDITY: "Yes=1," "No=0," "Unable to determine=0"; maximum score: 3		Instructions from the Downs & Black checklist	Additional instructions for how the items were applied in the current review to:	
			RCTs	Pre-post intervention studies
11	Were the subjects asked to participate in the study representative of the entire population from which they were recruited?	The study must identify the source population for patients and describe how the patients were selected. Patients would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample. Random sampling is only feasible where a list of all members of the relevant population exists. Where a study does not report the proportion of the source population from which the patients are derived, the question should be answered as unable to determine.	'unable to determine' when procedure and/or place of recruitment is not specified	idem
12.	Were those subjects who were prepared to participate representative of the entire population from which they were recruited?	The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population.	'unable to determine' when the number of participants is not given as a proportion to the number of recruited individuals	idem
13.	Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?	For the question to be answered yes the study should demonstrate that the intervention was representative of that in use in the source population. The question should be answered no if, for example, the intervention was undertaken in a specialist centre unrepresentative of the hospitals most of the source population would attend.	'unable to determine' when the background or profession of the instructor/therapist that provide the intervention is not clear or when the setting of the intervention is not stated	idem

Supplementary Material 3B: Continued

INTERNAL VALIDITY: "Yes=1," "No=0," "Unable to determine=0"; maximum score: 13		Instructions from the Downs & Black checklist	Additional instructions for how the items were applied in the current review to:	
			RCTs	Pre-post intervention studies
14.	Was an attempt made to blind study subjects to the intervention they have received?	For studies where the patients would have no way of knowing which intervention they received, this should be answered yes.	'no', because participants are always aware of the intervention in this context	idem
15.	Was an attempt made to blind those measuring the main outcomes of the intervention?		'no', when blinding is not addressed	n/a for studies with only one intervention. Otherwise, 'no', when blinding is not addressed
16.	If any of the results of the study were based on "data dredging" was this made clear?	Any analyses that had not been planned at the outset of the study should be clearly indicated. If no retrospective unplanned subgroup analyses were reported, then answer yes.		
17.	In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls?	Where follow-up was the same for all study patients the answer should yes. If different lengths of follow-up were adjusted for by, for example, survival analysis the answer should be yes. Studies where differences in follow-up are ignored should be answered no.		n/a, as this assessment applies to a between-group comparison
18.	Were the statistical tests used to assess the main outcomes appropriate?	The statistical techniques used must be appropriate to the data. For example non- parametric methods should be used for small sample sizes. Where little statistical analysis has been undertaken but where there is no evidence of bias, the question should be answered yes. If the distribution of the data (normal or not) is not described it must be assumed that the estimates used were appropriate and the question should be answered yes.	'no' when only t-tests were performed without correction for baseline-differences	

Supplementary Material 3B: Continued

INTERNAL VALIDITY: "Yes=1," "No=0," "Unable to determine=0"; maximum score: 13	Instructions from the Downs & Black checklist	Additional instructions for how the items were applied in the current review to:	
		RCTs	Pre-post intervention studies
19. Was compliance with the intervention/s reliable?	Where there was non-compliance with the allocated treatment or where there was contamination of one group, the question should be answered no. For studies where the effect of any misclassification was likely to bias any association to the null, the question should be answered yes.	'unable to determine', when nothing is mentioned about compliance/ attendance 'yes' when compliance/ attendance is similar across groups	'unable to determine', when nothing is mentioned about refraining from other forms of training outside the intervention
20. Were the main outcome measures used accurate (valid and reliable)?	For studies where the outcome measures are clearly described, the question should be answered yes. For studies which refer to other work or that demonstrates the outcome measures are accurate, the question should be answered as yes.		
21. Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?	For example, patients for all comparison groups should be selected from the same hospital. The question should be answered unable to determine for cohort and case-control studies where there is no information concerning the source of patients included in the study.	'yes' or randomization would have been impossible	n/a
22. Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time?	For a study which does not specify the time period over which patients were recruited, the question should be answered as unable to determine.	'yes' or randomization would have been impossible	n/a

Supplementary Material 3B: Continued

INTERNAL VALIDITY: "Yes=1," "No=0," "Unable to determine=0"; maximum score: 13	Instructions from the Downs & Black checklist	Additional instructions for how the items were applied in the current review to:	
		RCTs	Pre-post intervention studies
23. Were study subjects randomized to intervention groups?	Studies which state that subjects were randomised should be answered yes except where method of randomisation would not ensure random allocation. For example alternate allocation would score no be- cause it is predictable.	'yes' even though the method use to randomize is not clear	n/a
24. Was the randomized intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?	All non-randomised studies should be answered no. If assignment was concealed from patients but not from staff, it should be answered no.	'yes' if no other persons, than the therapist/ instructor, with influence on the participant and/or intervention knows about the allocation 'no' if this topic is not addressed at all	n/a
25. Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?	This question should be answered no for trials if: the main conclusions of the study were based on analyses of treatment rather than intention to treat; the distribution of known confounders in the different treatment groups was not described; or the distribution of known confounders differed between the treatment groups but was not taken into account in the analyses. In non- randomised studies if the effect of the main confounders was not investigated or con- founding was demonstrated but no adjustment was made in the final analyses the question should be answered as no.	'unable to determine' if the degree of compliance/ attendance is not reported 'unable to determine', when it is not clear if confounding characteristics were statistically different between groups	n/a
26. Were losses of patients to follow-up taken into account?	If the numbers of patients lost to follow-up are not reported, the question should be answered as unable to determine. If the proportion lost to follow-up was too small to affect the main findings, the question should be answered yes.		

Plantar Intrinsic Foot Muscle Activation during Functional Exercises compared to Isolated Foot Exercises in Younger Adults (study 3).

Published as:
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4

ABSTRACT

Background: Training the plantar intrinsic foot muscles (PIMs) has the potential to benefit patients with lower extremity musculoskeletal conditions as well as the aged population. Isolated foot exercises, often standard in clinical practice, are difficult to perform, whereas functional exercises are much easier to accomplish. However, it is unclear whether functional exercises are comparable to isolated foot exercises in activating the PIMs.

Objective: This study aims to compare the activation of PIMs between functional exercises versus isolated foot exercises.

Methods: Using surface electromyography (EMG), muscle activation of three PIMs was measured in four functional exercises (i.e., normal/unstable toe stance, toe walking, hopping) versus a muscle-specific isolated foot exercise in 29 younger adults, resulting in 12 comparisons.

Results: Functional exercises showed larger mean EMG amplitudes than the isolated foot exercises in 25% of the 12 comparisons, while there was no difference in the remaining 75%.

Conclusion: Functional exercises provoked comparable or even more activation of the PIMs than isolated foot exercises. Given that functional exercises are easier to perform, this finding indicates the need to further investigate the effectiveness of functional exercises in physical therapy to improve muscle function and functional task performance in populations that suffer from PIM weakness or dysfunction.

INTRODUCTION

Changes in plantar intrinsic foot muscle (PIM) morphology or dysfunction are associated with ageing [1] as well as with several lower extremity conditions (e.g., plantar fasciitis [2], Achilles tendinopathy [3], chronic ankle instability [4], hallux valgus [5,6], symptomatic pronated feet [7], and diabetic neuropathy [8]). Active contraction of these PIMs is related to controlling the mediolongitudinal foot arch when loaded [9] or balancing [10,11] as well as to stiffening the foot during push off [12]. Training the PIMs to improve these functions could benefit younger and older adults. However, the involvement of these specific muscles in foot exercises is yet understudied. Therefore, and to get a better understanding of the effectiveness of certain exercises to train the PIMs, the evaluation of muscle activation is needed.

Rehabilitation and prevention of PIM related conditions, or its secondary implications, generally involve prescription of exercises to strengthen the PIMs or to improve their function [13,14]. Due to the overlap in osteokinematic function between extrinsic and intrinsic foot muscles [15], isolated foot exercises that involve toe flexion (i.e., traditional foot exercises such as towel-curl and marble pick-up) allow the extrinsic foot muscles to compensate for intrinsic foot muscle weakness or dysfunction. In an attempt to exclude extrinsic foot muscle's contribution, isolated foot exercises (e.g., short foot exercise, toe spread-out exercise) have been designed that specifically target the PIMs in isolation. Studies that investigated the effects of these exercises demonstrated increased toe flexor strength [16,17], but without structural changes of the PIMs being observed [17]. Regarding biomechanical parameters, divergent results have been reported for the effect on foot function and balance control during gait [18]. The absence of structural adaptations and functional training results may be ascribed to constraints that are inherent to PIM training, such as the difficulty to perform PIM exercises and the dissimilarity with daily or sports activities. This is a clear argument to consider exercises that are more functional in nature.

Whereas functional exercises are based on automated motor control, the performance of PIM exercises requires a certain level of voluntary fine motor control. Even after training, this skill is insufficiently developed in a considerable subset of individuals [19,20], which inhibits the ability to correctly contract selected muscles, hampering the effectiveness of the exercises. In addition, the perceived difficulty is likely to impede exercise adherence [21]. In contrast, the more traditional isolated foot exercises (e.g., towel-curl, marble pick-up) are easier to accomplish and also target the PIMs [22]. However, as these exercises are characterized by a toe flexion movement, it is unclear to what extent these concentric exercises are effective in activating the PIMs in addition to the extrinsic toe flexor muscles, known as the primary toe movers [23].

Functional exercises, as opposed to isolated foot exercises (i.e., both traditional and PIM exercises), are habitual movements and challenge the PIMs the way these muscles act in usual daily activities or sports activities. For instance, tasks in daily life are accomplished

by a high level of coordinated neuromuscular control, which is reflected in functional exercises. Moreover, these tasks are often performed weight bearing, whereas isolated foot exercises usually are not. Specifically for the PIMs, these muscles behave eccentrically and concentrically in an alternated fashion during walking [24], as opposed to the primarily concentric contractions during isolated foot exercises. In addition, although PIMs are believed to contribute to balance by producing grip force [25,26], isolated foot exercises barely challenge the postural system. These discrepancies between how the PIMs act in these foot exercises compared to daily life activities can be defeated by increasing the functionality of the training and increasing the postural demand. Indeed, single leg stance and toe walking intensified the activation levels of the PIMs compared to double leg stance and regular walking, respectively [11,27]. Exercises that bring the center of pressure maximally distal to the metatarsophalangeal (MTP) joints might also be effective in increasing PIM activation. This is because these muscles, spanning the MTP joints, are then maximally forced to produce a toe flexion moment to resist the external moment generated by the ground reaction force and its larger moment arm. Likewise, tasks that require the body's center of mass to be raised or accelerated are potentially effective as these conditions challenge the PIMs in the role they have in functional activities [28,29].

In order to better design exercise interventions that effectively target the PIMs, insight in the activation of PIMs in functional exercises compared to isolated foot exercises is needed. Although some efforts have been made to examine PIM activation across various foot exercises [20,30–34], no studies exist that compared the effects of isolated foot exercises with functional exercises. Considering the potential of functional exercises in activating the PIMs and the limited scope of the existing literature, the current study primarily aims to compare the mean muscle activation of PIMs across functional and isolated foot exercises. In addition, we examined if several repetitions of dynamic functional exercises are needed to approximate the isolated foot exercises in terms of muscle activation integrated over time, because of the shorter bursts of muscle activation in these dynamic activities. As a secondary aim, we determined the effect of two variations of foot exercises on the activation of the PIMs. To this end, we examined if PIM activation increases when the exercise is isometric compared to concentric and when the center of pressure is brought more distally to the MTP joints.

MATERIALS AND METHODS

Design

To compare PIM activation across exercises performed within the same laboratory session, a crossover experimental design was used. Surface electromyography (sEMG) with ultrasound-guided placement of the electrodes was used to evaluate the immediate effect on muscle activation.

Participants

Participants were recruited by convenience sampling among students and staff members of the Fontys University of Applied Sciences, Eindhoven, the Netherlands (hereafter referred to as Fontys). Individuals were eligible when aged between 18 and 40 years, to ensure that the nervous system and motor unit characteristics are not affected by ageing [35–37]. Individuals who reported to have current lower extremity musculoskeletal symptoms, neurological or neuromuscular conditions, severe foot deformities (i.e., clubfoot or deformities that hinder daily life activities), or those with a history of trauma or surgical treatment of the lower extremity were excluded from participation. To avoid interference with the EMG equipment, individuals with implanted electronic devices, irritated skin, or with allergies to silver were also excluded. After giving verbal and written information, each participant provided written informed consent to participate in the study. The study population consisted of 29 participants (21 women, 8 men) with a mean age of 23.3 (sd: 3.8) years. The institutional ethics committee of Fontys confirmed that the protocol is in accordance with the European Code of Conduct for Research Integrity (registration number: 85willemse30082022).

Experimental procedures

All measurements were taken from the limb the participant chose most often as the supporting limb (i.e., dominant stance limb), when asked three times to stand on one leg.

To assess foot arch morphology and mobility, the foot was scanned with a 3D scanner (Tiger, Materialise, Leuven, Belgium) in a sitting position (i.e., ~10% weight bearing) and in single leg stance while lightly holding a bar to remain balanced (i.e., ~90% weight bearing) [38]. The knee was kept aligned with the ankle joint. From these scans the arch height index (AHI), a measure for foot posture, and the relative arch deformation (RAD), reflecting arch mobility, were estimated [38]. The AHI was calculated for both loading conditions as the ratio of the dorsum height at 50% of total foot length to the truncated foot length (i.e., total foot length minus the toes) [39]. The RAD was calculated as the difference in dorsum height between both weight bearing conditions, divided by the dorsum height in the 90% loaded condition and normalized to body weight (BW) by multiplying with 10^4/BW [38]. For each foot arch variable, the mean of three trials was taken as the final value to describe the study population in terms of foot arch characteristics. This data analysis was done using a custom-made Matlab R2020b script (Mathworks, Natick, MA, USA). The manual assessment of these foot arch variables previously showed good intra-tester en inter-tester reliability (ICC > 0.8) and fair validity with radiographic measurements (ICC >0.7) [38].

We collected activation data of four muscles with sEMG equipment (Trigno (Quattro sensor), Delsys inc., Natick, MA, USA). Three superficial PIMs were selected with closest proximity to the mediolongitudinal arch: m. abductor hallucis (AbH), m. flexor digitorum brevis (FDB) and m. flexor hallucis brevis (FHB). In addition, to answer one of the secondary

research questions, m. flexor hallucis longus (FHL) was selected to represent the extrinsic toe flexor muscles, because of its accessible muscle belly.

The electrode position for AbH and FHL was at the location of the muscle belly which was identified by using ultrasound [40] (Lumify, Philips Healthcare Inc., Bothell, WA,USA), because of the inter-individual variation in alignment of these muscles observed in our previous ultrasound study [41]. According to our scan protocol [41], the electrode position for AbH on its muscle belly was located by scanning the muscle in the longitudinal direction from the origin on the medial process of the calcaneal tuberosity towards just inferior to the navicular tuberosity. The electrode position for the FHL was just distal to the soleus insertion onto the Achilles tendon [42,43]. This reference point was imaged by first scanning the FHL from the medial side in the transverse plane just superior to the medial malleolus, then rotating the probe 90 degrees and, if necessary, sliding the probe in longitudinal direction. The electrode position for FHB and FDB was based on palpating anatomical bony landmarks [40]. For FHB, the electrode position was on the plantar side of the foot, midway the first metatarsal shaft [40], indicated by a line drawn between the medial process of the calcaneal tuberosity and the first MTP joint (Figure 1). The electrode position for FDB was the intersect between the line drawn from the medial process of the calcaneal tuberosity to the second ray and the line traced from the navicular tuberosity perpendicular to the long axis of the foot [40] (Figure 1).

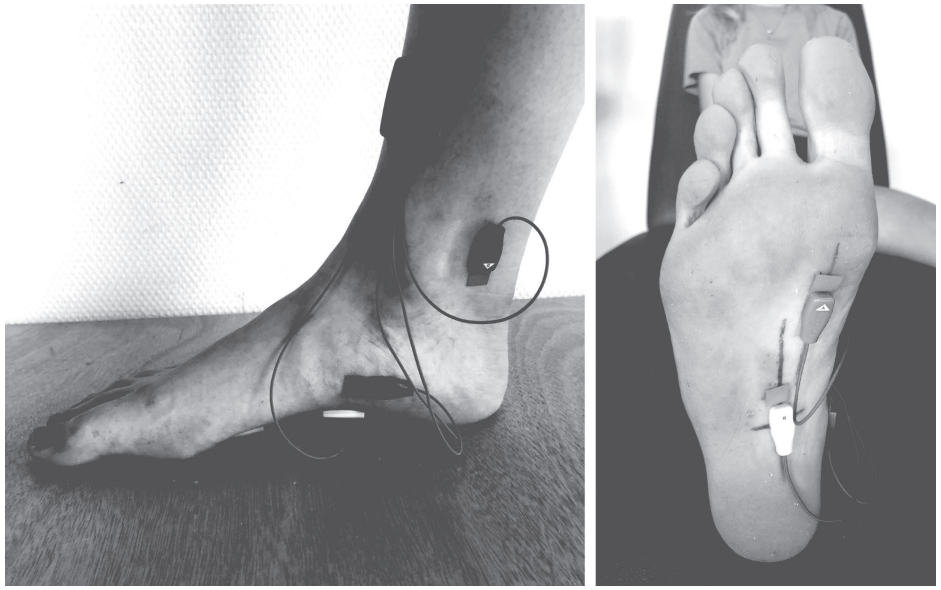


Figure 1: Electromyography electrode positions. The left picture shows the electrode positions for the (from proximal to distal) flexor hallucis longus, abductor hallucis, flexor digitorum brevis and flexor hallucis brevis. The right picture shows the electrode positions for flexor digitorum brevis (proximal electrode) and flexor hallucis brevis (distal electrode).

The skin at the identified electrode positions was prepared for optimal conduction of the electrical signal from the muscles to the electrodes. To this end, hair was removed and the skin rubbed with a hypoallergic abrasive paste aimed to clean the skin and to remove any impeding dead skin cells. The granular residue of the paste was removed by dabbing the skin with medical tape. The electrodes were attached to the skin with double sided adhesives and oriented parallel to the longitudinal direction of the muscle fibers. The sensor head (i.e., reference electrode) was placed on the medial aspect of the tibia (Figure 1).

Figure 2 shows the exercises of the experimental protocol. The series of exercises started with the reference exercise that was used to normalize the EMG amplitude for the experimental exercises. For the reference exercise, the participant was instructed to place the ball of the foot against the edge of a step, maintaining the plantar side of the foot parallel to the step surface, while holding a vertical post to stay balanced. Pilot testing showed that this exercise provokes higher levels of activation for all four muscles simultaneously compared to the muscle-specific reference exercises proposed by Kendall (2010) [44]. The protocol further consisted of five static isolated foot exercises (i.e., four PIM exercises and one traditional foot exercise) and four functional exercises (i.e., two static and two dynamic). The PIM exercises consisted of 'hallux grip' and 'lesser toe grip', 'toe spread-out' and 'short foot'. The traditional isolated foot exercise was the 'toe-curl' as this is characterized by an extensive toe flexion motion (i.e., concentric exercise). The static functional exercises were 'single leg toe stance', with and without forward lean on a firm surface, and single leg toe stance on a compliant surface (green-level balance pad, Theraband, Akron, OH, USA). The dynamic functional exercises consisted of 'toe walking' and 'hopping' in place. Due to the increasing risk of sensor detachment with exercise type (i.e., static foot exercise, static functional exercise, dynamic functional exercise), the order of exercise type was fixed, but to avoid as much as possible systematic error, the exercise order within the exercise types was random.

After the researcher had given verbal instruction about the exercise (Figure 2), the participant was allowed to practice the exercise once. Then, for each static exercise, three trials with approximately a 5-second contraction were performed with a 20-second rest period between the trials. The rest period between the exercises was 1 minute. The researcher verbally encouraged the participant to achieve maximal effort during the exercises. For the dynamic exercises, three consecutive repetitions were performed within one recording. Each recording ended with relaxed muscle status. The researcher rated the motor performance for each exercise on a 3-point scale (0 = does not initiate movement or starting position cannot be maintained; 1 = completes the exercise partially or with compensations, slowness, or obvious clumsiness; and 2 = completes the exercise with a standard pattern), modified from [19]. Trials with motor performance score < 2 were not included in the analysis. This is because ideally, the exercise performance is a learned skill in an intervention setting which is where we aim to do recommendations for. Each participant attained the

maximum motor performance score for the functional exercises. The distribution of this score for the isolated foot exercises is shown in Supplementary Material 4A.

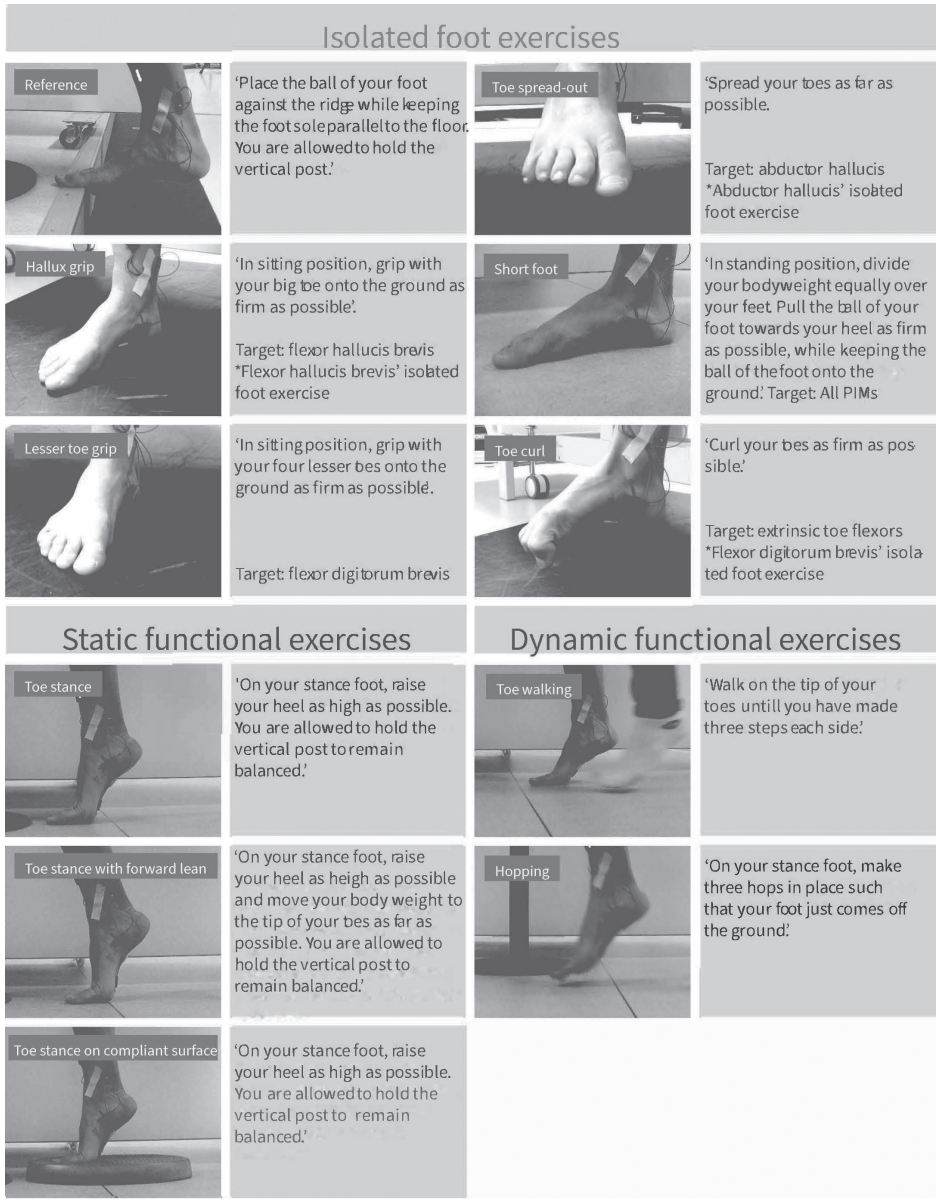


Figure 2: Exercises that were included in the protocol with the instructions verbally provided to the participants. For each isolated exercise, it is indicated which muscle (group) is targeted by the exercise. * indicates the muscle-specific isolated foot exercise that was used for the comparison with functional exercises (i.e., the isolated foot exercise that provoked the largest mean EMG amplitude for the corresponding muscle). PIMs: plantar intrinsic foot muscles.

Data acquisition and post-processing

EMG data for trials in which the sensor(s) detached were abandoned for further analysis (Supplementary Material 4B). The acquired EMG signals (EMGworks acquisition software, Delsys inc., Natick, MA, USA; 2222 Hz sample rate, bandwidth: 20-450 Hz) were processed in Matlab R2020b (Mathworks, Natick, MA, USA). First, the offset was subtracted from the signal. Then, a 6th order 140 Hz high-pass Butterworth filter was applied to attenuate low-frequency signal power [45] and the rectified resulting signal was smoothed to an EMG envelope with a 2nd order 1Hz low-pass Butterworth filter without phase lag [45].

The same onset and termination of the exercise for all muscles together was manually selected from the rectified high-pass filtered signals for each of the trials [46] (Supplementary Material 4C). First, the muscle with the most profound EMG signal was selected. This was the FHL, except for the isolated PIM exercises (i.e., FHB for hallux grip, FDB for lesser toe grip, AbH for toe spread-out). Using the EMG signal of that muscle, the onset of the exercise was determined as the moment where the EMG amplitude started to substantially increase and the termination was the point where the EMG amplitude returned to a resting level [46].

The EMG envelope for each exercise trial was expressed relative to the reference exercise. Two EMG amplitude parameters were then extracted. To compare the activation level of the muscles across the exercises, the mean amplitude (in %) over the exercise duration was used. However, the difference in exercise duration between static and dynamic exercises is not reflected in this parameter. Because contraction time also determines exercise effectiveness [47], the EMG amplitude integrated over time (iEMG in %·s) was calculated as well. For static exercises, iEMG was calculated for the middle 3 seconds of the exercise interval [48] to account for the variability in exercise duration. See Supplementary Material 4C for a visualization of the extracted parameters. The mean of the EMG amplitude parameters over the three trials was used for further analysis.

For the comparison with the functional exercises, one muscle-specific isolated foot exercise was selected. This was the exercise that provoked the largest mean EMG amplitude for that specific PIM. The muscle-specific isolated foot exercise was the hallux grip for the FHB, toe curl for the FDB and toe spread-out for the AbH (Figure 2). Supplementary Material 4D shows the mean EMG amplitude across all exercises in descending order of the median value.

The mean EMG amplitude and the iEMG was compared between the muscle-specific isolated foot exercise and the four functional exercises (i.e., toe stance, toe stance on a compliant surface, toe walking, hopping). The iEMG was only compared for dynamic functional exercises (i.e., toe walking, hopping), because the duration of the static functional exercises is invariant to the muscle-specific isolated foot exercise for this comparison.

Statistical analysis

SPSS 28.0 (IBM, Chicago, IL, USA) was used to analyze the data statistically. Since normal distribution was not satisfied in the majority of the dependent variables, Wilcoxon signed rank tests (α=0.05, one-tailed) were performed for each of the three PIMs to statistically test the difference in the mean EMG amplitude as well as in the iEMG between the isolated foot exercises and the functional exercises. The *p*-values were corrected for multiple testing (18 comparisons) using the Holm-Bonferroni approach. In case of differences in iEMG between the muscle-specific isolated foot exercise and functional exercises, it was also deduced from this parameter how many exercise repetitions were needed for comparable iEMG.

To compare the muscle activation between concentric and isometric foot exercises, the mean EMG amplitude was compared between the toe curl exercise (i.e., a concentric exercise) and the toe grip exercise (i.e., an isometric exercise; hallux grip for FHB, AbH and FHL; lesser toe grip for FDB). To test if PIM activation increases when body weight is brought more anteriorly to the MTP joints, normal single leg toe stance was compared with single leg toe stance with a forward lean. For each of these secondary questions a Wilcoxon signed rank test (α=0.05, one-tailed) was performed for each muscle (4 for toe curl vs toe grip; 3 for toe stance vs. toe stance with forward lean). The *p*-values were corrected for multiple testing using the Holm-Bonferroni approach.

RESULTS

Table 1 shows the demographics of the study population. The study population consisted of 29 participants (21 female and 8 male) with a mean age of 23.3 (sd: 3.8) years.

Table 1: demographics of the study population (n=29)

Variable	Mean ± sd; frequency (%)
Gender (F/M)	21 (72%) / 8 (28%)
Age (years)	23.3 ± 3.8
Body length (cm)	174 ± 11
BMI (kg/m²)	23.3 ± 3.1
Dominant stance limb (L/R)	9 (31%) / 20 (69%)
Arch Height Index, unloaded	0.38 ± 0.03
Arch Height Index, loaded	0.36 ± 0.03
Relative Arch Deformation (N^{-1})	7.8 ± 3.1

F: female, M: male, BMI: body mass index, L: left, R: right, sd: standard deviation

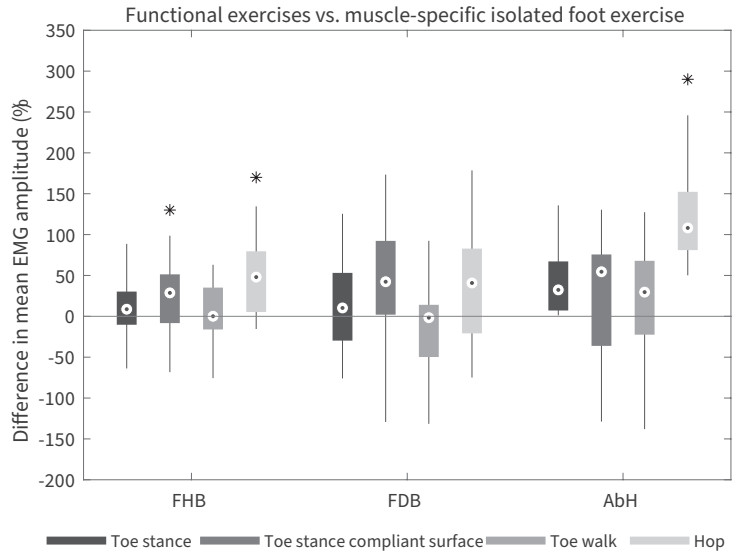
Figure 3 illustrates the median within-subject differences in the EMG amplitude parameters between the muscle-specific isolated foot exercise and each of the functional exercises.

Table 2 presents the absolute group's EMG amplitude parameters for each of the investigated exercises. Of the 12 comparisons, 3 showed a significantly greater mean EMG amplitude for the functional exercises and 9 comparisons showed similar activation between the muscle-specific isolated foot exercise and each of the functional exercises. During hopping, FHB and AbH exhibited a significantly larger mean EMG amplitude than during the muscle-specific isolated foot exercise (FHB – median difference: 48%, IQR: 4 to 80%, $p < 0.05$; AbH – median difference: 108%, IQR: 79 to 153%, $p < 0.05$). In addition, toe stance on a compliant surface showed a larger mean EMG amplitude for FHB compared to the muscle-specific isolated foot exercise (median difference: 29%, IQR: -9 to 54%, $p < 0.05$).

Table 2: Median (mdn) and interquartile ranges (IQR) for the mean electromyography (EMG) amplitude and the EMG amplitude integrated over time (iEMG) during the muscle-specific isolated foot exercise and functional exercises.

	Muscle-specific isolated foot exercise		Toe stance		Toe stance compliant surface		Toe walk		Hop	
	Mdn	**IQR**	**Mdn**	**IQR**	**Mdn**	**IQR**	**Mdn**	**IQR**	**Mdn**	**IQR**
EMG mean (%)										
Flexor hallucis brevis	56	46-92	74	44-96	92	69-121	64	49-82	109	77-145
Flexor digitorum brevis	60	35-119	77	54-109	111	86-164	59	40-79	114	73-209
Abductor hallucis	32	16-123	83	55-118	100	72-149	69	46-126	170	97-281
iEMG (%·s)										
Flexor hallucis brevis	173	141-296	n/a	n/a	n/a	n/a	64	48-82	21	15-34
Flexor digitorum brevis	189	95-329	n/a	n/a	n/a	n/a	55	42-83	25	15-43
Abductor hallucis	77	48-378	n/a	n/a	n/a	n/a	65	36-142	35	23-62

The muscle-specific isolated foot exercises were hallux grip for the flexor hallucis brevis, toe curl for the flexor digitorum brevis and toe spread-out for the abductor hallucis. Mdn: median, IQR: interquartile range, EMG: electromyography, iEMG: electromyography amplitude integrated over time, n/a: not applicable.



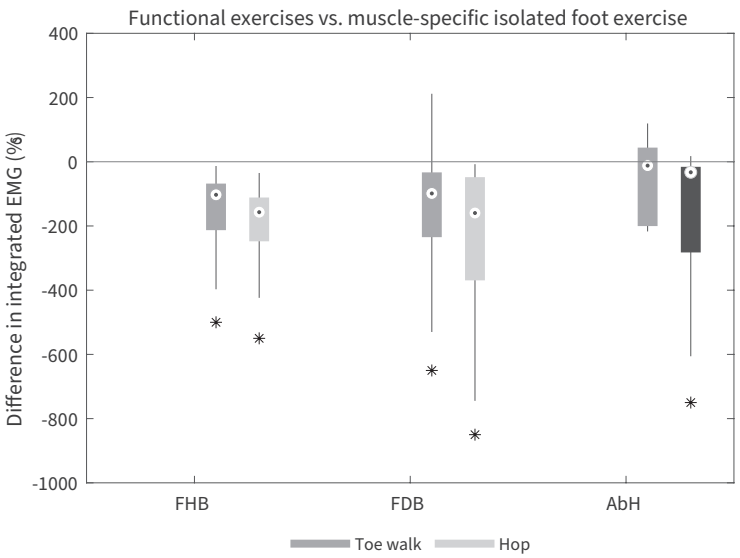


Figure 3: Median and interquartile range for the within-subject difference in mean EMG amplitude (upper graph) and EMG integrated over time (lower graph) between the muscle-specific isolated foot exercise and each of the functional exercises. Outliers are not shown to optimize visualization. * significant difference between the functional exercise and the muscle-specific isolated foot exercise p<0.05).

The magnitude of iEMG was significantly greater for the muscle-specific isolated foot exercise than the functional exercises for 5 of the 6 comparisons and similar for 1 comparison. During toe walking, iEMG was 2.8 times smaller than during the muscle-specific isolated foot exercise for FHB (median difference: -103%·s, IQR: -215 to -66%·s, p

< 0.05) and 2.9 times smaller for FDB (median difference: -99%·s , IQR: -248 to -30%·s, p < 0.05). In addition, iEMG for hopping was 9.1 times smaller for FHB (median difference: -157%·s , IQR: -255 to -111%·s, p < 0.05), 7.7 times smaller for FDB (median difference: -160%·s , IQR: -424 to -47%·s, p < 0.05) and 2.4 times smaller for AbH (median difference: -33%·s , IQR: -327 to -15%·s p < 0.05). For AbH, iEMG did not vary significantly across toe walking and AbH's specific isolated foot exercise.

Isometric exercises resulted in significantly larger mean EMG amplitude compared to concentric exercises for FHB (median: -14%, IQR: -33 to -5%, p < 0.05) and AbH (median: -8%, IQR: -72 to -4%, p < 0.05), whereas the opposite was shown for FDB (median: 23%, IQR: -13 to 84%, p < 0.05) and FHL (median: 48%, IQR: 24 to 86%, p < 0.05).

The mean EMG amplitude obtained during toe stance with forward lean did not differ significantly from normal toe stance for each PIM (median: 11%, IQR: -2 to 17%, p = 0.05 (FHB); median: 6%, IQR: -1 to 15%, p = 0.05 (FDB); median: 5%, IQR: -13 to 17%, p = 0.22 (AbH)).

DISCUSSION

The main aim of this study was to provide better insights in the activation of PIMs during functional exercises compared to isolated foot exercises. We demonstrated that functional exercises provoked comparable or even more activation of PIMs than isolated foot exercises. Despite the shorter duration of the dynamic functional exercises, performing a few repetitions of these exercises resulted in iEMG of which the magnitude was similar to the muscle-specific isolated foot exercise. Furthermore, isometric exercises were associated with larger PIM activation compared to concentric exercises, while forward leaning during the toe stance did not affect PIM activation.

Some functional exercises were more effective in activating the PIMs than the muscle specific isolated foot exercise, while others were equally effective. As all functional exercises were performed in a toe stance position, this position seems to activate the PIMs substantially. Toe stance requires the calf muscles to generate ankle plantar flexor force, which needs to be transmitted to the ground distal to the MTP joints. Therefore, the foot must serve as a rigid lever and the MTP joints must stiffen to resist the external toe extension moment generated by the ground reaction force. This functional interplay between the ankle and the foot may be facilitated by a shared excitatory drive between the ankle plantar flexors and the PIMs [49]. Toe stance position predisposes the body to an unstable posture. This increased postural challenge may also contribute to the high PIM activation levels during the functional exercises. Previous studies already demonstrated the active contribution of the PIMs to foot stiffening [10,28] and to remaining balanced [11,50], which is in agreement with the current provoked PIM activation levels during the functional exercises.

The magnitude of iEMG, which takes into account the duration of muscle activation, was in most comparisons smaller for the functional exercises than the muscle-specific isolated foot exercises. However, only 1 to 3 steps of toe walking and 3 to 9 hops are needed to approximate the iEMG of a 3-second muscle-specific isolated foot exercise (i.e., the iEMG was at most 2.9 (toe walking) and 9.1 (hopping) times smaller compared to the muscle-specific foot exercise), without being more time-consuming. Muscular adaptation is not only determined by muscle activation level (i.e., mean EMG amplitude), but also by the time that a muscle is activated [47], which is reflected by the iEMG. Therefore, our results for the iEMG, in addition to the results for the mean EMG amplitude, indicate that functional exercises, especially the less strenuous toe stance and toe walking, can be included in a therapeutic exercise program just as well as isolated foot exercises to activate the PIMs.

Isometric exercises seem more appropriate to train the PIMs as higher muscle activation was demonstrated during these exercises compared to concentric exercises. In several studies [51–53] isometric grip testing of the toes is the designated instrument to test PIM function, which concords with our findings. In contrast, the wide use of concentric exercises (e.g., the towel-curl exercise) in clinical practice to target the PIMs disagrees with our results. Concentric isolated foot exercises, however, seem to be suitable to train the extrinsic toe flexors as indicated by the higher activation of FHL during this type of exercise. Nevertheless, although isometric exercising involved the PIMs more than concentric exercising did, it still not performed better than the functional exercises.

The finding that PIM activation during toe stance and toe walking is similar to the isolated foot exercises is promising for physiotherapy practice, because of the many advantages of these functional exercises over isolated foot exercise. First, functional training complies with the principle of specificity of training. This coveys that the functional task targeted by the training will most likely improve when the trained motor pattern is consistent with this task [54]. Since the primary role of the PIMs is to contribute to balance and push off, a positive transfer is unlikely for isolated foot exercises such as spreading the toes. Together with our findings, this seems to indicate that the PIMs can be well trained by functional exercises that include toe stance. These exercises may lack specificity for the prevention or treatment of pronated feet related conditions as symptoms typically arise from the foot flat phase, but are deemed specific for individuals with PIM weakness such as older adults [1] or patients with diabetic neuropathy [8]. Ultimately, functional exercises should also match the cognitive and environmental nature of the target task [55], for example by interacting with objects or other individuals or while performing a concurrent cognitive task. Another, related, advantage of functional exercises is that these activate numerous other muscle groups in addition to the PIMs and therefore additional training results may arise, without being more time-consuming. However, the associated downside is that sufficient plantar flexor strength is required for toe stance, which is diminished in older adults [56]. Once this requirement is fulfilled, a physical therapist can integrate functional

exercises in therapy according to the person's capabilities related to the postural system or strength. In case of difficulties in maintaining balance, variations can be applied (e.g., using an external support, double-leg) in order to facilitate the execution of the exercises in toe stance position. In some situations, for example early in rehabilitation, it may be recommended to perform exercises without full weight bearing. In these cases, isolated foot exercises may be appropriate instead. Functional exercises also have adherence related benefits over isolated foot exercises. Isolated foot exercises require a selection of foot muscles to be innervated, which composes an unnatural motor pattern. A substantial number of healthy younger individuals proved incapable of executing such exercises [20,57], even after two weeks of daily training [20]. Although other individuals may be able to develop this motor skill [19], it is reasonable that their learning process was accompanied by frustration and annoyance. These negative feelings may lead to decreased adherence or discontinuing the program. In contrast, the easier performance of functional exercises potentially stimulates exercise adherence from the start [21]. Another aspect promoting adherence is the feasibility of integrating functional exercises, such as toe stance and toe walking, in daily routines, while isolated foot exercises require time that is exclusively dedicated to the execution of the exercises.

This is the first study that compared PIM activation between isolated foot exercises and functional exercises. Selecting the muscle-specific isolated foot exercise for the comparison that was most effective ensured a sensible comparison. It was, however, remarkable that this was not the short foot exercise for any of the PIMs, which is the most extensively investigated PIM exercise [18]. Furthermore, by including only the trials for which a normal motor pattern was observed, motor ability could not act as a confounding factor. Nevertheless, several limitations need to be considered. Most importantly, the participants were all asymptomatic younger individuals. Future studies should examine how the results apply to the target population, such as older adults with increased fall risk or patients with diabetic neuropathy. In addition, the functional exercises were all performed in toe stance position and are therefore less applicable to patients suffering with symptoms related to the foot flat phase of gait. Further, EMG data does not allow us to do inferences about longitudinal training effects in terms of adaptations in muscle function or strength. Although this relationship needs validation [58], our results encourage the design of an intervention study to evaluate the effect of functional exercises against the effect of isolated foot exercises. Such a study would also be suitable to answer the question if the training stimuli of functional exercises is adequate for PIM's structural adaptation, as well as functional improvements, to occur. The potential of functional exercises to provoke strength gains similar to isolated exercises is already demonstrated for neck, shoulder and trunk muscles [59]. Another limitation is that we used sEMG. By placing the electrodes on the skin, this method is, in contrast to needle EMG, not invasive and does not obstruct movements or the loading of the foot. In turn, sEMG has the drawback that crosstalk from adjacent or deeper muscles

is inevitable. Although this may be expected to be profounder when measuring small muscles, such as foot muscles, previous literature demonstrated that crosstalk for these muscles remains within reasonable boundaries [27]. Lastly, we have not objectified the performance of the task (e.g., grip force, toe stance kinematics, balance performance, walking speed). Although standardization was endeavored by the provided instructions, suboptimal performance cannot be ruled out as a confounder of the findings and should be addressed in future studies. Future studies are also recommended to use additional equipment (e.g., motion capture systems, force instruments) to more reproducibly define the onset and offset of the exercises or a specific phase for the dynamic exercises (e.g., the stance phase in toe walking or the take-off and landing phase of hopping).

CONCLUSION

The findings of this study demonstrate that functional exercises provoke comparable or even more activation of the PIMs than the most effective muscle-specific isolated foot exercise. This is a first step towards a more meaningful design of a physical therapy program to treat PIM weakness or dysfunction, especially considering the additional benefits of functional exercises against isolated foot exercises that promote optimal training effects. However, a longitudinal intervention study is required to demonstrate the occurrence of muscular and functional adaptations in target populations, such as in older adults with increased fall risk.

LIST OF ABBREVIATIONS

PIM: plantar intrinsic foot muscle; EMG: electromyography; MTP: metatarsophalangeal; sEMG: surface electromyography; AHI: arch height index; RAD: relative arch deformation; BW: body weight; ICC: intraclass correlation coefficient; ABH: abductor hallucis; FDB: flexor digitorum brevis; FHB: flexor hallucis brevis; FHL: flexor hallucis longus; iEMG: EMG amplitude integrated over time; mdn: median; IQR: interquartile range;

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DECLARATIONS

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Disclosure of interest

The authors report there are no competing interests to declare

Data availability

The dataset supporting the conclusions of this article is available on request in the DataverseNL repository, https://doi.org/10.34894/D5YSXA.

SUPPLEMENTARY MATERIALS

Supplementary Material 4A: Absolute and relative (%) frequencies of the motor performance score for the isolated foot exercises

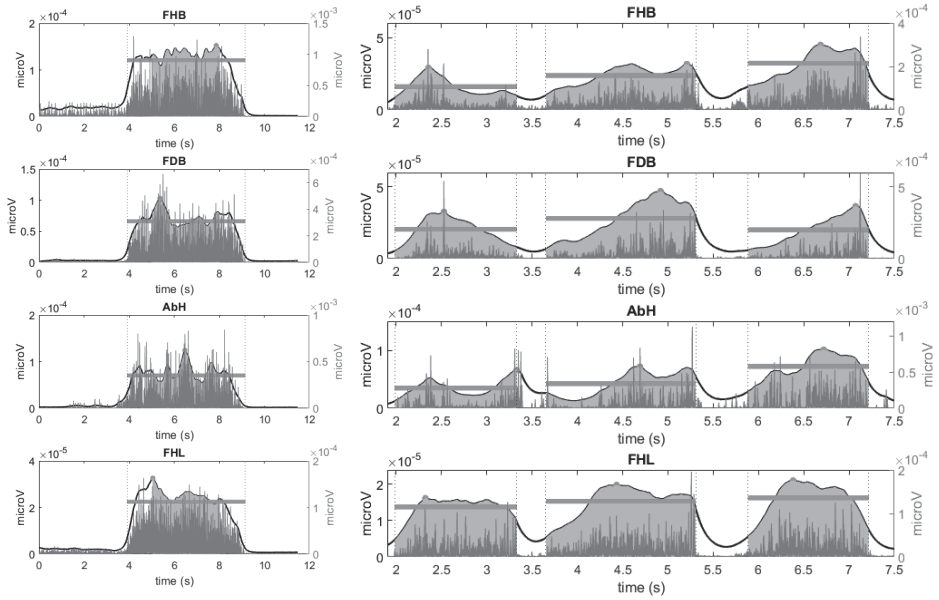
Motor performance score	Hallux grip	Toe curl	Toe spread-out	Lesser toe grip
0	-	-	-	-
1	1 (3%)	2 (7%)	13 (45%)	4 (14%)
2	28 (97%)	27 (93%)	16 (55%)	25 (86%)

Supplementary Material 4B: Number of participants in which sensors were detached in one, two or three trials of each exercise

	Reference	Hallux grip	Lesser toe grip	Toe curl	Toe spread-out	Short foot	Toe stance	Toe stance forward lean	Toe stance compliant surface	Toe walking	Hopping
FHB											
3 trials	-	2	2	5	3	3	4	3	3	11	7
2 trials	-	-	-	-	-	-	-	-	2	-	-
1 trial	1	-	-	-	1	1	-	-	-	-	-
FDB											
3 trials	1	-	1	-	-	1	-	2	2	4	4
2 trials	-	-	-	-	-	-	2	1	1	-	-
1 trial	-	1	-	-	-	3	3	1	-	-	-
AbH											
3 trials	2	1	-	1	1	2	3	3	3	4	4
2 trials	1	-	-	1	-	-	1	-	1	-	-
1 trial	-	-	-	-	-	-	-	-	-	-	1
FHL											
3 trials	-	-	-	-	-	-	-	-	-	1	-
2 trials	-	-	-	-	-	-	-	-	-	-	-
1 trial	-	-	-	-	-	-	-	-	-	-	-

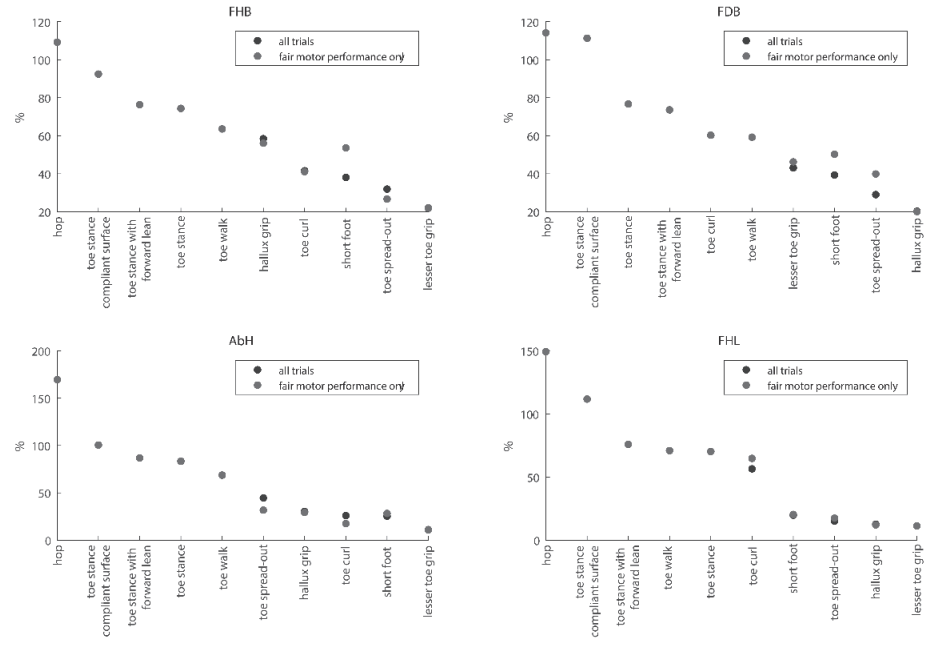
FHB: flexor hallucis brevis, FDB: flexor digitorum brevis, AbH: abductor hallucis, FHL: flexor hallucis longus.

Supplementary Material 4C: Representative EMG signal and parameters for a selection of exercises (n = 1)



Rectified and high-passed filtered EMG signal (right y-axis) and EMG envelope (left y-axis) toe stance on compliant surface (left) and for toe walking (right). Indicated EMG amplitude parameters are: mean (horizontal bar), area (grey-shaded area) and peak (dot). The vertical dashed lines indicate the onset and termination of the task (i.e., stance phase for toe walking). FHB: flexor hallucis brevis, FDB: flexor digitorum brevis, AbH: abductor hallucis, FHL: flexor hallucis longus.

Supplementary Material 4D: Mean EMG amplitude for the exercises in descending order of the group median



FHB: flexor hallucis brevis, FDB flexor digitorum brevis, AbH: abductor hallucis, FHL: flexor hallucis longus.

Effects of a 12-week intrinsic foot muscle strengthening training (STIFF) on gait in older adults: a parallel randomized controlled trial protocol (study 4)

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5

ABSTRACT

Background: Falling is highly prevalent among older adults and has serious impact. Age-induced mobility impairments, such as gait modifications, are strongly associated with increased fall risk. Among fall prevention interventions, those including exercises are most effective. However, there is an urgent need to further improve these kinds of interventions. Strengthening the plantar intrinsic foot muscles might benefit mobility in older adults, which may contribute to the reduction of fall risk. The aim of this paper is to provide a protocol to investigate the effect of a plantar intrinsic foot muscle strengthening training versus no training on gait and intrinsic foot muscle function in older adults who are involved in a functional exercise program.

Methods: For this assessor-blinded RCT, older adults (>65 years) are recruited who are involved in a group-based functional exercise program. Eligibility criteria include: being able to ambulate 10 meters barefoot without using a walking aid and reporting to have either fear of falling or experienced a fall in the previous 12 months or have difficulties with mobility, gait, or balance in daily life. Participants are randomly assigned to an intervention and a control group. The intervention group follows a 12-week plantar intrinsic foot muscle strengthening training. The training consists of isolated and functional foot exercises to be performed 5 times a week, each session lasting approximately 20 minutes. The training is supervised once a week and the intensity gradually increases based on the participant's progression. Both groups keep a diary to report physical activities, fall incidents and movement related discomfort. The control condition is limited to keeping this diary. Data are collected at baseline and post-intervention. The trial outcomes are the between group differences in the mean change from baseline in maximum gait speed (primary outcome measure), capacity and strength of the plantar intrinsic foot muscles, foot and ankle biomechanics during gait, and various other fall risk-related variables. ANCOVAs are used to analyze the trial outcomes.

Discussion: The results of this RCT will offer recommendations, related to plantar intrinsic foot muscle strengthening, to existing fall preventive exercise programs.

Trial registration: The trial is registered in the United States National Library of Medicine through ClinicalTrials.gov (NCT05531136, 07/26/2022)

BACKGROUND

Falling is highly prevalent among older adults and has serious impact. More than one third of the adults aged above 65 years fall at least once a year [1]. Once an individual has experienced a fall, well-being is often compromised as a result of injuries or by fearing another fall incident [2,3]. Increased fall risk is strongly associated with age-induced mobility impairments, such as gait modifications and balance deficits [2,4,5]. Among fall prevention interventions, those involving a functional exercise program aimed at improving mobility (i.e., gait, balance, coordination and functional task training [6]) seem to be most effective, reducing the rate of falls by 24% [7]. To further reduce this rate, there is an urgent need for strategies to improve these fall prevention interventions and, more generally, ongoing functional exercise programs for older adults [7].

Functional exercise programs, including fall preventive exercise interventions, are established without noticeable understanding of the plantar intrinsic foot muscles (PIMs), while there are indications that these muscles have a role in fall related aspects of mobility. The PIMs stabilize and stiffen the foot [8,9] and consequently contribute to balance and propulsive gait [10,11]. These mobility aspects are reflected in maximum gait speed, which has been associated with falling [12,13] and toe flexor strength [14]. Weakness of the PIMs in older adults [15] may thus have a detrimental effect on mobility and fall risk. Indeed, it was found that toe flexor weakness predicts falling in older adults [16,17]. Some evidence exists for the beneficial effect of PIM strengthening on propulsive capacity during gait, even in a population with unaffected PIMs and unimpaired mobility [18]. This suggests that strengthening the PIMs might improve mobility in older adults, which may contribute to the reduction of fall risk. Yet, this needs to be examined.

Several foot and ankle exercise interventions that also target the PIMS have been investigated in older adults [19–23]. While beneficial results were shown in separate studies for toe flexor strength [20,21] and gait parameters [23], the PIMs were not examined concurrently with mobility outcomes. Consequently, it remains unclear how improvements in mobility are linked to possibly enhanced function of the PIMs. Now that there is growing evidence for the importance of the PIMs in relation to mobility, a high-quality study that addresses this gap is needed to evaluate the effect of training the PIMs in older adults. The outcome will enable adequate advice towards fall preventive exercise interventions with regard to the incorporation of PIMs' exercises. Therefore, we set up a randomized controlled trial (RCT) that aims to examine the effect of a PIM strengthening training on fall-related mobility parameters in older adults.

The primary hypothesis in this study is that a PIM strengthening training versus no PIM strengthening training increases maximum gait speed in older adults who are involved in a functional exercise program. To investigate the trainability of the PIMs and how this translates into improved mobility in this specific population, this study further hypothesizes that this PIM strengthening training has a beneficial effect on PIM capacity,

isometric toe flexor strength, foot and ankle biomechanics during gait, comfortable gait speed, step length, balance during gait, self-reported judgement of mobility, physical activity, fall incidents, fear of falling and physical functioning.

METHODS

Design

The study design is an assessor-blinded superiority RCT with two parallel groups. Participants, older adults who are involved in a functional exercise program at the time of recruitment, are randomly assigned with a 1:1 ratio to the PIM strengthening training group and a control group. The functional exercise program is delivered outside the scope of this study and is continued by the participants as usual. The PIM strengthening training is delivered as a separate program for the purpose of this study. Measurements take place at baseline and directly after the 12-week intervention period at the movement analysis laboratory at Fontys University of Applied Sciences, Eindhoven, The Netherlands. The trial is registered in the United States National Library of Medicine through ClinicalTrials.gov (NCT05531136). Table 1 shows the key registration data. The protocol is approved by the medical research ethics committee of Maxima Medical Center, Veldhoven, The Netherlands (CCMO nr. NL80110.015.21). The study protocol is reported according to the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) statement 2013 [24] (see Supplementary Material 5A for the completed SPIRIT checklist) and the CONSORT (Consolidated Standards of Reporting Trials) Statement for Randomized Trials of Nonpharmacologic Treatments [25] (see Supplementary Material 5B for the completed CONSORT checklist).

Table 1: Trial registration data

Primary Registry and Trial Identifying Number	*ClinicalTrials.gov: NCT05531136*
Date of Registration in Primary Registry	*07/26/2022*
Secondary Identifying Numbers	*CCMO: NL80110.015.21* *NWO: 023.013.063*
Source(s) of Monetary or Material Support	*Funding agency: The Dutch Research Council (NWO)*
Primary Sponsor	*Fontys University of Applied Sciences, Eindhoven, The Netherlands*
Secondary Sponsor(s)	*n/a*
Contact for Public Queries	*Lydia Willemse, MSc.: lydia.willemse@fontys.nl; +31885089836; PO Box 347, 5600 AH Eindhoven, The Netherlands.*

Table 1: Continued

Contact for Scientific Queries	*Lydia Willemse, MSc.: lydia.willemse@fontys.nl; +31885089836; PO Box 347, 5600 AH Eindhoven, The Netherlands.*
Public Title	*Effect of a Foot Muscle Strengthening Program in Mobile Older Adults (STIFF3)*
Scientific Title	*Effect of a Foot Muscle Strengthening Program in Mobile Older Adults (STIFF3)*
Countries of Recruitment	*The Netherlands*
Health Condition(s) or Problem(s) Studied	*Fall risk*
Intervention(s)	*Arm Title 1: Foot strengthening training, Arm Type 1: Experimental, Arm Description 1: 12-week foot strengthening training in addition to an already joined functional exercise program. The training consists of foot strengthening exercises prescribed for 5 daily sessions a week, of which 1 supervised, 20 minutes per session on top of the regular exercise program to prevent falling. The foot strengthening training is progressing and consists of isolated and functional exercises. Participants keep a training diary.* *Arm Title 2: Control, Arm Type 2: No Intervention, Arm Description 2: The control group continues the functional exercise program as usual. The subjects in this group are asked to keep a diary in which the subjects weekly report other physical activities, fall incidents and mobility related discomfort. The trainer calls the participants in the control group every week to pay attention to these topics.*
Key Inclusion and Exclusion Criteria	*Minimum Age: 65 Years; Sex: All; Accepts Healthy Volunteers: Yes; Criteria: Inclusion Criteria: be 65 years of age or over, be able to ambulate 10 meter barefoot without using a walking aid, engage in a functional exercise program delivered to a group of older adults by an educated or certified physical therapist or trainer (e.g., fall preventive exercise program, senior fit programs), report to have 1) fear of falling OR 2) experienced a fall in the previous 12 months OR 3) difficulties with mobility, gait, or balance, be able to arrange their own transport to the movement analysis laboratory. Exclusion Criteria: The respondent is a mentally incapacitated adult, Self-reported presence of any disorder interfering with the execution of the exercise program.*

Table 1: Continued

Study Type	*Study Type: Interventional; Primary Purpose: Prevention; Study Phase: n/a; Interventional Study Model: Parallel; Model Description: The study design is an assessor-blinded RCT with two parallel groups. Participants are randomly assigned in a 1:1 ratio to either the intervention or the control group by the use of a computer-generated randomization list managed by an independent project administrator. Blocking, the size of the blocks undisclosed, is applied in order to ensure the balanced allocation at several time points in the trial; Number of Arms: 2; Masking: Investigator, Outcomes Assessor; Masking Description: Once a participant has accomplished the baseline measurements, the assessor requests group allocation. The project administrator then sends the allocation to the trainer, who assigns the participant to the allocated group. The nature of the intervention precludes blinding of the participants and the trainers, however staff members involved in the recruitment of participants and in the assessment of measurement variables remain blinded to the group allocation until the post-processing of data that involves any subjectivity has been completed. Allocation: Randomized.*
Date of First Enrollment	*08/11/2022*
Sample Size	*42 [anticipated]*
Recruitment Status	*Recruiting*
Primary Outcome(s)	*Title: maximum gait speed; Description: The post-intervention difference between the intervention and control group in maximum gait speed, Time Frame: 12 weeks.*
Key Secondary Outcomes	*Title: Foot muscles' morphology derived from ultrasound imaging, Time Frame: 12 weeks;* *Title: Lower extremity biomechanics during gait assessed with 3D motion and ground reaction force capturing, Time Frame: 12 weeks; Title: Spatiotemporal gait parameters assessed with 3D motion and ground reaction force, Time Frame: 12 weeks; Title: Balance during gait assessed with 3D motion and ground reaction force capturing, Time Frame: 12 weeks; Title: Self-reported mobility limitations, Time Frame: 12 weeks; Title: Physical activity engagement, Time Frame: 12 weeks; Title: Fall incidents during the intervention, Time Frame: 12 weeks; Title: Fear of falling assessed by the (Falls Efficacy Scale-International) FES-I questionnaire, Time Frame: 12 weeks; Title: Isometric toe flexor strength assessed by a pressure plate during maximal toe press, Time Frame: 12 weeks; Title: Physical functioning assessed by the Short Physical Performance Battery (SPPB), Time Frame: 12 weeks;*
Ethics Review	*Board Status: Submitted, approved; Approval Number: W21.104; Board Name: METC; Board Affiliation: Maxima MC; Board Contact: Phone: +31408889528; Email: metc@mmc.nl; Address: De Run 4600, Veldhoven, The Netherlands.*
Completion date	*n/a*
Summary Results	*n/a*
IPD sharing statement	*n/a*

Participants

Recruitment

Older adults (>65 years) who are involved in a group-based functional exercise program are recruited at fall prevention classes and senior sports and exercise classes in and around the city of Eindhoven, The Netherlands. Participants are recruited by the primary investigator (LW) via verbal communication about the study outline to the group of older adults and via posters and leaflets at the site of the exercise classes, and in a local newspaper. Interested people are asked to share their contact details and they receive a hard copy of the information letter and the consent form. After two weeks, the researcher calls the respondent, providing the opportunity to ask questions and to ask for willingness to participate in the study. If so, the eligibility is examined based on the selection criteria. See Figure 1 for the flow of participants and Figure 2 for the participant timeline.

Selection

In order to be eligible to participate in the study, respondents should 1) be 65 years of age or over, 2) be able to ambulate 10 meter barefoot without using a walking aid, 3) be involved in a functional exercise program delivered to a group of older adults by an educated or certified physical therapist or instructor (e.g., fall preventive exercise program, senior fit programs), 4) report to have fear of falling or to have experienced a fall in the previous 12 months or to have difficulties with mobility, gait, or balance in daily life, 5) be able to arrange their own transport to the movement analysis laboratory. Respondents who report presence of any disorder interfering with adherence or the execution of the exercises are excluded. To this end, a general explanation of the intervention and an exemplary exercise (i.e., toe pressing) is given. Mentally incapacitated individuals are also excluded from participation. The informed consent form is signed before data collection, first by the participant and then by the researcher. After having received written informed consent to participate, the participant is included in the study.

Sample size

We test the primary hypothesis that the mean change from baseline at post-intervention in maximum gait speed is in the positive direction and larger in the intervention group than in the control group. Using the anchor-based approach [26] for the difference in maximum gait speed between older adults at high (M: 1.54 m/s, sd: 0.37 m/s) and low (M: 1.83 m/s, sd: 0.33 m/s) fall risk [13] and between older adults with (M: 0.96 m/s, sd: 0.32 m/s) and without (M: 1.23 m/s, sd: 0.36 m/s) a fall history [12], we decided the minimal clinically important effect size to be *d-0.79* according to these formulae:

$$d = \frac{1.83 - 1.54}{\sqrt{\frac{0.33^2 + 0.37^2}{2}}} = 0.83 \quad (12)$$

$$d = \frac{1.23 - 0.96}{\sqrt{\frac{0.36^2 + 0.32^2}{2}}} = 0.79 \quad (13)$$

For this effect size, which equals $\eta^2 = 0.135$ [27], to be detected with ANCOVA while applying β-*0.0* and α-0.05(one-tailed), the sample size should be *n-42* according to our calculation in G*power 3.1.9.2 software.

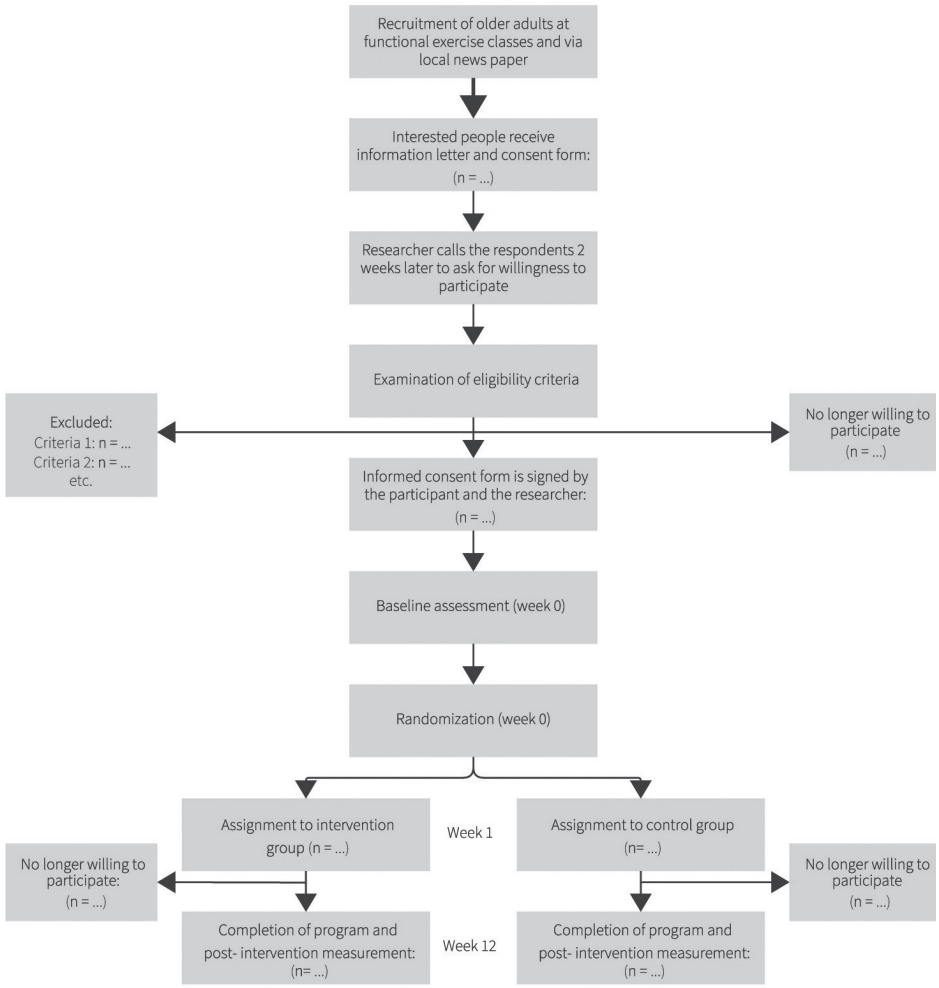

Figure 1: Flow of participants.

	STUDY PERIOD				
	Intake	Baseline		Allocation	Post-intervention
TIME POINT		Wk -1	Wk 0	Wk 1	Wk 12
SETTING	Phone	Home	Lab	Phone	Lab
ENROLMENT:					
Eligibility screening	X	X			
Informed consent		X			
Allocation				X	
INTERVENTIONS:					
PIM strengthening training				←	→
Control				←	→
ASSESSMENTS:					
Primary outcome variable:					
Maximum gait speed			X		X
Secondary outcome variables:					
Foot muscles' morphology			X		X
Foot and ankle biomechanics during gait			X		X
Spatiotemporal gait parameters			X		X
Balance during gait			X		X
Isometric toe flexor strength			X		X
Self-reported mobility limitations		X			X
Physical activity engagement		X		←	→
Fall incidents during intervention period				←	→
Fear of falling		X			X
Physical functioning		X			X
Other outcome variables:					
Movement related discomfort				←	→
Exercise adherence				←	→
Population descriptives:					
Demographics		X			
Body length and weight			X		
Mobility related conditions		X			
Cognitive functioning			X		
Health related quality of life		X			
Hand grip strength		X			
Physical activity behavior		←	→		
Characteristics of the functional exercise program	X				

Figure 2: Participant timeline showing enrolment, interventions, and assessments.

Randomization and blinding

Participants are randomly assigned in a 1:1 ratio to either the intervention or the control group by the use of a computer-generated (randomizer.org) randomization list managed by an independent project administrator. Blocked randomization, the size of the blocks being undisclosed, is applied to ensure the balanced allocation at several time points during the trial. Once a participant has accomplished the baseline measurements, the primary investigator asks the project administrator to send the group allocation to the trainer, who assigns the participant to the allocated group. The nature of the intervention precludes blinding of the participants and the trainers, however the primary investigator and assistant assessors remain blinded to the group allocation until the post-processing of data that is exposed to subjectivity (i.e., segmentation of ultrasound images) is completed. At the end of the post-intervention measurement, the group assignment is guessed by the primary investigator to evaluate the success of the blinding procedures. The primary investigator is the same person who performs the data analysis.

Interventions

PIM training program

The intervention group follows a 12-week PIM strengthening training. The training has been developed with a design thinking approach [28]. A first draft of the program was based on existing literature concerning foot strengthening programs [20,29–34], training principles [35] and the behavior change wheel [36]. It then went through several iteration rounds with older adults, (foot and ankle) physiotherapists, podiatrists and a human movement scientist. The final training program prescribes 20 minutes of PIM strengthening exercises (see the training guide in Supplementary Material 5C). The training consists of both isolated and functional foot exercises, of which the intensity gradually increases based on the participant's progression, to be executed 5 days a week. Figure 3 shows the exercises included in the training, together with the number of repetitions, the contraction time and pose for the easiest intensity level of the training. Once a week, the training is supervised by a 4th years physiotherapy student who receives extensive education in delivering the training in a standardized fashion prior to delivering the training. A trainer's guide (see Supplementary Material 5D) provides the trainer guidance in delivering the training. A weekly meeting with the trainers and the researcher intends to promote adherence of the trainers to the protocol. In addition to the education of the trainers, the standardization of the training is also achieved by instructional videos of each exercise along with written instructions provided in the training guide (see Supplementary Material 5C). This training guide further includes a training log, in which the participant reports the perceived difficulty for each exercise and each training session using a 5-point Likert scale [29]. In addition, the training guide comes along with a diary that serves to monitor adherence to the prescribed program, physical activities, fall incidents and movement related discomfort. For safety reasons, the participant is instructed to report movement related discomfort in the lower extremities immediately

to the trainer. In this case, the training will be continued with lesser intensity until the discomfort has disappeared. The participant decides if the supervised training is a group session at Fontys Allied Health Professions or on individual basis delivered at home. Each session commences with a warm-up and ends with a cool-down, including stretching.

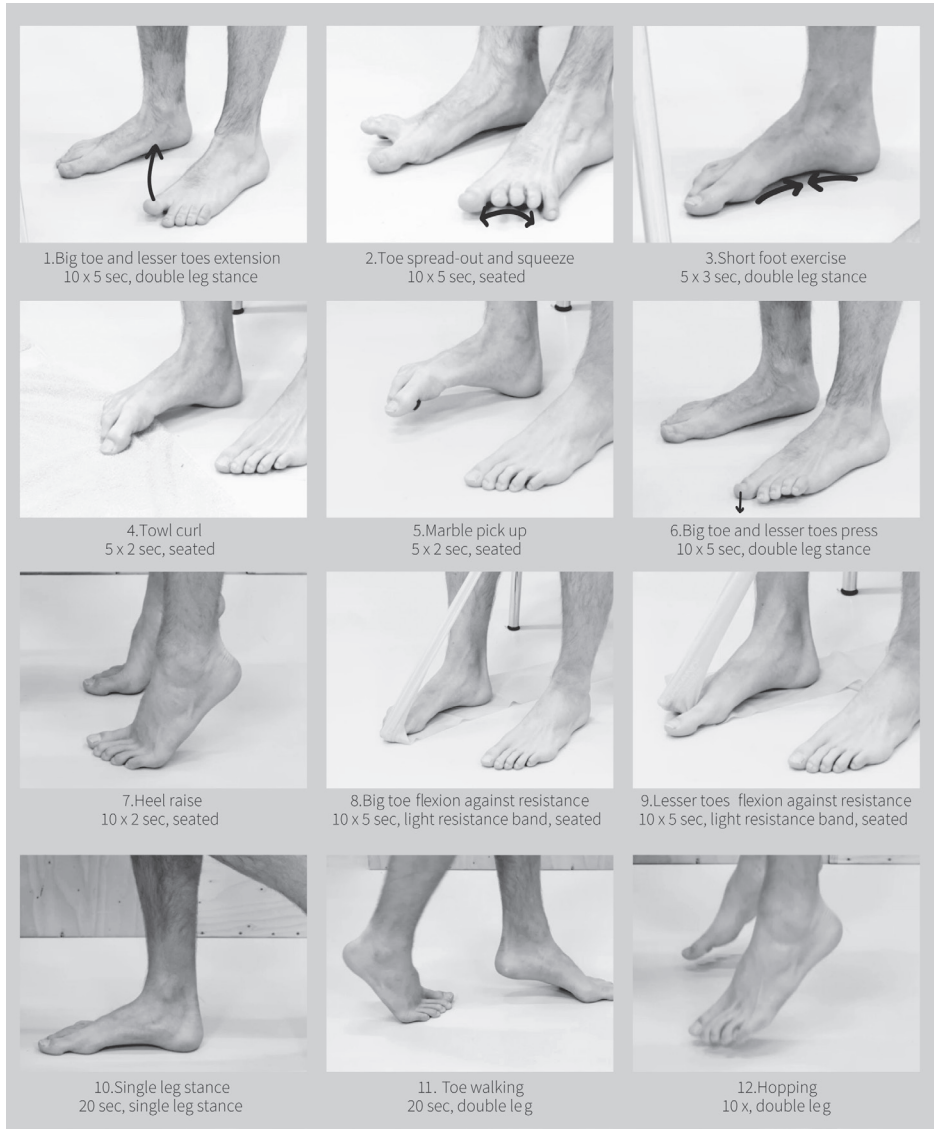

Figure 3. The 12 exercises included in the PIM strengthening training. For each exercise, the number of repetitions, the contraction/exercise duration and the pose is presented for the easiest intensity level of the training program.

At the onset of the training, each participant starts the exercises at the easiest level. When the participant perceives the exercise without any difficulty for 5 consecutive training sessions and the trainer scores maximum motor performance using a 3-point scale, modified from Fraser and Hertel (2019) [29], the trainer sets the level of intensity to the next level (see page 6 of the trainer's guide in Supplementary Material 5D). If the duration of the training session exceeds 20 minutes, for example due to more advanced intensity levels (i.e., more repetitions), the trainer discusses with the participant how to limit the duration of training sessions in accordance with preset restrictions (see page 7 of the trainer's guide in Supplementary Material 5D).

To promote adherence, the training guide visualizes completed sessions, which is discussed with the trainer as part of every supervised session. The personal guidance by the trainer and the participant's choice for either a home visit by the trainer or joining a group session also anticipates maximum adherence to the exercise regime.

Control group

The participants in the control group are asked to keep a diary (see Diary (control) in Supplementary Material 5E) in which the participants weekly report other physical activities, fall incidents and movement related discomfort. The trainer calls the participants in the control group every week paying attention to these topics.

Data collection procedures

Baseline data are collected prior to the group allocation. The outcome variables per time point are presented in the participant timeline, Figure 2. The baseline data are collected during a home visit and a laboratory session, separated by approximately one week. We introduced the home visit (~1 hour) as it facilitates a personal introduction to the study and it reduces the duration of the baseline laboratory session, limiting the risk for fatigue. The home visit is completed by trained assistant assessors. The primary investigator is in charge of the data collection at the motion analysis laboratory (baseline and post-intervention; ~3 hours each) while assisted by assistant assessors. Unilateral outcome variables are taken from the dominant stance leg, determined by single leg stance. The trainer instructs the participant right before the post-intervention measurement to not reveal the group assignment.

Participant retention is promoted by the close and personal guidance by the trainers throughout the intervention period for both trial groups and the prospect of a gift card to be received at the post-intervention measurement. Reasons for non-retention is logged by the researcher.

To ensure standardized data collection and to promote data quality, the procedure for each measurement occasion is described in a standard operation plan, which is used to train the primary investigator and assistant assessors. To promote complete and replicable data sets, the data or data identifiers are recorded in a data collection form.

Outcome measures

Primary and secondary outcome variables are measured at baseline and post-intervention and are used to determine the trial outcomes, which are the between group differences in the mean change from baseline at post-intervention in these outcome variables. Population descriptives are used to characterize both study groups at baseline. Other outcome variables relate to adverse events and exercise adherence. Each variable is evaluated in both groups, except for exercise adherence.

Primary outcome variable

The outcome variable to examine the primary aim is maximum gait speed. Maximum gait speed reflects propulsive capabilities and is able to discriminate between older adults with and without a fall history [12] and between older adults with and without increased fall risk [13]. Maximum gait speed is defined as the gait speed while walking at fast walking speed ("like having to catch the bus, but not running"). Maximum gait speed is assessed using the marker-based motion capture analysis that is also used to obtain foot and ankle biomechanics, which is elaborated hereafter.

Secondary outcome variables

Foot muscle's morphology

Ultrasound is used to assess the morphology of intrinsic and extrinsic foot flexor muscles, reflecting their capacity, and was previously used to understand foot function in younger populations [37–39]. Ultrasonography is found to be a valid instrument to measure muscle size of lower extremity muscles in older adults [40].

The ultrasound scans for the assessment of foot muscle morphology are performed by the primary investigator who has extensive experience in scanning these tissues in older adults. In previous research, the reliability and measurement error of these measurements were found to be adequate to detect group mean hypertrophy in older adults as a response to training [41].

A reliable ultrasound protocol [41], modified from Crofts et al. [42] is used to measure the thickness and cross-sectional area of foot muscles using a portable ultrasound device with a 4-12 MHz linear array transducer (Philips Ultrasound, Lumify). The thickness is assessed for abductor hallucis (AbH), flexor digitorum brevis (FDB), quadratus plantae (QP), flexor hallucis brevis (FHB), abductor digiti minimi (AbDM), tibialis anterior (TA), peroneus longus together with the peroneus brevis (PER), and flexor hallucis longus (FHL). In addition, the cross-sectional area is assessed for ABH and FDB. The protocol [41] prescribes the participant's pose and the scanning procedure. Three cine-loops are made for each muscle with repositioning of the transducer, followed by a single segmentation per scan.

ImageJ software (National Institute for Health, United States) is used for the offline segmentation of the scans. To measure the thickness and cross-sectional area of the muscle, a best quality still image is selected from the cine-loop. The thickness of a tissue is represented by the perpendicular distance between the epimysia. The cross-sectional area includes all muscle tissue of the muscle of interest that is visible on the image. The mean of three trials for each measurement is taken for further analysis.

Foot and ankle biomechanics during gait

Foot and ankle kinematics and kinetics are assessed during walking at comfortable walking speed ("like walking in the park") using a 3-dimensional (3D) marker-based motion capture system (Codamotion Ltd.; 4 CX1 units, 100 Hz) time synchronized with a recessed force plate (Advanced Mechanical Technology, Inc., OR 6–7, 1000 Hz). In accordance with the modified kinematic Rizzoli foot model [43,44], and with the addition of landmarks from the kinetic foot model of Bruening at al. [45], 16 anatomical landmarks are identified on the lower leg and the foot, which is shown in Figure 4 and Table 2. A four-marker pointer stick is used to locate four of these landmarks (medial malleolus, lateral malleolus, tibial tuberosity and femoral head), whereas individual markers are placed directly on the other 12 landmarks.

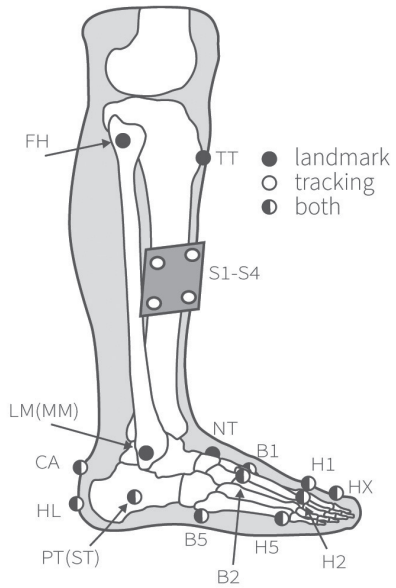

Figure 4. Location of the cluster markers, pointed landmarks, and landmark markers. The marker configuration is a combination of that proposed by the kinematic Rizzoli foot model [43,44] and the kinetic foot model of Bruening et al. [45]. The figure key differentiates between markers used to define the anatomical model in the static pose, markers used to track the segments' motion in the gait trials, and markers used for both. Hidden medial markers (i.e., ST and MM) are indicated in parentheses behind their lateral counterparts. The full descriptions of the abbreviations (landmarks) are provided in Table 2. This figure is re-used from Bruening at al. [45], with permission from Elsevier.

Table 2. Description of markers. These are used to define the segments of the anatomical model in the static pose and to track these segments' motion in the gait trials.

Markers / landmarks	Description
Cluster markers	
S1-4	Cluster on the shank with 4 markers
Pointed landmarks	
TT	Most anterior prominence of the tibial tuberosity
FH	Most proximal apex of the fibular head
MM	Distal apex of the medial malleolus
LM	Distal apex of the lateral malleolus
Landmark markers	
CA	Upper central ridge of the calcaneus posterior surface, i.e. Achilles' tendon attachment
HL	Most distal point of attachment area of the Achilles tendon on the calcaneus
ST	Most medial apex of the sustentaculum tali
PT	Lateral apex of the peroneal tubercle
NT	Most medial apex of the navicular tuberosity
B1	First metatarsal base, dorso-medial aspect of the first metatarso-cuneiform joint
H1	First metatarsal head, dorso-medial aspect of the first metatarso-phalangeal joint
HX	Most distal and dorsal point of the head of the proximal phalanx of the hallux
B2	Second metatarsal base, dorso-medial aspect of the second metatarso-cuneiform joint
H2	Second metatarsal head, dorso-medial aspect of the second metatarso-phalangeal joint
B5	Fifth metatarsal base, dorso-lateral aspect of the fifth metatarso-cuboid joint
H5	Fifth metatarsal head, dorso-lateral aspect of the fifth metatarso-phalangeal joint
Virtual markers	
SK_{prox}	Projection of TT on the plane passing through LM, IM and FH
IM	Intermedius malleoli, midpoint between MM and LM
CA_{proj}	Projection of CA target onto the ground during the static standing pose, tracked in the calcaneus reference frame
CU	Point at 2/3 of the distal distance between PT and B5 [46]
MTC	Midtarsal joint center, midpoint between CU and NV [45]
MPC	First metatarsophalangeal joint center, projection of H1 vertically ½ distance to the floor [45]
HAL_{dist}	Projection of HX vertically ½ distance to the floor [45]
MET_{dist}	Projection of H2 vertically ½ distance to the floor [45]
FT_{dist}	Projection of H2 on the plane passing through CA, H1 and H5

The landmarks conform to the Rizzoli foot model [43,44] unless referred to Bruening et al. [45] or Deschamps et al. [46].

Table 3. The anatomical model's segment definitions, segment properties and the markers used to track the segments' motion.

Segment	Primary axis	Extra target in primary plane	Tracking markers	Proximal radius	Distal radius	Proportion of body mass
Shank	SK_{prox} – IM [44]	LM [44]	S1-S4 [47]	0.5 · (|SK_{prox}-FH|)	0.5 · (|LM-MM|)	0.0465 [48]
Calcaneus	HL – MTC [45]	CA [47]	HL, PT, ST [47]	0.5 · (|LM-MM|) [47]	0.5 · (|LM-MM|) [47]	0.0145 [48] · 0.3 [46]
Midfoot	MTC – B2 [46]	TN	B2, TN, B5	0.5 · (|TN - CU|)	0.5 · (|B5 - B1|)	0.0145 [48] · 0.3 [46]
Metatarsus	B2 – MET_{dist} [46]	H2	B1, H2, B5	0.5 · (|B5 - B1|)	0.5 · (|H5 - H1|)	0.0145 [48] · 0.3 [46]
Hallux	MPC – HAL_{dist} [45]	H1 [47]	HAL_{dist}, H1, HX	(|HX – HAL_{dist}|) [47]	(|HX – HAL_{dist}|) [47]	0.0145 [48] · 0.1 [46]
Foot	CA – FT_{dist} [44]	H1 [44]	CA, H1, H5	0.5 · (|PT – ST|)	0.5 · (|H5 – H1|)	0.0145 [48]

The full descriptions of the abbreviations (markers/landmarks) are provided in Table 2. The shank and foot segments are modelled according to the Rizzoli foot model [44], the calcaneus and hallux segments are modelled according to Bruening et al. [45] and the midfoot and metatarsus segments are modelled according to Deschamps et al. [46]. Specifications without citations indicate that these are lacking in the literature and are sensibly determined by the authors of the current paper.

After several practice trials and recording a static standing pose, used to create the anatomical model, 5 good trials are recorded using a 5-step protocol to minimize fatigue. A good trial is defined as when only the measured foot is in full contact with the force plate. Spatiotemporal parameters and joint kinematics and kinetics are obtained during the stance phase using Visual 3D software (C-Motion, Inc.). Missing marker data are handled by interpolating the data with a 3th order polynomial function. Marker data and ground reaction force data are filtered by applying a Butterworth filter (6 Hz and 20 Hz cut-off frequency, respectively). Initial contact and toe-off are determined by a vertical ground reaction force threshold of 10 N.

Segment reference frames are created for the shank and the 4-foot segments (i.e., rearfoot, midfoot, metatarsus, hallux). The shank is modelled according to the kinematic Rizzoli foot model [43], which is suitable for our kinetic purpose. The foot model is based on the kinetic foot model of Bruening et al. [45,47], but divides the forefoot segment into a midfoot and a metatarsus segment according to the 4-segment foot model proposed by Deschamps et al. [46]. As such, our model has 4 joint centers: ankle (midpoint between medial and lateral malleoli), Chopart joint (midpoint between navicular and cuboid bone), Lisfranc joint (second metatarsal base) and first metatarsophalangeal (MTP1) joint (vertical projection first metatarsal head ½ distance to floor). The segments are modeled as cones of which the radii and masses are presented in Table 3 together with the exact segment definitions and the markers used to track the segments during the gait trials. Inertial properties are set to Visual 3D's default values [49]. The model also contains a zero-mass dummy segment linking the calcaneus to the shank, such that it places the ankle joint center in the correct position [47]. Segment reference frames are oriented with the mediolateral axis pointing laterally to the right side of the body, the anteroposterior axis pointing forwards and the inferosuperior axis pointing upwards.

Joint motions during the gait trials are obtained from the orientation of the distal segment with reference to the proximal segment, allowing 6 degrees of freedom, using the Cardan rotation order flexion/extension, abduction/adduction, and internal/ external rotation. In addition, to assess mediolongitudinal foot arch (MLA) integrity during gait, the MLA is defined as the angle between two linked line segments (i.e., CA_{proj}-NT, NT-H1) projected on the sagittal plane of the foot segment [43] (see Table 3 for the foot segment definition).

Joint kinetics are calculated through inverse dynamics. The sagittal net internal ankle, Chopart, Lisfranc and MTP1 joint moment are calculated in the proximal segment's reference frame. In addition, the power in these joints is derived as the scalar dot product of the joint moment and angular velocity. Joint kinetics are only considered once the net internal sagittal joint moments are negative (i.e., once the CoP has passed the distal end of the joint's proximal segment in the anterior direction [10]). Kinetic variables are normalized to body weight.

The obtained stance phase kinematic and kinetic outcome variables for each trial are MLA deformation (i.e., change in MLA from initial contact to its maximum), MLA recoil (i.e., change in MLA from its maximum to toe-off), peak sagittal internal joint moment (ankle, Chopart, Lisfranc, and MTP1 joint), peak positive scalar joint power (ankle, Chopart, Lisfranc, MTP1 joint) and peak negative scalar joint power (Chopart, Lisfranc, MTP1 joint). Each outcome variable is averaged over the trials.

Gait Speed

Preferred gait speed is assessed during the comfortable walking speed trials described above. Maximum gait speed is assessed in five additional trials in which the participants are instructed to walk as fast as possible over the walkway ("like having to catch the bus, without running"). For both conditions, gait speed is calculated as the rate of change in heel marker position along the anteroposterior axis of the lab coordinate system between two consecutive foot strikes of the ipsilateral foot. These foot strike events are identified as the frames where the sagittal velocity of the heel marker drops below 500 mm/s [50,51].

Balance during gait

Balance during gait is examined through calculating the lateral margin of stability [52]. This variable quantifies stability in dynamic situations by relating the body's center of mass (CoM) to the center of pressure (CoP) [52], while accounting for the velocity of the CoM and considering the human body as an inverted pendulum [52]. To this end, participants perform 5 additional gait trials at preferred walking speed while the body's contour is tracked using 8 video camera's (Qualisys AB, Miqus video, 50 Hz) time synchronized with the collection of the ground reaction force (Advanced Mechanical Technology, Inc., OR6-7, 1000 Hz). The remainder of the procedure is as described before. The video recordings are post-processed using Theia software (Theia Markerless, Inc., Theia3D) to result in the position of the CoM. The extrapolated center of mass, a quantity needed to obtain the margin of stability, is calculated for each time instance as the position of the CoM, plus its velocity times a factor equal to $\sqrt{l/g}$, where l is the maximum height of the CoM and g is the gravitational acceleration. The margin of stability is defined as the minimum lateral distance between the extrapolated center of mass and the mean CoP position during single leg stance [53]. Contralateral foot-off and foot strike are defined as when the sagittal velocity of the model's distal end of the toes' segment exceeds 500 mm/s and the heel marker drops below 500 mm/s, respectively [50,51]. The margin of stability is averaged over the trials.

Step length

The step length is derived from the gait analysis used to assess balance during gait. Step length is defined as the distance between the contralateral heel landmark position at foot strike and the following ipsilateral heel landmark position at the force plate hit along the lab's anteroposterior axis.

Isometric toe flexor strength

To assess toe flexor strength, the participant is asked to stand on both feet, hip width apart, with one foot on the pressure plate (Materialise NV). The participant is then verbally encouraged to push down as hard as possible for the duration of approximately 3 seconds with either the hallux or the lesser toes, while the entire foot remains on the floor [54,55]. Movement of the other toes is allowed. The upper body is kept in an upright position and the knees near maximally extended, which is visually inspected by the assessor. Both test conditions are practiced once and completed three times in alternated fashion with a rest period of 30 seconds between the trials. The automated zone divisions are manually corrected afterwards (Materialise NV, Footscan v9). The peak force under each of both plantar regions is normalized to body weight and averaged over 3 trials.

Self-reported mobility limitations

As a proxy of fall risk [17,56], the participant is asked a single question about whether or not experiencing difficulties with mobility, gait or balance in daily life.

Physical activity engagement

The participant is asked to weekly report in the diary (see below) the time spent in physical activities in bouts of at least 10 minutes duration that is experienced by the participant at least as moderate intense (≥5 on a 10-point scale of how hard one feel he or she is exercising) [57].

Fall incidents during intervention period

The participant is asked to report any fall incidents that occurs during the intervention period in their diary (see below). A fall is defined according to the Prevention of Falls Network Europe, as 'an unexpected event in which the subject comes to rest on the ground, floor, or lower level' [58]. In case of a fall, the participant is inquired about the circumstances (i.e., what, how and when) and the consequences (e.g., injuries) of the fall incident. The number of falls is also documented.

Fear of falling

Fear of falling is assessed by the Fall Efficacy Scale-International (FES-I) [59] and is found to be associated with gait modifications [60]. The FES-I is a 16-item questionnaire in which an individual grades his concern about falling during various activities on a 4-point scale, resulting in a total score ranging from 16 to 64. A higher score indicates a greater concern. The Dutch translation of FES-I that is used in this study has acceptable reliability and validity [61].

Physical functioning

Performance on gait speed, balance and lower extremity strength is assessed using the Short Physical Performance Battery (SPPB) [62]. The SPPB is a widely used test in the

older population and the outcome is predictive of a variety of health outcomes. More specifically, SPBB score was shown to be associated with falling [63]. The SPPB consists of 5 short tests: 3 10-second balance test (i.e., double leg stance, semi-tandem stance, tandem stance), 4-meter walk test and a timed chair-stand-test. The test results in a score, ranging from 0 to 12. A higher score indicates better performance.

Population descriptives

Demographics
The demographics age, gender and living situation (i.e., dependent/independent, living together/alone) are reported.

Body length and weight
Body length and weight are assessed using a digital stadiometer (Dong Sahn Jenix co., DS-103).

Mobility related conditions
The participant is asked about the use of walking aids, uncorrected visual impairments, uncorrected hearing loss, musculoskeletal and neurological conditions, use of medicines, presence of dizziness, and number of falls over the past 12 months. Additionally, the dorsal flexion passive range of motion at the hallux metatarsophalangeal joint is assessed and hallux valgus is graded using the Manchester scale [64–66]. Protective sensibility of the plantar side of the foot is evaluated according to the Dutch guideline for the diabetic foot (2017) with a 10-gram Semmes-Weinstein monofilament.

Cognitive functioning
Cognitive functioning is assessed by the Montreal Cognitive Assessment (MoCA), addressing 8 domains of cognitive functioning [67]. It exhibits good reliability and validity [67] and it was shown to be superior compared to the Mini-Mental State Examination in distinguishing among a group of individuals with mild cognitive impairment showing less ceiling effects [68]. The maximum score is 30, indicating maximum cognitive functioning.

Health related quality of life
The 36 item Short Form Health Survey (SF-36) is used to assess health related quality of life [69]. The survey addresses 8 domains, among which physical functioning and mental health, both being related to balance and gait. The item scores are transformed such that a higher score indicates better health. Total scores and the scores on the physical functioning domain and mental health domain are expressed as a score out of 100. The Dutch translation of the SF-36 used in this study proved to be a reliable and valid instrument for the general population [70].

Hand grip strength
Hand grip strength is measured using a hydraulic hand grip dynamometer (Baseline, 12-0241 LiTE). Hand grip dynamometry, reliable for measuring grip strength in older adults [71], is proposed a fundamental element of physical examination of older adults [72]. The participant, seated and having the dominant arm rested on a table with the elbow in 90 degrees of flexion, is encouraged to exert maximal grip strength. After a practice trial, the maximum force of one trial is recorded.

Physical activity behavior
A physical activity monitor (ActivPAL, PAL Technologies Ltd.) [73,74] is used to record physical activity 24 hours a day for a maximum of 7 days between the home visit and the baseline laboratory session. This wearable is used to obtain average daily time spent sedentary, standing and stepping (i.e., cycling and walking). In addition, the average daily stepping time with cadence ≥ 75 steps per minute in bouts of at least 10 minutes is obtained (46).

Characteristics of the functional exercise program
The setting (e.g., physiotherapy practice, senior gym class) and the weekly frequency and duration of the functional exercise program in which the participant is involved is documented. Also weekly, it is verified whether the participant is still involved in the functional exercise program.

Other outcome variables

Movement related discomfort
The participants in the PIM strengthening training group weekly report movement related discomfort experienced during the training in their diary. Both the PIM strengthening training group and the control group weekly report movement related discomfort experienced throughout the week (outside the training) in their diary enabling the comparison between the groups for the occurrence of adverse events.

Exercise adherence
The participant notes the completion of each unsupervised training session in the diary. The attendance to the supervised session is registered by the trainer. Overall adherence to the training is expressed in the number of completed sessions as a percentage of the total number of prescribed training sessions.

Statistical analysis
All statistical analyses are completed using SPSS 28.0 (IBM) software. Baseline and post-intervention data, as well as changes from baseline, are summarized per group by descriptive statistics (i.e., means and standard deviations for continuous variables and

absolute and relative frequencies for categorical variables). In addition, the between group differences in mean change from baseline are presented with its 95% confidence interval.

Missing data are explored in terms of numbers and characteristics. If the proportion of missing data is below 5% or when the missing data occurs completely at random, complete case analysis is performed. If these criteria are not met, multiple imputation is used to handle the missing data [75].

The primary analyses test the hypotheses that the mean change from baseline in the primary outcome variable (maximum gait speed) and secondary outcome variables is superior for the intervention group compared to the control group. To this end, the data for each participant that completed the post-intervention measurements are included as randomized to perform an intention-to-treat analysis. An additional per-protocol analysis is conducted, including only the participants from the PIM strengthening training group who completed ≥ 75% of the prescribed session. Analyses of covariance (ANCOVA) are performed with the baseline value of the outcome variable included as covariate [76,77], after having checked the assumptions (i.e., no outliers, normal distribution of dependent variable, independency covariate and treatment effect, linear relationship between covariate and dependent variable, homogeneity of regression slopes, homogeneity of variance of dependent variable). Additionally, in separate linear regression analyses, the potential modification of the intervention effect is explored for the potential modifiers 'change from baseline in physical activity', 'change from baseline in muscles' morphology' and 'change from baseline in isometric toe flexor strength'. α=0.05 (one-tailed) is applied to draw conclusions on the statistical analyses.

Variables designated as 'other outcome variables' are analyzed using a descriptive approach.

DISCUSSION

The proposed protocol presents the rational and methodology for an RCT to investigate the effect of a PIM strengthening training on mobility related outcome variables in older adults who are involved in a group-based functional exercise program. This responds to the identified need for a high-quality study on the effect of such a training on outcome variables that are meaningful to this target population in the sense of decreasing fall risk [18].

We have strived for high-quality methodology by randomization and concealed allocation, blinding of assessors, collecting confounders and maximizing adherence and retention. Although we make substantial effort to blind the assessors, it is not inconceivable that the group allocation is revealed by either the participant at the post-intervention measurement or the trainer, who is in close contact with the primary investigator. The guess of the allocation after the post-intervention measurement will show whether assessor blinding was accomplished successfully.

Another internal validity limitation relates to the contrast between the trial arms. Ideally, any effect may be ascribed to the PIM strengthening training. However, because it is impossible to blind participants in an exercise program, related bias may occur [78]. In addition, participating in the PIM strengthening training may promote physical activity, among which attendance to the functional exercise group. We attempted to minimize this bias by introducing the diary for the control group, containing similar questions related to mobility and physical activity. Nevertheless, we included physical activity as a secondary outcome variable. This enables us to evaluate the confounding effect of change from baseline in physical activity on change from baseline in other outcome variables.

The design of the PIM strengthening training took into account factors to optimize the intervention effect. Some of these factors correspond well to clinical practice whereas others do less. The progressive nature agrees with the principle of overload, which is common practice in physical therapy and is recommended for functional training to prevent falling [6]. In addition, the training is delivered and supervised by a 4th year physiotherapy student who is able to properly provide instructions and coach the participant to adhere to the training, similar to the practice of fall preventive exercise programs. However, the intensity of the training, targeting primarily the feet, 5 times a week for 20 minutes, is not common practice. This may compromise generalizability to existing fall preventive exercise programs, which usually involve a weekly 1-hour session in which all muscle groups are addressed. Nevertheless, knowing that a 12-week intensive PIM strengthening training can improve mobility may advocate the integration of such exercises in fall preventive and ongoing exercise programs.

Some other factors also endorse the external validity. Regarding the population, we decided to recruit the participants in the target setting, which is in fall preventive or functional exercise programs. Additionally, we adopted broad eligibility criteria, which further supports the generalizability of the findings to the target population. Regarding the intervention, the training consists of both resistance and functional exercises, which seems to be most effective to prevent falling in older adults [7].

The results of this RCT give guidance relating PIM strengthening to existing fall preventive exercise programs. To this end, all training materials (i.e., written instructions, training guide and the instructional videos) will be made available once the intended peer-reviewed article has been published open access.

LIST OF ABBREVIATIONS

MTP1: hallux' metatarsal phalangeal joint; PIM: plantar intrinsic foot muscle; RCT: randomized controlled trial; STIFF: STrengthening the Intrinsic Foot Flexor muscles.

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DECLARATIONS

Ethics approval and consent to participate
The protocol is approved by the medical research ethics committee of Maxima Medical Center, Veldhoven, The Netherlands (CCMO nr. NL80110.015.21).

Availability of data and materials
The datasets generated and/or analyzed during the current study are not publicly available but are available from the corresponding author on reasonable request.

Competing interests
The authors declare that they have no competing interests.

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Authors' contributions
All authors have made substantial contributions to the conception and design of the study. LW drafted the manuscript and BV, EW, and MP revised the manuscript. All authors read and approved the final manuscript.

SUPPLEMENTARY MATERIALS

Supplementary Material 5A: SPIRIT checklist

Section/item	Item No.	Description	Reference to where item is addressed
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Title
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Abstract / Design, setting and protocol
	2b	All items from the World Health Organization Trial Registration Data Set	Table 1
Protocol version	3	Date and version identifier	Methods: Design, setting and protocol
Funding	4	Sources and types of financial, material, and other support	Declarations: Funding
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Authors / Declarations: Authors' contributions
	5b	Name and contact information for the trial sponsor	Table 1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Declarations: Funding
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Background
	6b	Explanation for choice of comparators	Background

Supplementary Material 5A: Continued

Section/item	Item No.	Description	Reference to where item is addressed
Objectives	7	Specific objectives or hypotheses	Background
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Methods: Design, setting and protocol
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Methods: Participants
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Methods: Interventions
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Methods: Interventions
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Methods: Outcome measures / Methods: Interventions
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Methods: Design, setting and protocol
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Methods: Outcome measures
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1 / Methods: Randomization and blinding / Methods: Data collection procedures / Additional File 2

Supplementary Material 5A: Continued

Section/item	Item No.	Description	Reference to where item is addressed
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Methods: Participants (Sample size)
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Methods: Participants (Recruitment)
Methods: Assignment of interventions (for controlled trials)			
Allocation:			Methods: Randomization and blinding
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Methods: Randomization and blinding
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Methods: Participants (recruitment) / Methods: Randomization and blinding
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Methods: Randomization and blinding
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	Methods: Randomization and blinding

Supplementary Material 5A: Continued

Section/item	Item No.	Description	Reference to where item is addressed
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Methods: Data collection procedures / Methods: Outcome measures Data collection forms can be obtained from the investigator
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Methods: Data collection procedures
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Described in the protocol approved by the ethics committee
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Methods: Statistical analysis
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Methods: Statistical analysis
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Methods: Statistical analysis
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a: Local standards do not require a DMC

Supplementary Material 5A: Continued

Section/item	Item No.	Description	Reference to where item is addressed
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Methods: Outcome measures
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/ institutional review board (REC/IRB) approval	Methods: Design, setting and protocol
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	n/a
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Methods: participants
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Described in the protocol approved by the ethics committee
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Declarations: Competing interests
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Described in the protocol approved by the ethics committee
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	Described in the protocol approved by the ethics committee

Supplementary Material 5A: Continued

Section/item	Item No.	Description	Reference to where item is addressed
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Discussion
	31b	Authorship eligibility guidelines and any intended use of professional writers	Declarations: authors' contributions
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Provided in the protocol approved by the ethics committee
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

Supplementary Material 5B: CONSORT 2017 Checklist for Nonpharmacologic Treatments

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions Refer to CONSORT extension for abstracts for NPT trials	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3-4
	2b	Specific objectives or hypotheses	4

Supplementary Material 5B: Continued

Section/Topic	Item No	Checklist item	Reported on page No
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio When applicable, how care providers were allocated to each trial group	4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants When applicable, eligibility criteria for centers and for care providers	6
	4b	Settings and locations where the data were collected	4-5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered Precise details of both the experimental treatment and comparator	19-21
	5a	Description of the different components of the interventions and, when applicable, description of the procedure for tailoring the interventions to individual participants.	20
	5b	Details of whether and how the interventions were standardized.	19-20
	5c	Details of whether and how adherence of care providers to the protocol was assessed or enhanced	19-20
	5d	Details of whether and how adherence of participants to interventions was assessed or enhanced	20
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8-19
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined When applicable, details of whether and how the clustering by care providers or centers was addressed	6-7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a

Supplementary Material 5B: Continued

Section/Topic	Item No	Checklist item	Reported on page No
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (e.g., participants, care providers, those administering co-interventions, those assessing outcomes) and how	7
	11b	If relevant, description of the similarity of interventions	n/a
	11c	If blinding was not possible, description of any attempts to limit bias	7,8
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes When applicable, details of whether and how the clustering by care providers or centers was addressed	21-22
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	21
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider or in each center	n/a
	13b	For each group, losses and exclusions after randomisation, together with reasons	n/a
	13c	For each group, the delay between randomization and the initiation of the intervention	n/a
	New	Details of the experimental treatment and comparator as they were implemented	n/a

Supplementary Material 5B: Continued

Section/Topic	Item No	Checklist item	Reported on page No
Recruitment	14a	Dates defining the periods of recruitment and follow-up	n/a
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group	n/a
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	n/a
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	n/a
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group	22-23
Generalisability	21	Generalizability (external validity) of the trial findings according to the intervention, comparators, patients, and care providers and centers involved in the trial	22-23
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	n/a
Other information			
Registration	23	Registration number and name of trial registry	5
Protocol	24	Where the full trial protocol can be accessed, if available	n/a
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	24

Supplementary Material 5C: Training guide
The training log is only presented for exercise 1 and the diary is only presented for week 1.

ID:

STIFF TRAINING GUIDE

For the study into foot muscles and the ability to move in older adults

Fontys Allied Health Professions in collaboration with SGE

Fontys

STIFF

SGE

Your participation in the study

You are participating in the study on the effect of foot training on balance and walking. For this purpose, you have been assigned to the group that will undergo the **foot training**. You can read more about this on the following pages.

It is of utmost importance for the study that the researcher, Lydia Willemse, does not know that you are involved in the foot training. Therefore, please try to keep this unrevealed when you see her at the last measurement.

We consider it very important that you report any emerging symptoms or discomfort during or outside the training to the trainer. If necessary, we will examine together whether and how you can continue the training.

! **Always report discomfort during or after training to the trainer and note this in the diary**

The timeline of the study

MEASUREMENT 1A: HOME — Date measurement 1A:

MEASUREMENT 1B: FONTYS — Date measurement 1B:

4 x self training 1 x with trainer	**WEEK 1**	Date with trainer: Location:
4 x self training 1 x with trainer	**WEEK 2**	Date with trainer: Location:
4 x self training 1 x with trainer	**WEEK 3**	Date with trainer: Location:
4 x self training 1 x with trainer	**WEEK 4**	Date with trainer: Location:
4 x self training 1 x with trainer	**WEEK 5**	Date with trainer: Location:
4 x self training 1 x with trainer	**WEEK 6**	Date with trainer: Location:
4 x self training 1 x with trainer	**WEEK 7**	Date with trainer: Location:
4 x self training 1 x with trainer	**WEEK 8**	Date with trainer: Location:
4 x self training 1 x with trainer	**WEEK 9**	Date with trainer: Location:
4 x self training 1 x with trainer	**WEEK 10**	Date with trainer: Location:
4 x self training 1 x with trainer	**WEEK 11**	Date with trainer: Location:
4 x self training 1 x with trainer	**WEEK 12**	Date with trainer: Location:

MEASUREMENT 2: FONTYS

Location Fontys:
Rachelsmolen 1
Building R12
5612 MA Eindhoven

The foot training

The foot training consists of a **12-week** program. Each week you will train 4 x 20-30 minutes at home without a trainer (it may take a little more time in the beginning) and 1 x 30 minutes with a trainer.

For the **training with the trainer**, you can choose whether you want to receive the trainer at home or you visit us at Fontys Allied Health Professions where you can train with other participants. The training will be given by a 4th year physical therapy student. On the previous page you will find the contact information. The trainer will discuss with you when and where the training will take place.

You perform the **training without the trainer** by yourself using this training book and the instructional videos. Below the exercise instructions, you will find your additional instructions for performing the exercises. Here it says in which position you perform the exercise and with how many repetitions or how many seconds you should perform the exercise. When this changes, the trainer will indicate this on that page. You should always follow the bottom instructions. Your goal, unless otherwise agreed, is to do all the exercises. This takes about 20-30 minutes each session.

The image of each exercise is accompanied by a QR code that you can scan with your smartphone or tablet. This will lead you to an instructional video for each exercise. If you do not have a smartphone or tablet, that is not a problem. The trainer will discuss with you how to still access the videos. The QR code on the right will lead you to the introductory video.

When performing standing exercises, for safety, always have something nearby that you can hold onto, such as the back of a sturdy chair or the kitchen counter.

The complete foot training

Want to do all the exercises in one run using the instructional videos? Then, scan this QR code:

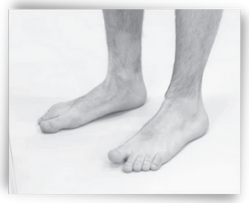
Training log and diary

For the study, it is important that we know how you experience the exercises. We therefore ask you to indicate on the right-hand page of the exercise book how feasible you perceived the execution of the exercise. Fill in this page each time you have performed an exercise. You do this for your left foot and right foot seperately by placing a circle around the smiley that best fits your experience.

Very easy | Somewhat easy | Neutral | Somewhat difficult | Very difficult

Only circle the smiley if you performed the exercise or if you attempted to perform the exercise.

At the back of the training book you will find the diary containing some more general questions. We also ask that you fill these out after each training session.



Exercise 1: Big toe and lesser toes extension

Instruction:

- Place your feet flat on the floor at hip width;
- Lift the big toe of the left foot off the floor while the lesser toes remain on the floor;
- Hold this for **5 seconds**;
- Now lift the little toes up while keeping your big toe on the ground;
- Hold this for 5 seconds;
- After you have done all the repetitions, repeat everything with your other foot.

Keep the ball of the foot on the ground

Position	Side	Repetitions	Rest	Repetitions	Moment of adjustment (week, training#)
Seated	L / R	10 x 5sec			

Very easy
Somewhat easy
Neutral
Somewhat difficult
Very difficult

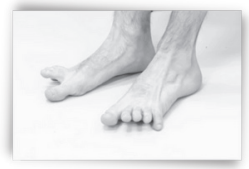
Exercise 1: Big toe and lesser toes extension

Week	Training	Feasibility LEFT	Feasibility RIGHT
1	1		
	2		
	3		
	4		
	5		
2	1		
	2		
	3		
	4		
	5		
3	1		
	2		
	3		
	4		
	5		
4	1		
	2		
	3		
	4		
	5		
5	1		
	2		
	3		
	4		
	5		
6	1		
	2		
	3		
	4		
	5		

Exercise 1: Big toe and lesser toes extension

Very easy
Somewhat easy
Neutral
Somewhat difficult
Very difficult

Week	Training	Feasibility LEFT	Feasibility RIGHT
7	1		
	2		
	3		
	4		
	5		
8	1		
	2		
	3		
	4		
	5		
9	1		
	2		
	3		
	4		
	5		
10	1		
	2		
	3		
	4		
	5		
11	1		
	2		
	3		
	4		
	5		
12	1		
	2		
	3		
	4		
	5		



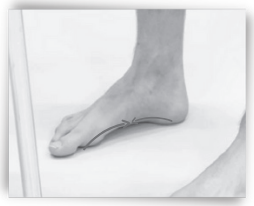
Exercise 2: Toe spread and squeeze

Instruction:

- Sit on a chair;
- Place your feet flat on the floor at hip width;
- Lift the toes of the left foot off the floor and spread the toes as far apart as possible;
- Hold this for **5 seconds**;
- Now squeeze the toes of the same foot together;
- Hold this for **5 seconds**;
- After you have done all the repetitions, repeat everything with your right foot.

You may train both feet at the same time

Position	Side	Repetitions	Rest	Repetitions	Moment of adjustment (week, training#)
Seated	L / R	10 x 5sec			



Exercise 3: Short foot exercise

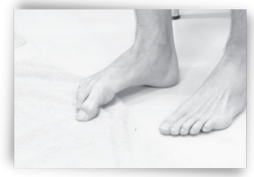
Instruction:

- Check the table below to see if you perform this exercise standing or sitting;
- Place your feet flat on the floor at hip width;
- Pull the ball of the foot toward the heel, without curling the toes;
- While doing this, keep the ball of the foot and the heel on the floor;
- Hold for **3 seconds**
- After you have done all the repetitions, repeat everything with your other foot

This is a tough exercise, but keep trying.

The movement is only small..

Position	Side	Repetitions	Rest	Repetitions	Moment of adjustment (week, training#)
Seated	L / R	10 x 3sec			



Exercise 4: Towel curl

Equipment:

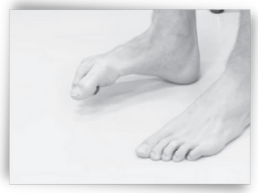
- Towel

Instruction:

- Sit on a chair;
- Place the towel in front of you on the floor;
- Place your feet flat on the floor at hip width;
- With the toes of one foot, curl up the towel a little bit and hold for **2 seconds**;
- Release the towel to grab the towel a little further;
- After you have done all the repetitions, repeat everything with your other foot

This is a tough exercise, but keep trying.

Position	Side	Repetitions	Rest	Repetitions	Moment of adjustment (week, training#)
Seated	L / R	5 x 2 sec			



Exercise 5: Marble pick up

Equipment:

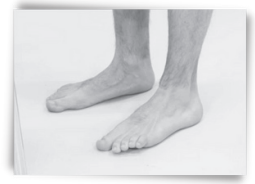
- Marble or else a cap, eraser or similar object.

Instruction:

- Sit on a chair;
- Put your feet flat on the floor at hip width;
- Place the object in front of you on the floor;
- Grasp the object with your toes and hold for **2 seconds**;
- Release the object again;
- After you have done all the repetitions, repeat everything with your other foot.

This is a tough exercise, but keep trying.

Position	Side	Repetitions	Rest	Repetitions	Moment of adjustment (week, training#)
Seated	L / R	5 x 2 sec			



Exercise 6: Big toe and lesser toes press

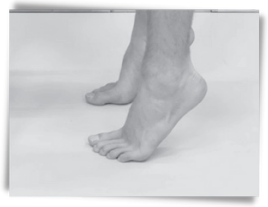
Instruction:

- Stand on two legs;
- Place your feet flat on the floor at hip width;
- Push the big toe against the floor as firm as possible without curling the toes;
- Hold this for **5 seconds**;
- Now push the smaller toes into the ground as firm as possible;
- Hold this for **5 seconds**;
- Do this for the number of repetitions stated below.

When you start cramping, stop for a moment.

Stretching the toes may help reduce cramping

Position	Side	Repetitions	Rest	Repetitions	Moment of adjustment (week, training#)
Seated	L / R	10 x 5 sec			



Exercise 7: Heel raise

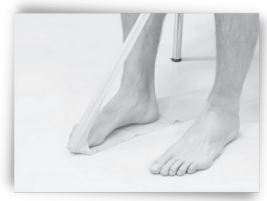
Instruction:

- Check the table below to see in which position you perform this exercise;
- Place your feet flat on the floor at hip width;
- Then lift your heel as high as you can while keeping your toes on the ground;
- Hold for **2 seconds**;
- Now slowly lower your heel(s) until the foot (feet) are flat on the floor again;
- Did you perform this exercise on one leg? Then repeat everything with your other foot on the floor.

Like grabbing something off a high shelf

You may perform this exercise anywhere and anytime

Position	Side	Repetitions	Rest	Repetitions	Moment of adjustment (week, training#)
Seated	L / R	10 x 2 sec			



Exercise 8: big toe flexion against resistance

Equipment:

- Resistance band

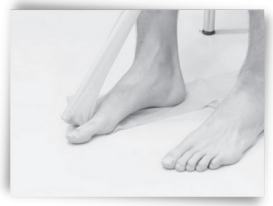
Instruction:

- Sit on a chair and place your feet flat on the floor at hip width;
- Place the resistance band under your foot with one end under the heel and the other around the big toe
- Stand up with the band in your hand to create tension;
- Push the big toe into the band;
- Hold this for **5 seconds**;
- After you have done all the repetitions, repeat everything with your other foot.

The more tension on the band, the harder the exercise

Keep the ball of your foot on the floor

Position	Side	Repetitions	Rest	Repetitions	Moment of adjustment (week, training#)
Seated	L / R	10 x 5 sec			



Exercise 9: Lesser toes flexion against resistance

Equipment:

- Resistance band

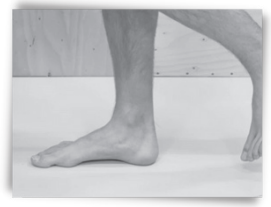
Instruction:

- Take a seat on a chair and place your feet flat on the floor at hip width;
- Place the resistance band under your foot with one end under the heel and the other around the four smaller toes;
- Stand up with the band in your hand to create tension;
- Push the toes into the band;
- Hold this for **5 seconds**;
- After you have done all the repetitions, repeat everything with your other foot.

The more tension on the band, the harder the exercise

Keep the ball of your foot on the floor

Position	Side	Repetitions	Rest	Repetitions	Moment of adjustment (week, training#)
Seated	L / R	10 x 5 sec			



Exercise 10: single leg stance

Instruction:

- When doing this exercise, always hold the back of a chair, or something similar;
- Place your feet flat on the floor at hip width;
- Then lift one foot slightly off the floor;
- Keep the supporting leg bent;
- Try to hold this position according to the duration in the table below;
- Repeat the exercise with your other foot.

Put your foot back on the floor briefly when you lose your balance

Keep your eyes straight ahead

Position	Side	Repetitions	Rest	Repetitions	Moment of adjustment (week, training#)
Single leg stance	L / R	20 sec			

Exercise 11: toe walking

Only when heel raising succeeds properly

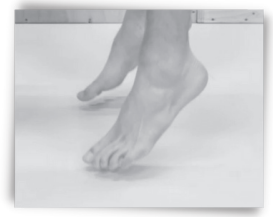
Instruction:

- When doing this exercise, always walk past something you can have support from, such as a table or wall;
- Stand on your toes;
- Try to walk on your toes for **20 seconds**.

Try to tiptoe as high as possible

Rest when needed

Position	Side	Repetitions	Rest	Repetitions	Moment of adjustment (week, training#)
n/a	n/a	20 sec			



Exercise 12: Hopping

Only when toe walking succeeds properly

Instruction:

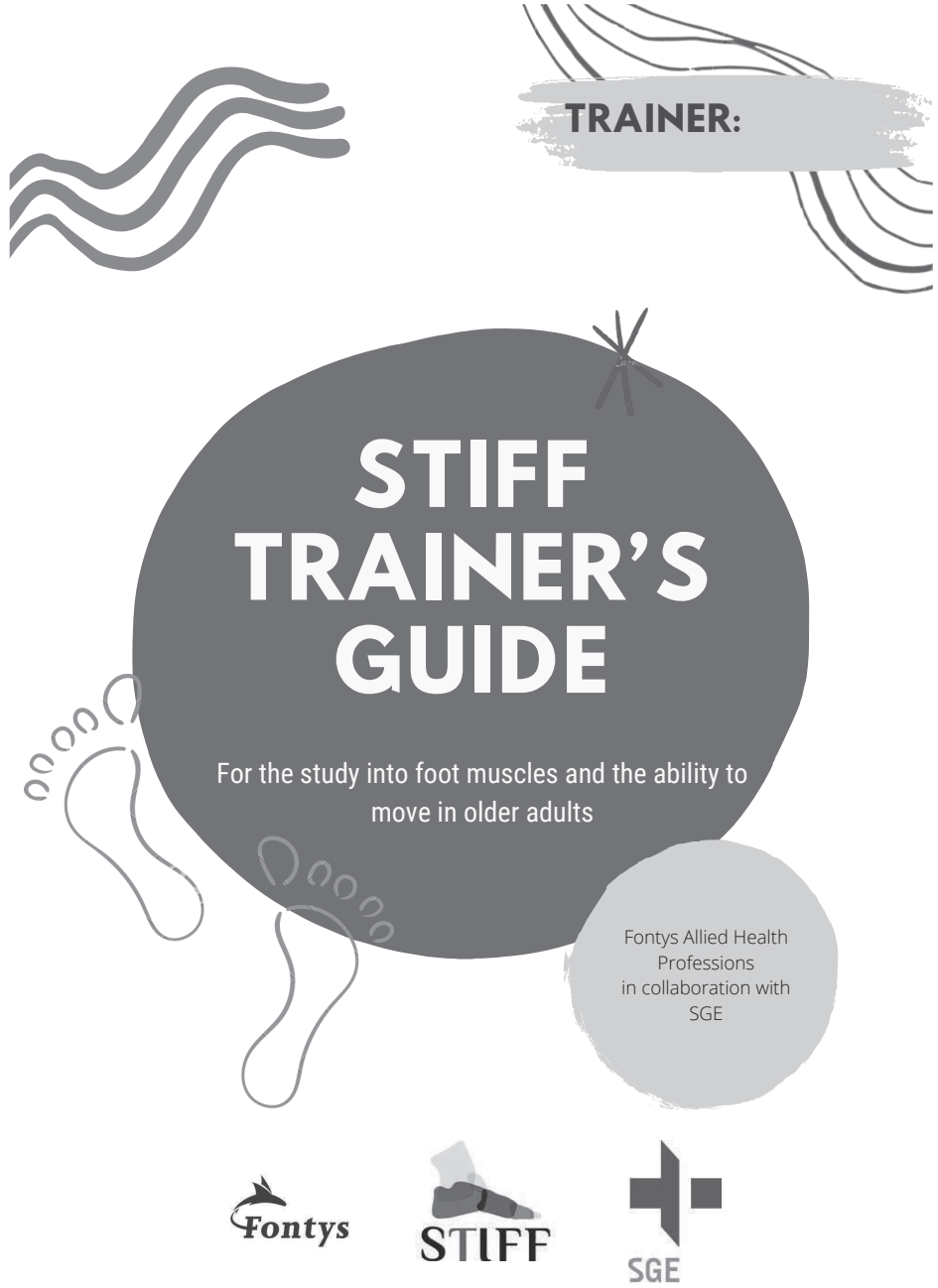
- Check the table below to see if you are performing this exercise on two legs or one leg;
- Always hold the back of a chair, or something similar, when doing this exercise;
- Place your feet flat on the floor at hip width;
- Lift the heel(s) slightly off the floor;
- Now make a small jump, with the toes only just off the ground;
- Land on your toes;
- Did you perform this exercise on one leg? Then repeat everything with your other foot.

The toes need only just, if at all, come off the ground

Position	Side	Repetitions	Rest	Repetitions	Moment of adjustment (week, training#)
Double leg stance	L / R	10 x			

Week 1	
For each training, please describe here in a few words how you experienced the **unsupervised training** and how long it took.	
Training #1	
Training #2	
Training #3	
Training #4	
Have you completed the **supervised training** this week?	Yes / No If yes, please indicate the date:
Indicate here any **discomfort** you experienced **while** doing the exercises. *For example: lower foot cramping when performing exercise x*	
Indicate here what **physical activities** of at least moderate intensity you engaged in outside the foot training that lasted >10 min. consecutively.	
Indicate here any mobility-related **discomforts** you experienced **outside** the foot training, *such as pain in your ankle, foot, leg or lower back.* Please also indicate here if, unexpectedly, you have fallen.	

Supplementary Material 5D: Trainer's guide



Your contribution to the study

You are one of the trainers of the study into the effect of foot training on balance and walking in older adults. All the information about this study can be found in the protocol, the participant information letter, the training guide for the participants in the intervention group and the diary of the control group. You will also complete the train the trainer workshop. It is important that you have thoroughly familiarized yourself with the information. This trainer's guide contains some additional information and tools that you will use to properly guide and monitor the participants.

As a trainer, you have a very important job in this study. From the moment the research support person has informed the chief trainer that a participant has been assigned to either the intervention group or the control group, your job is to:

1. introduce the control or intervention guidelines to the participant
2. make the weekly arrangements with the participant for the training sessions with trainer (intervention) or weekly call the participants (control)
3. organize the group training sessions on campus
4. instruct and motivate the participant on the exercises
5. encourage the participant to adhere to the program
6. determine and document the progression level of the exercises
7. report any discomfort during or outside the training that relates to mobility to the research support person and consult with the researcher (without disclosing the group assignment)

It is very important for the study that the researcher, Lydia Willemse, does not know which group the participants are assigned to. Therefore, emphasize this during the final training session or call.

Do not use the participant's name in any documentation, but instead use the participant ID

Overview of all participants

This overview lists all the participants, the group assignment and the trainer who will take care of the participant during the 12 weeks.

ID	Group (I / C)	Trainer	Location (home / campus)	Trainingsgroup
99	I	PP	home	Tuesday 14.00-14.30 / n/a

Overview participants per trainer

This overview lists each trainer's participants, the appointments made and a checkbox for if a participant actually did the supervised training (intervention group) or if the trainer discussed the diary with the participant (control group).

ID	14					
Group (I / C)	I					
Location (home/campus)	home					
#1	2-10, 10.00 ☐	☐	☐	☐	☐	☐
#2	☐	☐	☐	☐	☐	☐
#3	☐	☐	☐	☐	☐	☐
#4	☐	☐	☐	☐	☐	☐
#5	☐	☐	☐	☐	☐	☐
#6	☐	☐	☐	☐	☐	☐
#7	☐	☐	☐	☐	☐	☐
#8	☐	☐	☐	☐	☐	☐
#9	☐	☐	☐	☐	☐	☐
#10	☐	☐	☐	☐	☐	☐
#11	☐	☐	☐	☐	☐	☐
#12	☐	☐	☐	☐	☐	☐

The supervised training

Each training session, keep a fixed order of the following steps so you can't forget anything.

1. Explain what you and the participant will do during training
2. Using the diary, ask if any discomforts occurred during or outside the training that are related to mobility. If yes, see flow chart.
3. Using the diary, ask how the unsupervised training sessions went
4. **Go through each exercise from the training guide together,** score the motor performance, note the exercise level in the participant's training guide and mark the completed training
   - → Watch instructional video together
   - → Verbally explaining the exercise
   - → Perform the exercise together
   - → Have the participant circle the smiley himself/herself in the training guide
5. Make an appointment for the next supervised training session
6. Emphasize the importance of reporting mobility discomforts during or outside the training to the trainer
7. Motivate the participant to do the exercises according to the program and using the videos

! **If a participant wants to quit the study: notify the research support person immediately**

Progression in the level of exercises

In **week 1**, always start with the **lowest level**. When advancing to the next level?
The participant perceives the exercise as very easy **AND** maximum motor performance during all repetitions
Write down the adjusted instructions for the next level on the left page of the training book

Exercise	Repetitions	Posture	Level +	Level ++	Level +++
1: Big toe and lesser toes extension	10 x 5 sec	double leg stance	30 sec rest + 5 x 5 sec	not 5 x but 10 x	30 sec rest + 5 x 5 sec
2: Toe spread and squeeze	10 x 5 sec	seated	30 sec rest + 5 x 5 sec	not 5 x but 10 x	30 sec rest + 5 x 5 sec
3: Short foot exercise	5 x 3 sec	double leg stance	single leg stance	30 sec rest + 5 x 3 sec	30 sec rest + 5 x 3 sec
4: towel curl	5 x 2 sec	seated	30 sec rest + 5 x 2 sec	idem	idem
5: Marble pick up	5 x 2 sec	seated	30 sec rest + 5 x 2 sec	idem	idem
6: Big toe and lesser toes press	10 x 5 sec	double leg stance	30 sec rest + 5 x 5sec	not 5 x but 10 x	30 sec rest + 5 x 5 sec
7: Heel raise	10 x 2 sec	seated	double leg stance	single leg stance	30 sec rest + 5 x 2 sec
8: Big toe flexion against resistance	10 x 5 sec	zittend, yellow band	red band	green band	
9: Lesser toes flexion against resistance	10 x 5 sec	seated, yellow band	red band	green band	
10: Single leg stance	20 sec	single leg stance	+ 10 sec	idem	idem
11: Toe walking	1 x 20 sec	double leg stance	30 sec rest + 1 x 20 sec	idem	idem
12: Hopping	10 x	both legs	one leg	30 sec rest + 5 x	not 5 x, but 10 x

Only when heel raising level +

Only when toe walking ' level +

What if the training takes >30 minutes?

The training time may be shortened if the participant spends more than 30 minutes training. At least 20 minutes of actual training must be done, excluding instructions, chitchatting and rest between exercises. A participant may train for longer than 30 minutes at their own discretion. Follow these instructions to shorten the training sessions:

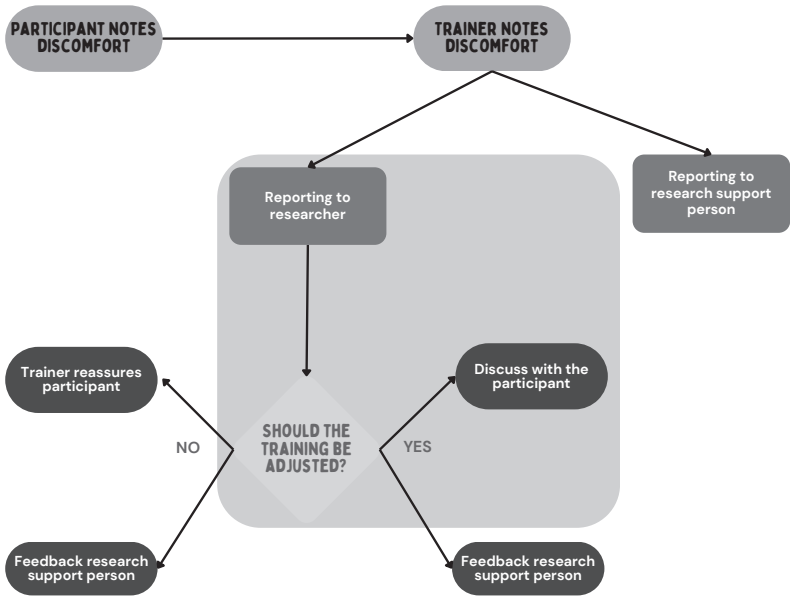
1. Training with two feet at the same time (only if the quality of movement is not diminished by this).
2. Use the long video to go through all the exercises in one run.
3. Discuss with the participant which exercises will be shortened or omitted.
   - In the first weeks: only shorten exercises by repetitions, preferably do not omit exercises.
   - In the following weeks: omit exercises or combine fewer reps and omitting exercises.

When exercises need to be omitted, adhere to the guideline below so that all muscles are addressed in the training program. Note the adjustments in the training guide in the table below the explanation of the exercise and the reason why it was adjusted.

Exercises that must be kept in the training	At least one of the following exercises must be kept in the training	May be omitted from the training
• Grote tenen en kleine tenen in de grond duwen • Tenen spreiden en samenknijpen • Short foot exercise	• Handdoek grijpen / knikker grijpen / grote teen en kleine teen flexie met weerstand • Tenenstand / tenen lopen / hoppen	Big toe and lesser toe extension

Flow chart discomfort

In the following way, discomforts are reported and followed up. These are not only discomforts that can be directly linked to foot training. In general, it is about discomforts related to mobility that occur during or outside the training. For example, pain in the lower back.



Motor performance

ID:

Motor performance:
0: no movement or position cannot be maintained
1: exercise can be partially completed or with difficulty or compensation
2: exercise can be completed with typical performance

Exercise	Side	Wk1	Wk2	Wk3	Wk4	Wk5	Wk6	Wk7	Wk8	Wk9	Wk10	Wk11	Wk12
1	L												
	R												
2	L												
	R												
3	L												
	R												
4	L												
	R												
5	L												
	R												
6	L												
	R												
7	L												
	R												
8	L												
	R												
9	L												
	R												
10	L												
	R												
11	L												
	R												
12	L												
	R												

Supplementary Material 5E: Diary (control group)

ID:

STIFF DIARY

For the study into foot muscles and the ability to move in older adults

Fontys Allied Health Professions in collaboration with SGE

Fontys STIFF SGE

Your participation in the study

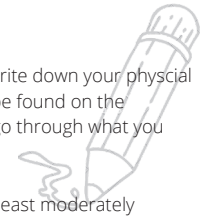
You are participating in the study on the effect of foot training on balance and walking. For this, you are assigned to the group that only keeps a diary and completes the measurements. You can read more about this on the following pages.

It is of utmost importance for the study that the researcher, Lydia Willemse, does not know that you are assigned to the control group. Therefore, please try to keep this unrevealed when you see her at the last measurement.

The timeline of the study

Location Fontys:
Rachelsmolen 1
Building R12
5612 MA Eindhoven

The diary



For the study, it is important that you keep a diary, in which you write down your physcial activities and, if any, discomfort you encountered. This diary can be found on the following pages. One of the trainers below will call you weekly to go through what you filled out there.

Please write down only those activities that you perceive to be at least moderately intense and that last at least in bouts of 10 minutes. For example, going for a walk or riding a bike. You do not need to write down household chores.

Week 1	
Indicate here what **physical activities** of at least moderate intensity you engaged in that lasted >10 min. consecutively.	
Monday	
Tuesday	
Wednesday	
Thursday	
Friday	
Saturday	
Sunday	
Indicate here any **mobility-related discomforts** you experienced, *such as pain in your ankle, foot, leg or lower back.* Please also indicate here if, unexpectedly, you have fallen.	

Effects of a 12-week intrinsic foot muscle strengthening program (STIFF) on gait, balance and concerns about falling in physically active older adults: an assessor-blinded randomized-controlled trial (study 5)

Submitted as:
Willemse L, Wouters EJM, Pisters MF, Vanwanseele B. Effects of a 12-week intrinsic foot muscle strengthening program (STIFF) on gait, balance and concerns about falling in physically active older adults: an assessor-blinded randomized-controlled trial. 2025. Under review.

6

ABSTRACT

Falling is a major concern in the ageing population. Strengthening the plantar intrinsic foot muscles (PIM) may improve gait and balance in older adults and, therefore, may have potential for fall prevention.

The aim of the present study is to examine the effect of a PIM strengthening program on gait, balance and functional outcomes in older adults.

For this assessor-blinded RCT, older adults (> 65 years) with potentially increased fall risk were recruited at functional exercise classes and randomly assigned to an intervention (12-week supervised and progressive PIM strengthening program) and a control group. The trial outcomes were between-group differences in mean change from baseline in maximum gait speed (primary outcome), balance during gait, foot and ankle biomechanics during gait and concerns about falling and within-group differences in capacity and strength of foot muscles.

Thirty-three participants were included. No between-group differences were found for change in maximum gait speed. However, the intervention group showed a larger reduction in concerns about falling. In addition, the intervention group showed increased capacity and strength of foot muscles, but this was not related to other findings.

This study did not show an effect of PIM strengthening training on maximum gait speed in older adults who are involved in a functional exercise program. However, it seems to reduce concerns about falling. This advocates further research on the benefits of integrating PIM strengthening exercises in functional exercise programs. In addition, future studies are needed to unravel the mechanism behind the reduction in concerns about falling.

HIGHLIGHTS

- Plantar intrinsic foot muscles are trainable in older adults
- Training the plantar intrinsic foot muscles reduced concerns about falling
- Gait analysis did not show improvement after plantar intrinsic foot muscle training

INTRODUCTION

Falling is a major concern in the worldwide ageing population. One third of older adults encounter one or more falls per year [1,2]. Falling is the leading cause of severe injuries and often contributes to losing independence [3]. Furthermore, severe injuries are the fifth leading cause of death in older adults [4]. The associated direct medical costs accounted 1% of the total healthcare budget in the Netherlands in 2019 [3], illustrating the impact on society. Due to the consequences, falling is often feared by older adults [5], which is triggered by the experience of a fall [6]. Concerns about falling lower physical activity [7], which consequently compromises physical and mental well-being [7]. Since the population continues to age, the prevention of falls in older adults is an urgent concern.

Physical exercise is the most effective way to reduce fall rates, though there is room for further improvement. A systematic review [8] showed that incorporating functional, balance and resistance exercises reduced the rate of falls by 36%. This aligns with the observation that impairments in mobility (i.e., balance and gait) most strongly predict falling [4]. More recently, decreased isometric toe plantar flexor strength, credited to the plantar intrinsic foot muscles (PIMs) [9], was also associated with increased risk of falling [10,11]. In spite of this, the exercise programs included in the review cited earlier [8] primarily target muscles proximal to the feet. This indicates that the effectiveness of exercise programs may be improved by including PIMs' exercises.

Strengthening the PIMs may improve gait and balance in older adults and, therefore may have potential to benefit fall prevention. The PIMs act to stabilize the foot, which promotes postural control [12]. The more challenging the balance task, the more active the PIMs are [13]. During gait, the PIMs further stiffen the toes in the propulsive phase such that positive mechanical work can be done in the midfoot, which aids propulsion [14]. Balance capabilities and propulsive gait are reflected by maximum gait speed, which is a measure associated with falling [15,16]. It was also found that toe flexor strength is associated with maximum gait speed [17]. This suggests that weakness of the PIMs in older adults may harm gait, which may explain their association with increased fall risk. Some evidence was found for the beneficial effect of PIM training on propulsion in younger, unaffected adults [18]. In older adults, foot and ankle exercise interventions that also target the PIMs, enhanced toe flexor strength [19,20] and improved comfortable gait speed [21]. However, the effect of strengthening the PIMs on maximum gait speed and other fall risk-related mobility parameters in older adults needs to be investigated.

The primary aim of the present study is to examine the effect of a PIM strengthening training program versus no training on maximum gait speed in older adults who are involved in a functional exercise program. To investigate the trainability of the PIMs and how this translates into improved mobility, the secondary aim is to examine the effect of the training on foot and ankle biomechanics during gait, comfortable gait speed, step length, balance during gait, PIM capacity, isometric toe flexor strength, self-reported

mobility impairments, physical activity, fall incidents, concerns about falling and physical functioning. The findings of this study provide guidance to existing fall prevention exercise program with regard to the incorporation of exercises targeting the PIMs.

METHODS

Design

The study design was an assessor-blinded superiority randomized controlled trial (RCT) with two parallel groups. A detailed description of the protocol for this study is available in a corresponding publication [22]. The current method section provides a summary of this protocol. This paper reports the trial according to the CONSORT (Consolidated Standards of Reporting Trials) guidelines for trials of nonpharmacologic treatments [23]. The trial was registered in the United States National Library of Medicine through ClinicalTrials.gov (NCT05531136). The protocol was approved by the medical research ethics committee of Maxima Medical Center, Veldhoven, The Netherlands (CCMO nr. NL80110.015.21).

Participants

Older adults who were involved in a group-based functional exercise program were recruited between November 2022 and February 2024 in and around the city of Eindhoven, The Netherlands. Eligible for participation were individuals 1) aged 65 years or older, 2) able to walk 10 m without using a walking aid, 3) involved in a functional exercise program delivered to a group of older adults by an educated or certified physical therapist or instructor, 4) reporting to have either concerns about falling or to have experienced a fall in the previous 12 months or to have difficulties with mobility, gait or balance in daily life. Excluded from participation were individuals reporting presence of any disorder interfering with adherence to the program or with the execution of foot exercises. Each participant provided written informed consent prior to inclusion.

A priori sample size calculation (G*power 3.1.9.2) revealed that 42 participants were needed to detect a minimal clinically important effect size for maximum gait speed (d = 0.79 [15]). However, recruitment stopped after 34 participants were included due to reaching the end of funding.

Randomization and blinding

After the baseline measurements, the participants were randomly assigned in a 1:1 ratio to either the intervention or the control group. Blinding to the group allocation was limited to the assessors until the post-processing of the data by the primary investigator (LW) had been completed. The primary investigator guessed the group allocation at the post-intervention measurement.

Interventions

The intervention consisted of a 12-week PIM strengthening program prescribing 20 minutes of isolated and functional strengthening exercises to be performed 5 times a week. The exercise intensity gradually progressed based on the individual's performance. Once a week, the training was supervised by an undergraduate physical therapist trained in delivering the treatment. A training guide provided the participants with written and visual instructions about the program and its exercises, including links to instructional videos. The training guide also contained a diary to monitor adherence, physical activities, fall incidents, and movement related discomfort.

The control condition consisted of keeping a diary to report physical activities, fall incidents and movement related discomfort and a weekly phone call from the trainer.

Outcome measures

Primary and secondary outcome variables, assessed at baseline and directly post-intervention, were used to determine the between-group differences in the mean change from baseline. Unilateral outcome variables were taken from the dominant stance leg only.

Maximum gait speed, the outcome variable to address the primary aim of the study, was assessed while walking as fast as possible. Foot and ankle biomechanics were assessed during the stance phase at comfortable walking speed. A 5-step protocol was applied using a 3-dimensional marker-based motion capture system (Codamotion Ltd.; 4 CX1 units, 100 Hz) time synchronized with a recessed force plate (Advanced Mechanical Technology, Inc., OR 6–7, 1000 Hz). Extracted joint kinetics included peak internal sagittal moment and peak negative and positive scalar power in the ankle, Chopart joint, Lisfranc joint and the first metatarsophalangeal joint (MTP1), which were obtained by an inverse dynamic approach. Additionally, the mediolongitudinal arch (MLA) was determined as the angle between 2 line segments linking the rearfoot and the metatarsus. The kinematic output consisted of MLA deformation (i.e., change in MLA from initial contact to its maximum) and recoil (i.e., change in MLA from its maximum to toe-off). In addition, preferred gait speed and step length were simultaneously obtained.

Balance during gait was examined through the minimum lateral margin of stability (MoS_{lat}) [24] during the single leg stance phase of walking at preferred speed using a markerless motion capture system (Qualisys AB, QTM, 8x Miqus videao, 50Hz), time synchronized with a force plate (Advanced Mechanical Technology, Inc., OR 6–7, 1000 Hz).

Using ultrasound (Philips Ultrasound, Lumify, 4-12 MHz linear array transducer), the thickness and/or cross-sectional area of intrinsic (abductor hallucis (AbH), flexor digitorum brevis (FDB), quadratus plantae (QP), flexor hallucis brevis (FHB), abductor digiti minimi (AbDM)) and extrinsic (tibialis anterior (TA), peroneus longus and brevis (PER), and flexor hallucis longus (FHL)) foot flexor muscles was assessed in rest to reflect their force generating capacity.

Hallux and lesser toe flexor strength, normalized to body weight, were assessed by pushing the toe(s) as hard as possible in a pressure plate (Materialise NV) in a bilateral standing pose [25].

Self-administered outcome measures included single-item mobility limitations, concerns about falling using the Fall Efficacy Scale-International (FES-I) [26], weekly duration of at least moderate intense physical activities spent in bouts of ≥ 10 minutes, the number of fall incidents during the intervention period and physical functioning using the Short Form Health Survey (SF36) [27]. Physical functioning was also physically assessed using the Short Physical Performance Battery (SPPB) [28].

In addition to primary and secondary outcome variables, adherence was evaluated and expressed in the percentage of completed PIM training sessions relative to the prescribed sessions. To characterize the groups at baseline a number of variables were examined: age, gender, living situation, body length, BMI, Montreal Cognitive Assessment (MoCa) score [29], hand grip strength and foot conditions (i.e., abnormal (<60°) MTP1 dorsal flexion range of motion, absence of protective sensibility, hallux valgus severity [30]). In addition, using a physical activity monitor (ActivPAL, PAL Technologies Ltd.), the weekly time spent standing, walking/cycling and sedentary and the average daily stepping time with elevated intensity (cadence ≥ 75 steps per minute) in bouts of ≥ 10 minutes was recorded.

Statistical methods

All statistical analyses were completed using SPSS 28.0 (IBM) software. Analyses of covariance (ANCOVA, the baseline value of the outcome variable being the covariate, $\alpha = 0.05$, two-tailed) were run on complete cases to test the between-group differences in mean change from baseline in the primary outcome variable (maximum gait speed) and secondary continuous outcome variables by an intention-to-treat approach. Proportions of participants who improved on the single-item assessed mobility and who fell during the intervention period were compared between groups by running chi-squared test or, if cells have expected count <5, Fisher's exact test. Additionally, pre-post within-group comparisons for outcome variables at the level of the muscles were analyzed by dependent t-tests ($\alpha = 0.05$, one-tailed).

Separate linear regression analyses explored the potential modification of the intervention effect for the change from baseline in 1) physical activity, 2) muscle's force generating capacity and 3) toe flexor strength, each treated dichotomously (> 10% vs. ≤ 10% increase).

RESULTS

Thirty-four participants were randomly assigned and received the intended treatment at home (Figure 1). One participant from the intervention group withdrew from the study after 5 weeks of training due to caregiver duties. The final study population consisted of 33 participants (17 control group, 16 intervention) who all lived independently. Characteristics are presented in Table 1. The median adherence to the prescribed number of training sessions was 99% (IQR: 97% - 100%).

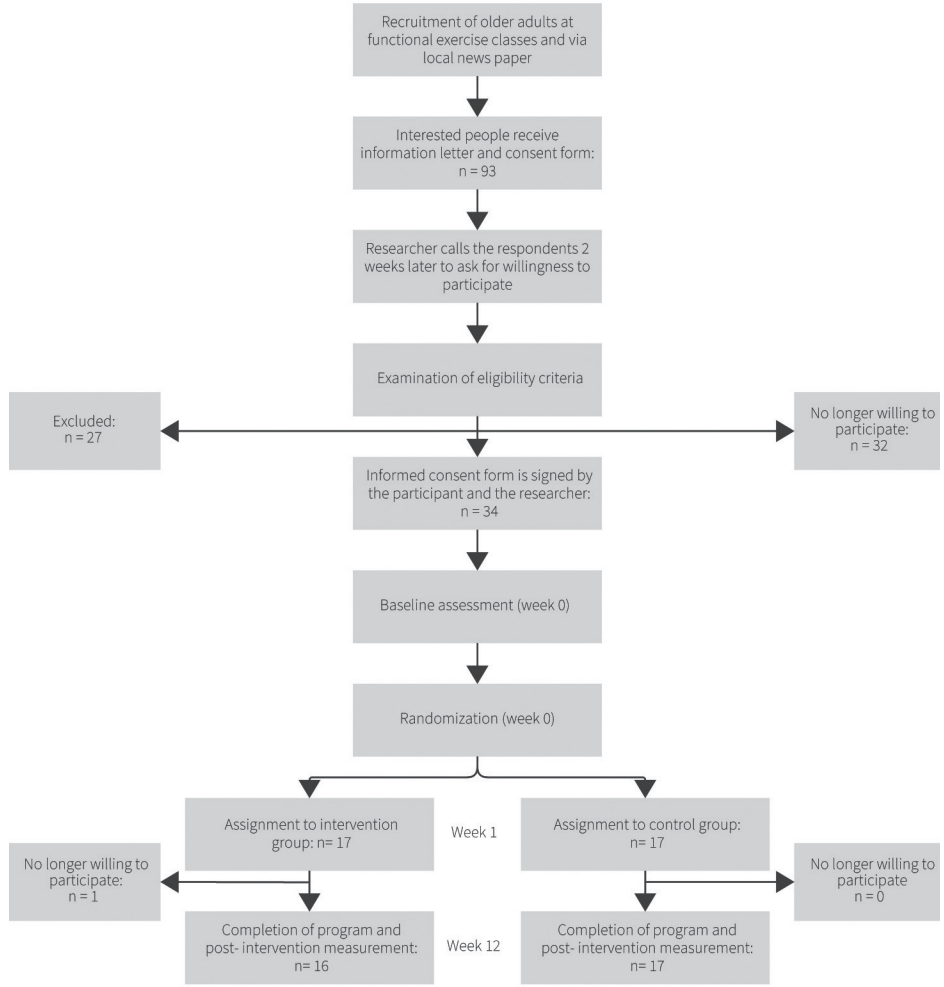


Figure 1. Flow chart of the participants.

Table 1. Characteristics of the study population. Continuous variables are presented in median and interquartile range (IQR). Categorical variables are presented in percentages.

	PIM training group (n = 16)	Control group (n = 17)
Gender (female / male)	63% / 38%	47% / 53%
Age (years)	78.4 (73.3 – 83.6)	76.6 (71.3 – 82.1)
Living situation (together/alone)	50% / 50%	35% / 65%
Fallen in the past 12 months (yes/no)	44% / 56%	47% / 53%
Hand grip force (kg)	26 (21 – 30)	24 (21 – 39)
SF36		
Physical functioning	80 (70 – 94)	85 (70 – 95)
Emotional Wellbeing	76 (64 – 88)	84 (74 – 88)
General Health	65 (56 – 75)	70 (65 – 83)
Body length (m)	1.66 (1.60 – 1.75)	1.69 (1.57 – 1.78)
BMI (kg/m²)	27.5 (25.4 – 29.6)	26.2 (23.6 – 30.6)
MoCa score	26 (23 – 27)	26 (26 – 27)
Time standing (hours/day)	4.2 (3.1 – 4.7)	4.3 (3.5 – 5.3)
Time walking/cycling (hours/day)	1.5 (1.3 – 1.8)	1.6 (1.4 – 2.4)
Time walking/cycling >75 spm in bouts (hours/day)	2.2 (0 – 4.2)	0.9 (0 – 4.3)
Time Sedentary (hours/day)	9.3 (8.4 – 10.7)	9.2 (8.4 – 12.4)
ROM MTP1 (≥ 60° / < 60°)	57% / 43%	10 / 3
Protective sensibility (present / absent)	47% / 53%	47%/ 53%
Hallux valgus severity (A / B / C / D)	31% / 38% / 13% / 19%	35% / 47% / 0% / 17%

BMI: body mass index, MoCa: Montreal Cognitive Assessment, Spm: steps per minute, ROM: range of motion, MTP1: hallux metatarsophalangeal joint.

The results for the primary and secondary outcome variables are presented in Table 2. There was no statistically significant between-group difference in the change in maximum gait speed. However, there was a statistically significant between-group difference in change in concerns about falling. Within-group comparisons revealed a statistically significant increase of FDB CSA and PER thickness and greater hallux flexor force in the intervention group.

The lack of an intervention effect on the primary outcome variable (i.e., maximum gait speed) and the demonstrated intervention effect on concerns about falling were not modified by predefined factors (i.e., change from baseline in physical activity, muscle's morphology and toe flexor strength).

Table 2. Within-group and between-group results for the primary and secondary outcome variables.

	PIM training group (n = 16)				Control group (n = 17)				Intervention group vs control group	
	n	Pre	Post	Change from baseline	n	Pre	Post	Change from baseline	Difference in change from baseline	
		Mean (sd)	Mean (sd)	Mean (sd)		Mean (sd)	Mean (sd)	Mean (sd)	Mean (95% CI)	η2
Spatiotemporal gait parameters										
Maximum gait speed (m/s)	15	1.61 (0.28)	1.61 (0.29)	0.01 (0.15)	17	1.54 (0.35)	1.49 (0.39)	-0.05 (0.21)	0.06 (-0.07 – 0.19)	
Comfortable gait speed (m/s)	15	1.14 (0.19)	1.15 (0.17)	0.03 (0.12)	17	1.09 (0.25)	1.10 (0.28)	0.01 (0.14)	0.01 (-0.08 – 0.11)	
Step Length (m)	14	0.61 (0.05)	0.62 (0.05)	0.00 (0.03)	15	0.61 (0.09)	0.61 (0.10)	0.00 (0.07)	0.01 (-0.03 – 0.04)	
Muscle morphology										
AbDM th (cm)	16	0.78 (0.13)	0.77 (0.12)	-0.01 (0.09)	17	0.69 (0.18)	0.69 (0.15)	0.00 (0.09)	-0.01 (-0.07 – 0.06)	
AbH CSA (cm²)	15	1.45 (0.42)	1.50 (0.45)	0.06 (0.16)	16	1.78 (0.40)	1.79 (0.46)	0.01 (0.19)	0.05 (-0.08 – 0.18)	
AbH th (cm)	16	0.89 (0.17)	0.89 (0.16)	0.00 (0.13)	16	0.91 (0.16)	0.90 (0.16)	-0.01 (0.07)	0.01 (-0.06 – 0.09)	
FDB CSA (cm²)	16	1.68 (0.36)	1.78 (0.43)	**0.11 (0.17) ***	17	1.73 (0.41)	1.77 (0.37)	0.04 (0.18)	0.07 (-0.05 – 0.19)	
FDB th (cm)	16	0.85 (0.13)	0.86 (0.15)	0.01 (0.07)	17	0.89 (0.15)	0.87 (0.11)	-0.02 (0.10)	0.03 (-0.03 – 0.09)	
FHB th (cm)	16	1.11 (0.13)	1.08 (0.12)	-0.03 (0.08)	17	1.06 (0.18)	1.05 (0.17)	-0.01 (0.06)	-0.02 (-0.07 – 0.03)	
FHL th (cm)	16	2.40 (0.24)	2.44 (0.31)	0.04 (0.15)	17	2.22 (0.35)	2.19 (0.30)	-0.03 (0.23)	0.07 (-0.07 – 0.20)	
PER th (cm)	16	1.45 (0.31)	1.52 (0.31)	**0.07 (0.11) ***	17	1.41 (0.30)	1.43 (0.31)	0.02 (0.15)	0.04 (-0.05 – 0.14)	
QP th (cm)	16	0.60 (0.09)	0.59 (0.09)	-0.01 (0.06)	17	0.62 (0.10)	0.62 (0.10)	0.01 (0.05)	-0.02 (-0.06 – 0.02)	
TA th (cm)	16	2.67 (0.29)	2.65 (0.30)	-0.02 (0.17)	17	2.64 (0.34)	2.59 (0.40)	-0.06 (0.12)	0.03 (-0.07 – 0.14)	

Table 2. Continued

	PIM training group (n = 16)				Control group (n = 17)				Intervention group vs control group	
	n	Pre	Post	Change from baseline	n	Pre	Post	Change from baseline	Difference in change from baseline	
		Mean (sd)	Mean (sd)	Mean (sd)		Mean (sd)	Mean (sd)	Mean (sd)	Mean (95% CI)	η2
Balance during gait										
Margin of Stability	14	0.02 (0.01)	0.03 (0.01)	0.00 (0.02)	15	0.03 (0.01)	0.03 (0.02)	0.01 (0.02)	0.00 (-0.02 – 0.01)	
Toe flexor strength										
Hallux (% BW)	16	9.27 (7.79)	11.43 (7.18)	**2.16 (4.91) ***	17	13.61 (7.61)	14.64 (8.20)	1.03 (6.78)	1.13 (-3.09 – 5.36)	
Lesser toes (% BW)	16	4.22 (3.36)	5.40 (3.72)	1.18 (3.82)	17	5.14 (2.13)	5.80 (3.65)	0.66 (3.25)	0.52 (-1.99 – 3.03)	
Mobility limitations (yes/no)		75% / 25%	56% / 44%			82% / 18%	59% / 41%			
Concerns about falling	16	23.0 (3.8)	21.1 (3.6)	-1.9 (3.4)	17	21.8 (4.4)	22.8 (5.9)	1.0 (3.6)	**-2.9 (-5.4 – -0.4) ***	**0.14**
Physical activity (hours/ week)	16	4.9 (2.3)	3.9 (1.6)	-1.1 (2.6)	17	5.1 (4.4)	4.4 (2.4)	-0.8 (3.1)	-0.3 (-2.4 – 1.7)	
Falls (≥1 / no falls)	16		19 % / 81 %		17		0 % / 100 %			
Physical Functioning (SF36)	16	77.2 (21.7)	80.9 (14.0)	3.8 (11.9)	17	77.2 (22.5)	74.7 (21.4)	-2.5 (7.7)	6.2 (-0.9 – 13.3) *[a]	
Physical functioning (SPPB)	16	11.5 (0.8)	11.1 (1.0)	-0.4 (0.8)	17	10.9 (1.7)	10.5 (1.5)	-0.4 (1.2)	0.0 (-0.7 – 0.8)	
Foot and ankle biomechanics in sagittal plane										
MLA deformation (deg.)	12	12.10 (3.05)	11.50 (3.15)	-1.24 (3.85)	17	13.11 (3.54)	12.63 (3.77)	-0.48 (2.96)	-0.76 (-3.35 – 1.84)	
MLA recoil (deg.)	15	14.02 (6.93)	13.05 (6.91)	-0.57 (4.63)	17	14.65 (6.73)	12.58 (5.20)	-2.06 (4.16)	1.49 (-1.68 – 4.66)	

Table 2. Continued

	PIM training group (n = 16)				Control group (n = 17)				Intervention group vs control group	
	n	Pre	Post	Change from baseline	n	Pre	Post	Change from baseline	Difference in change from baseline	
		Mean (sd)	Mean (sd)	Mean (sd)		Mean (sd)	Mean (sd)	Mean (sd)	Mean (95% CI)	η2
Peak moment ankle (Nm)	14	-1.24 (0.14)	-1.28 (0.15)	-0.02 (0.07)	16	-1.30 (0.21)	-1.29 (0.21)	0.01 (0.08)	-0.04 (-0.09 – 0.02)	
Peak power[+] ankle (W)	14	1.24 (0.52)	1.19 (0.73)	0.00 (0.43)	16	1.71 (1.03)	1.45 (0.88)	-0.20 (0.47)	0.19 (-0.15 – 0.53)	
Peak moment Chopart (Nm)	14	-1.02 (0.31)	-1.09 (0.12)	-0.05 (0.27)	16	-1.11 (0.16)	-1.11 (0.17)	0.01 (0.08)	-0.06 (-0.20 – 0.09)	
Peak power[+] Chopart (W)	14	1.46 (0.98)	0.90 (0.54)	-0.53 (0.73)	16	1.17 (0.66)	1.07 (0.57)	-0.07 (0.56)	-0.46 (-0.95 – 0.02)	
Peak power[-] Chopart (W)	14	-0.65 (0.18)	-0.69 (0.23)	-0.02 (0.24)	16	-0.69 (0.17)	-0.71 (0.26)	0.01 (0.27)	-0.02 (-0.22 – 0.17)	
Peak moment Lisfranc (Nm)	14	-0.43 (0.10)	-0.45 (0.09)	-0.02 (0.06)	16	-0.46 (0.08)	-0.46 (0.11)	-0.01 (0.06)	-0.01 (-0.06 – 0.04)	
Peak power[+] Lisfranc (W)	14	0.16 (0.13)	0.18 (0.15)	0.03 (0.16)	16	0.26 (0.19)	0.22 (0.17)	-0.04 (0.09)	0.07 (-0.03 – 0.16)	
Peak power[-] Lisfranc (W)	14	-0.32 (0.16)	-0.25 (0.11)	0.06 (0.13)	16	-0.29 (0.20)	-0.20 (0.08)	0.09 (0.20)	-0.04 (-0.16 – 0.09)	
Peak moment MTP1 (Nm)	14	-0.14 (0.06)	-0.10 (0.04)	0.04 (0.06)	17	-0.10 (0.05)	-0.10 (0.05)	0.00 (0.04)	0.04 (0.00 – 0.08)	
Peak power[+] MTP1 (W)	14	0.18 (0.07)	0.19 (0.11)	0.02 (0.10)	14	0.18 (0.18)	0.14 (0.12)	-0.01 (0.13)	0.03 (-0.06 – 0.12)	
Peak power[-] MTP1 (W)	14	-0.64 (0.35)	-0.52 (0.31)	0.09 (0.20)	17	-0.57 (0.29)	-0.61 (0.36)	-0.04 (0.15)	0.12 (-0.01 – 0.26)	
Adverse events	16		13% (foot pain)							
Correct group allocation guess	16		63%		17		77 %			

* p < 0.05, [a] violation of ANCOVA assumptions, PIM: plantar intrinsic foot muscle, CI: confidence interval, AbDM: abductor digiti minimi, ABH: abductor hallucis, FDB: flexor digitorum brevis, FHB: flexor hallucis brevis, FHL: flexor hallucis longus, PER: peroneus, QP: quadratus plantae, TA: tibialis anterior, BW: body weight, SF36: Short Form Health Survey, SPPB: Short Physical Performance Battery, MLA: mediolongitudinal arch, MTP1: hallux metatarsophalangeal joint. Missing data appeared to be completely at random as these resulted from technical issues with the equipment (balance during gait, foot and ankle biomechanics) or the inability of identifying the AbH muscle using the proposed scan protocol.

DISCUSSION

This study did not show an increase in maximum gait speed after a 12-week PIM strengthening program in older adults. However, the program was effective in reducing the concerns of older people about falling. In addition, the size of FDB and peroneus and hallux flexor strength increased in the intervention group in response to the PIM training.

In contrast to our expectations, the PIM training did not improve maximum gait speed as measured in our laboratory setting. In parallel, other related variables, such as balance during gait and foot joints' power, also did not improve. Several reasons may explain this lack of observed improvements. First, ageing may alter foot and ankle structures and neuromechanical functions to such an extent that training the PIM muscles is not sufficient to restore mechanical (e.g., providing stiffness) and energetic (e.g., producing propulsive power) foot functions [31]. Second, the timeframe of 12 weeks might be too short for gait adaptations to occur. Muscular responses and the subsequent transfer to functional performance were likely delayed due to the participants' unfamiliarity with the exercises [32]. Moreover, functional improvements may need longer than 12 weeks of exercise in older adults [33]. Third, barefoot gait analysis in a laboratory setting might be inadequate to examine older adults' natural gait [34]. Walking barefoot may be uncomfortable especially to older adults, as ageing comes with diminished heel fat pad [35] to absorb impact shocks. Awareness of being recorded, wearing sensors and the cognitive demand that was required from the participants during the measurement session were anecdotally expressed by the participants to explain a cautious gait pattern. These issues may be resolved in future studies with innovative approaches that allow for biomechanical analysis of foot joints during shod walking in a natural environment. This type of measurement may be more suitable to unravel if training the PIM muscles improves gait in older adults [31].

Although laboratory-based gait analysis did not show improvements, the PIM strengthening program appeared to be effective in reducing concerns about falling. The scale we used (FES-I) assessed concerns while doing 16 everyday activities, of which 5 items explicitly include walking. We speculate that improved daily life walking may have preceded reduced concerns about falling, which is in line with the association found between gait abilities and concerns about falling [36]. However, the exact mechanism behind the reduced concerns could not be disclosed by our findings. Nevertheless, the presented reduction in concerns about falling is considered clinically important as it exceeded the difference between multiple-fallers vs. non-multiple fallers and between high vs. low physical fall risk that was revealed by a prospective study in a comparable sample [37]. Reducing concerns about falling is a common target of exercise interventions for older adults [38] and this may lead to increased physical activity and physical functioning, decreased risk for depression or for declines in quality of life [6]. These factors, in turn, decrease the likelihood and risk of falling. Our findings are more

encouraging than a previously investigated toe and ankle training program in older adults [20] that failed to reduce concerns about falling. This may be explained by the longer, more comprehensive and progressive nature of our intervention. The large reduction in concerns about falling further exceeds the small to moderate reduction that was found for general physical exercise interventions [38], which suggests that targeting the foot muscles is a promising complement to these interventions.

The muscle adaptations in the intervention group signify the trainability of older adults' foot muscles that have a role in mobility. As a response to the PIM strengthening program, both the FDB's and peroneal size and the hallux flexor strength increased. The change in muscle morphology of 6% (FDB) and 5% (peroneus) exceeded the smallest detectable change [39] and is therefore considered true muscle hypertrophy, which indicates restored capacity to produce force. As previous studies demonstrated, the contribution of these muscles to postural balance and propulsive gait [13,14,40,41], hypertrophy of these muscles might contribute to mobility improvements. The increased capacity of specifically the peroneus might further contribute to balance by compensating for a less stable foot [42], a typical condition in older adults. However, both suggestions were not supported by our lab-based gait analysis after the limited timeframe of 12 weeks, leaving the longer-term benefits of the observed hypertrophy to remain unclear. In addition to hypertrophy, we noted that hallux flexor strength increased with 2.2% of body weight in the intervention group. According to a previous study [10], this enhanced ability corresponds to a substantial (i.e., 15%) reduction in risk for falling. Future studies are needed to determine if hypertrophy of FDB and peroneus and increased hallux flexor strength indeed result in these suggested improvements in mobility and fall risk.

The observed reduction in concerns about falling advocates further research on the benefits of integrating PIM strengthening exercises in existing functional exercise programs for older adults to improve mobility, including fall prevention interventions. Our program was quite intensive and solely focused on the foot muscles. However, integration in existing programs allows to distribute the training volume over a longer period and to investigate the longer-term effects, including the effects on fall rate. These studies may also investigate who, in particular, benefits from these exercises, thereby contributing to an individualized approach in the treatment of fall risk factors.

The strength of this study was that the blinding of assessments was confirmed by the results of the group allocation guess, which was closer to true change than complete predictableness. However, this study had several limitations to consider. Most importantly, the generalizability to clinical practice is limited, because of the limited financial sources available in clinical practice to provide individual supervision by a trainer at home. Another limitation relates to the participant selection. Our participants already participated in an exercise program at the start of this study, reported to be physically active throughout the week and were mobile enough to travel to our institute.

Consequently, they may already had good scores on the outcome measures at baseline. The PIM strengthening program is, however, also suitable to a population with lower health status. For such a population, larger and additional effects may be expected due to greater potential for improvement in outcome measures.

CONCLUSION

This RCT did not show an effect of PIM strengthening program on maximum gait speed in older adults. However, it demonstrated that training the PIMs reduces their concerns about falling and that the PIMs in older adults are trainable. This advocates further research on the benefits for mobility and fall risk of integrating PIM strengthening exercises in physical exercise programs, including fall prevention programs. In addition, future studies are needed to unravel the mechanism behind the reduction in concerns about falling.

LIST OF ABBREVIATIONS

RCT: randomized controlled trial; PIM: plantar intrinsic foot muscle; ABH: abductor hallucis; FDB: flexor digitorum brevis; QP: quadratus plantae; FHB: flexor hallucis brevis; AbDM: abductor digiti minimi; TA: tibialis anterior; PER: peroneus longus and brevis; FHL: flexor hallucis longus; MTP1: hallux metatarsophalangeal joint; MLA: mediolongitudinal arch; MoS_{lat}: minimum lateral margin of stability; CoM: center of mass; CoP: center of pressure; FES-I: Fall Efficacy Scale-International; SPPB: Short Physical Performance Battery; BMI: body mass index; MoCa: Montreal Cognitive Assessment; SF36: 36 item Short Form Health Survey; ANCOVA: Analyses of covariance; Spm: steps per minute; ROM: range of motion.

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DECLARATIONS

Author contributions

All authors have made substantial contributions to the conception and design of the study. LW collected and analyzed the data, supervised by EW, MP and BV. LW drafted the manuscript and BV, EW, and MP reviewed and revised the manuscript. All authors read and approved the final manuscript.

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Data statement

The dataset supporting the conclusions of this article is available on request in the DataverseNL repository, https://doi.org/10.34894/HVENKA.

“The ‘yay’ feeling never faded, especially because I felt the improvement” – Understanding adherence to a foot strengthening training in older adults: an interview study using thematic analysis (study 6)

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ABSTRACT

Introduction

Falls among older adults are an increasing concern. Foot exercise programs may reduce fall risk, but adherence is low to moderate. This study aimed to acquire an in-depth insight into how adherence to a foot strengthening program is influenced.

Methods

Twelve older adults (7 women, 5 men, aged 69-91 years) assigned to a 12-week supervised foot strengthening program, as part of a randomized controlled trial, were interviewed between April 2023 and July 2024 to explore their perspectives on and experiences with the program. Reflexive thematic analysis was used with an experiential and inductive orientation to collect and approach the data. The semi-structured interviews were guided by open-ended questions based on behavior change theory. Coding was done iteratively and driven by the data. Themes were developed as the analytic output.

Results

The final themes were: “Getting started”, “Hanging in”, “Settled into the rhythm” and “Perceiving health benefits is the ultimate”. These central themes were additional to the positive evaluation of intervention features: clear instructions from the trainer, supportive materials, and flexibility in timing and content of the training program.

Conclusion

Adherence to a foot strengthening program is influenced by factors that change over the course of the intervention. These factors are linked in this study to typical phases encountered consecutively by the participants. The last phase involves the exercises becoming habitual practice, which is, like the second-to-last phase, not reached by every participant. This timeline, as well as the influencing factors that are presented for each phase, offer professionals a tool to approach individuals appropriately to maximize adherence to a foot strengthening program. It also guides the development of similar interventions.

INTRODUCTION

Falls among older adults are becoming an increasing concern as the population continues to age. One third of adults aged 65 years or older fall annually [1], resulting in injuries in one third of the cases [2]. Falling poses a risk to mobility, independent living and well-being of the individual [3]. Therefore, falling also has a major impact on both their social surrounding as well as on the public health care system [4]. For these reasons, it is important to ensure uptake of and adherence to effective fall prevention interventions.

Falling can be most effectively prevented through participating in interventions that contain an exercise program [5]. Additionally, there is emergent evidence for the benefits of foot exercises in reducing the risk for falling. For instance, foot strengthening training improved postural balance in older adults [6,7]. Furthermore, a multifaceted podiatry intervention, including a foot exercise program as a major component, reduced the rate of falls [8] as well as the number of fallers [9]. However, adherence, defined as the rate of prescribed sessions completed, is generally low to moderate for such foot exercise programs [8–11] and may hamper their effectiveness [12].

Although the barriers and facilitators to adhere to general physical exercise programs in older adults are quite well established (e.g., self-efficacy, supervision, and outcome expectations [13,14]), they may differ or may manifest differently when it comes to a foot training program. For example, the benefits of general physical exercise to improve health are well understood, whereas the potential benefits of performing foot exercises may be less obvious [15]. Another relevant feature of foot exercises is the challenging motor control required for some of these foot exercises [16]. Few studies attempted to explore predictors of adherence to a foot exercise intervention in older adults [17,18]. However, the diary records [17] and the experiences with a one-week intervention [18] are not sufficient to reach a thorough understanding of factors that determine adherence to such interventions that typically last for 12 weeks or longer. Further research is thus needed to provide insight into how adherence to foot exercise interventions or programs can be maximized, where adherence is defined as the extent to which a person executes the prescribed number of training sessions.

This study aimed to gain an in-depth understanding of how factors influence adherence to a foot strengthening program. We achieved this by exploring perspectives on and experiences with this program among older adults participating in our randomized controlled trial (STrengthening the Intrinsic Foot Flexor muscles (STIFF)) [19]. This trial was designed to investigate the effect of a supervised foot strengthening program on maximum gait speed, as a proxy of fall risk, in older adults who regularly participate in an ongoing functional exercise class for seniors. Insights gained from this qualitative study may help clinicians deliver equivalent exercise interventions or programs with appropriate participant guidance. In addition, insights may guide the design of new interventions.

METHODS

Design

Semi-structured individual interviews were used to qualitatively explore perspectives and experiences of older adults who participated in the foot strengthening program of the STIFF trial [19]. This type of interviewing was chosen as we expected that this would allow participants to talk freely about their own thoughts and views, while keeping the interviews structured around predetermined topics.

Reflexive thematic analysis [20] was used to rigorously collect and approach the data. We adopted an experiential orientation in this research, since we were interested in views and experiences articulated by participants [20]. According to reflexive thematic analysis, the analytic input of the researcher is key in data collection, coding and theme development to generate thorough insights. The experiential orientation combined with respecting this role of the researcher practically means that we intend to make sense of what participants communicate while ensuring our interpretation remains recognizable to what is articulated. We further acknowledged, in accordance with critical realism and contextualism [20], that both participants' expressions and our own interpretation is context-contingent as these are shaped by norms and perspectives, the practice of the researcher, but also by the interaction between researcher and participant. This report is written according to The Standards for Reporting Qualitative Research [21].

Foot strengthening program

The foot strengthening program [19], to which participants were assigned, prescribed 20-minute sessions to be performed 5 days a week for a duration of 12 weeks. The training program has been developed with a design thinking approach [22]. It was first drafted based on existing literature concerning foot strengthening programs [6,16,23–27], training principles [28] and behavior change techniques [29]. It was further designed together with older adults, (foot and ankle) physiotherapists, podiatrists and a human movement scientist. The program consisted of both isolated foot exercises (e.g., pressing their toes against the ground) as well as functional exercises (e.g., raising their heels). Several decisions were made in the design of the program to maximize adherence. For example, a trainer supervised the training once a week to coach on self-belief, and to provide feedback and social support. Instructions were further provided in a training book, which included a diary, and by videos of the exercises. The training was tailored to each individual participant. For instance, intensity gradually increased based on the participant's progress and the participant decided whether the training took place one-on-one at home or in a group session at our institute. If the training sessions excessively exceeded 20 minutes, the trainer and the participant agreed upon a selection of the exercises according to predefined guidelines. To further promote adherence, the diary section of the training book was used to monitor completed sessions and progression on exercise execution, which was discussed with the trainer as part of every supervised session. Based on these self-reported data, the

adherence rate was determined by the rate of prescribed supervised and unsupervised training sessions that were completed. The participants were measured before and directly after the intervention period in our movement analysis laboratory to biomechanically and functionally assess gait and balance. At baseline, participants reported the time they were physically active throughout the week with at least moderate intensity (≥ 5 on a 10-point scale of perceived exertion) in bouts of ≥ 10 minutes.

Participants

Participants assigned to the foot strengthening program of the STIFF trial were consecutively invited to participate in this qualitative study. The information letter of the trial provided them with the initial information about this qualitative study. During the post-intervention measurement, the researcher explained this information verbally, including that they would be invited for an interview once the blinding had revealed their assignment to the foot strengthening program. The inclusion criteria for the STIFF trial were: 1) age 65 years or over, 2) able to ambulate 10 meters barefoot without using a walking aid, 3) being involved in a functional exercise program delivered to a group of older adults by an educated or certified physical therapist or instructor (e.g., fall preventive exercise program, senior fit programs), 4) report having concerns about falling or having experienced a fall in the previous 12 months or having difficulties with mobility, gait, or balance in daily life. Respondents who reported presence of any disorder interfering with adherence or the execution of the exercises were excluded from the STIFF trial. Mentally incapacitated individuals were also excluded from participation. These selection criteria resulted in a group of participants who were fairly mobile, had at least minor indication of increased fall risk and who physically exercise on a regular basis. We stopped inviting participants when we were able to code a new interview with already existing codes and theme development did not require additional interviews. All participants provided written informed consent. This study was approved by the medical research ethics committee of Maxima Medical Center, Veldhoven, The Netherlands (CCMO nr. NL80110.015.21).

Interviews

The interviews took place between April 2023 and July 2024 and were scheduled within two weeks following the post-intervention measurement of the STIFF trial. The participants chose the venue for the interview, either at home or in a private room at our institute. The interviewer was the primary researcher of the STIFF trial (LW). She met the participants twice prior to the interview for two three-hour measurement sessions for the STIFF trial. She was closely engaged in the design of the training program and had a good understanding of the context in which the training took place. She further has experience in doing qualitative research [30]. An observer assisted the interviews by making notes, and by hinting the interviewer according to the interview guide. It was a deliberate choice for the interviewer to be someone familiar to the participant, as this was expected to help evoke thoughtful perspectives. Before the interview started and

to avoid socially desirable responses, the participants were assured that being honest and critical would be most helpful. The semi-structured interviews were supported by an interview guide containing open-ended questions that were based on the behavior change wheel (see Supplementary Material 7A) [31]. The interviews had a natural flow, primarily directed by the participants' input. This means that the order of the questions was flexible and questions were left behind if the topic was already addressed satisfactorily. Attention was paid to avoid suggestive questioning and to ask follow-up questions appropriately. Questions and probes in the interview guide were iteratively rephrased as the interviews progressed, to ensure richness in the data and to explore preliminary ideas and variation in greater depth. The interviews lasted approximately 30 minutes and were audio-recorded. After the interview, the Exercise Adherence Rating Scale (EARS) was administered to quantify adherence behavior [32]. The achievable sum score on the six items of the EARS ranges from 0 to 24, with higher scores indicating greater adherence. The recordings of the interviews were transcribed verbatim, including vocal utterances. Any personal information was removed. Identifier codes were used to differentiate between participants. The participants received a summary of the interview and were invited to comment on the interpretation of the interviewer.

Data analysis

Atlas.ti 24 (Scientific Software Development GmbH) was used to apply and refine codes, and to link them in the initial theme development. We took an inductive orientation to the data, i.e., coding was driven by the data, and themes were developed to become the analytic output, setting aside the topics of the interview guide.

The researcher (LW) was familiar with the data, as she interviewed all participants. At several instances, she critically engaged with the data by stepping back and asking analytical questions that overarched the whole data set. Notes of provisional ideas were kept in a memo book.

The coding process started after three interviews. Transcripts were systematically reviewed, and fragments parsed out that were related to the research question. Code labels were assigned to the fragments to capture their meaning analytically. Two researchers (LW and either BH or KB) coded the first three interviews independently and discussed the accounts after each coded interview to enhance the interpretation in the code labels. The remainder of the interviews was coded by one researcher (LW). Early in the coding process, the wording of the code labels stayed close to the fragment. This later evolved to more analytical and refined codes. Codes could be semantic or latent to capture both explicit as well as implicit meanings. To connect fragments across the data set, while differentiating between meanings, the code list was refined after coding nine transcripts. At this point the researcher felt confident with the developed analytic insights gained from the codes. Throughout the entire coding process, when code labels were refined, attached fragments were revisited. The first nine transcripts were re-coded in reversed order after the last transcript was coded.

Initially, potential themes were developed by one researcher (LW) through clustering codes around a central concept to capture patterns of shared meaning. This provisional thematic mapping was discussed with another researcher (EW) to review and refine the themes and to determine the most relevant and insightful themes considering the research question and the wider context these themes apply to. With these refined themes, we revisited the transcripts to check if the themes still fitted the original data. The themes were then defined and given a final name.

RESULTS

Table 1 shows the characteristics of the sample. We interviewed 12 participants (7 women, 5 men). Participants were interviewed at their homes, except for one participant who was interviewed at our institute. The mean age of the participants was 78.3 (SD: 6.9) years. The median adherence to the foot strengthening program, expressed as the rate of prescribed supervised and unsupervised sessions that were completed, was 97.5% (IQR: 96.7-100%). The median total score on the six items of the EARS was 23.5 (IQR: 20-24). The participants reported being physically active with at least moderate intensity for, on average, 4.8 (SD: 2.6) hours a week. One participant (adherence: 100%, physical activity: 6.5 hours/week, EARS not completed) declined the invitation for the interview due to informal care duties.

Table 1. Participant characteristics.

ID	Gender	Age (years)	Adherence rate (%)	EARS score	Physical Activity (hours/week)	Interview date
Q01	Male	91	100	20	3.5	2023-04-14
Q02	Male	74	100	23	2.3	2023-04-14
Q03	Female	69	97	24	3.8	2023-05-11
Q04	Female	73	97	21	3.3	2023-04-25
Q05	Female	84	93	24	6.0	2023-05-23
Q06	Male	76	97	24	1.5	2024-01-30
Q07	Male	81	100	19	4.5	2024-04-12
Q08	Male	87	100	24	5.0	2024-03-26
Q09	Female	73	97	24	5.0	2024-05-07
Q10	Female	85	98	20	12.0	2024-06-13
Q11	Female	76	92	24	6.0	2024-07-01
Q12	Female	72	100	22	4.8	2024-07-01

Adherence is defined as the rate of prescribed supervised and unsupervised sessions that were completed. EARS: Exercise Adherence Rating Scale (score: 0-24). Physical activity is reported by the participants as the duration of weekly physical activity with at least moderate intensity (≥ 5 on a 10-point scale of perceived exertion) in bouts of ≥ 10 minutes.

Table 2 provides insight into the variation among the dataset in relation to the overall perspectives of the participants towards the foot strengthening program.

Table 2. Matrix presenting participants overall thoughts in relation to the training.

ID	Motivation to participate	Believes about the benefits of the training for oneself (at the start)	Attitude towards training sessions	Appearance of perceived benefit	Continuation of training
Q01	Contribute to scientific research	Unlikely	Annoying	Possibly improved balance, retrospectively	Definite no
Q02	Curiosity	Skeptical	Effortless, routine	Improved stability and greater confidence in physical abilities during program	Continued doing some of the exercises (triggered by complaints)
Q03	Foot problems	Probably	Effortless, but a little boring	Improved stability and less neuropathic pain at 1/2	Continued doing some of the exercises
Q04	Instability, fear of falling and walking uncertainty	Possibly	Effortless, routine	Improved stability during training period	Intention to continue doing some of the exercises
Q05	Foot problems	Possibly	Ranged from enjoying to frustrating, depending on the exercise	Greater confidence in physical abilities, retrospectively	No (started another program)
Q06	Instability and walking uncertainty	Undoubtedly	Effortless, routine	Improved stability, control over the feet and greater confidence in physical abilities at 2/3	Continued doing exercises 1-2 times a week
Q07	Instability	Probably	Quiet boring	Improved stability at 2/3-3/4	Intention to continue training if stability falls back
Q08	Maintaining independence	Undoubtedly	Effortless, routine	Greater confidence in physical abilities at 1/2	Continued doing some of the exercises

Table 2. Continued

ID	Motivation to participate	Believes about the benefits of the training for oneself (at the start)	Attitude towards training sessions	Appearance of perceived benefit	Continuation of training
Q09	Foot problems	Probably	Effortless, routine	Improved stability, mobility and confidence in feet at 1/3	Intention to continue training after a period of rest
Q10	Instability	Undoubtedly	Effortless, routine	Progression in exercise performance, while presented with increased foot pain and in the absence of other perceived benefit	Intention to continue training after pain has decreased
Q11	Maintaining mobility, contribute to scientific research	Probably	Effortless, pleasurable	Improved confidence in and control over the feet	Continued doing the most challenging exercises
Q12	Instability	Undoubtedly	Effortless, routine	Improved stability and control over feet after 12 weeks	Intention to continue some of the exercises

Participants positively evaluated a range of intervention features: the trainer's instructions were clear, materials were supportive, and the training offers sufficient flexibility in timing and content. In addition, the home setting was a suitable environment for the training to take place. The instructional videos of the exercises were used occasionally by a few participants. Although these factors relate to adherence, they provided limited new insights and were therefore not centralized in a theme. The final themes were: "Getting started", "Hanging in", "Settled into the rhythm" and "Perceiving health benefits is the ultimate". Figure 1 schematically illustrates the chronological linkage between these themes, mapped on the timeline of the intervention. Supplementary Material 7B reveals the underlying codes and exemplary citations in addition to the citations presented per theme below.

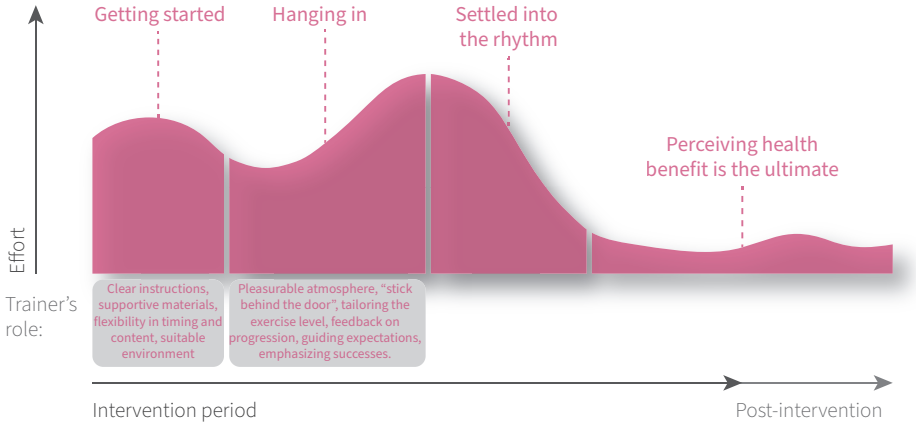

Figure 1. Schematic model of the chronological linkage between the themes explaining adherence to the foot strengthening program. The height of the graph represents the amount of effort to adhere to the program. The width of the graph represents the timeline, including both the intervention period and the post-intervention period. The model is hypothetical and not all participants were "settled into the rhythm" within the intervention period. The role of the trainer, as articulated by the participants, is shown for the corresponding themes.

Getting started

This theme captures the process of getting started with the exercise regime. This includes the observed starting obstacles and participants' thoughts to overcome these obstacles.

The starting phase of the program came along with some specific hurdles faced by the participants. First of all, integrating five training sessions per week into their daily and weekly routines was quite a challenge. It also took some time to get familiar with the exercises, which made the sessions more time-consuming than expected in the beginning. Some participants were also uncertain about their capabilities once the training materials were provided.

> *"At first, with that band, I found it a bit of a fuss and hassle. ... And in the beginning, there was the counting too. You have to find your own way of handling it, you know?" (Q03, female, 69 years)*

> *"Yeah, in the beginning, there were some pretty challenging exercises. You've never trained your toes like you do in this program – like lifting just your big toe while keeping the others down. I thought, no way, I could never do that." (Q12, female, 72 years)*

These starting obstacles were conquered by participants' initial motivation to sign up for the study, by positive expectations about the program and their attitude towards the program. Typically, participants were strongly motivated to join the program because of experiencing instability and uncertainty in walking and to preserve their independence in daily life. These motivators were accompanied by feelings of curiosity, and sometimes

skepticism, towards the possible benefits for oneself and the drive to prove oneself. In this sense, participants considered the program as an experiment for themselves which contributed to their motivation to get started.

> *"To be completely honest… I even showed it to my daughters, and they were like, 'Mom, what are you getting yourself into!' I said, well, listen, it can't hurt. So despite their cynicism, I stuck with it… bring it on!" (Q05, female, 84 years)*

> *"In the beginning, I also thought, I can't imagine that just having strong muscles in your foot would actually stop you from losing your balance." (Q02, male, 74 years)*

Hanging in

This theme encompasses the enablers to keep disciplined once the participants got started. These enablers were basically presented after a few weeks of training and include a positive state of mind, self-motivating strategies, and facilitators provided by the program.

When the program proceeded, participants realized that 12 weeks was quite a long period to commit to the training intensity. However, there was no doubt that the participant would complete the program, regardless of their initial motivation (i.e., intrinsic or extrinsic) as if this was an inherent feature for this population.

> *"And, I believe that if I commit to something, I have to see it through and do it well." (Q11, female, 76 years)*

> *"I didn't want to let the whole organization down, so I, I, I did my exercises not just for myself, but also for you all, you know? I mean, you could say, well, it doesn't do much for me, but I wanted to show solidarity with you all, and with [trainer's name] too. I couldn't let myself down — or let you down either." (Q02, male, 74 years)*

Therefore, at this point, the program was generally perceived neutral, as just something that you do. Though, there were some supportive aspects that made the program acceptable, and sometimes even enjoyable. Most importantly, the sessions with the trainer were perceived as pleasurable and occasionally acted as a "stick behind the door". Another important motivating mechanism was

the reinforcement of beliefs in the value of the exercises through actually doing them. Putting the foot muscles to work made the participants more aware of their significance and training gave them a sense of fulfillment.

Challenging exercises were the most appealing to the participants. This was facilitated either by the trainer through tailoring the program to the individual or by the participants actively seeking for challenges themselves. In addition, some exercises were inherently

challenging. For example, when participants were unable to voluntarily perform the required motions. This was occasionally accompanied by negative feelings like disappointment and frustration. However, failure in execution, and the concomitant amazement, made participants competitive in successfully making these exercises. It was as if this acted as a substitute subgoal, compensating for the lack of feedback related to the goal of the training, the absence of peer contact and the fact that the end of the program was not yet in sight. Self-talk was a major facilitator of this inner competition.

Noticing progression in the execution of the exercises, mostly by seeing greater ranges of motion or by feedback from the trainer, was encouraging. When participants eventually successfully executed these challenging exercises, they felt a sense of pride and joy, which was extra motivating to adhere to the program. Yet, the alternation with easier exercises was appreciated as this contributed to a sense of self-efficacy. The trainer was supportive in all these processes, for example, by proving guidance on expectations, or by emphasizing successes.

> *"… and also that you could actually see your toes spreading apart. At first, it was barely noticeable, but as you go on, even my two 'Siamese twins' (toes) that are usually stuck together started to join in!" (Q09, female, 73 years)*
>
> *"Yeah, just because I want to do it for myself, you know, try something that doesn't work, but keep trying anyway." (Q03, female, 69 years)*

For a few participants, adherence relied more on self-discipline than it did for the majority. Completing the program was then metaphorically compared to activities like sports, labor or studying. This was especially true for the few participants who felt a need that was not fulfilled by the program. This involved curiosity about how one is performing compared to others or their own progression. In addition, preferring a different style of exercises (e.g., more dynamic, moving towards music) was also mentioned. Nevertheless, even under these circumstances, ceasing the program was not considered an option. Once a training session had started, it was fine again and over before they noticed.

> *"… that curiosity about the end result, the improvement, how did the others do?" (Q02, male, 74 years)*
>
> *"I had to force myself. Because sometimes you're just lazy, even I am... Then I think, 'I still have to do so many more,' and it's like with sports. When you do sports, you sometimes have to get yourself together to do it, but once you've done it, you feel good again, you know?" (Q09, female, 73 years).*

Settled into the rhythm

This theme describes the state to which "the rhythm" refers. It hints at the decreased effort to adhere to the program. The theme includes the integration of the training in daily routine, the routine within the training, and the experience of the training becoming an ordinary habit in daily life. The theme also refers to the emotional state evoked by doing the training.

Regardless of the initial motivation to participate, a certain rhythm was achieved when the enablers were experienced to a sufficient degree. At that point, the training had become an effortless part of daily routines. Most often, the timing of the training was pragmatically linked to an existing daily activity, such as after showering or right before putting on shoes. Sometimes, the training was done whenever time allowed, although finding a moment during the day was not a challenge.

> *"If I didn't have to go anywhere in the morning, I'd do it in the morning before I got dressed, before I put on my shoes. So, I'd do it after breakfast." (Q10, female, 85 years)*
>
> *"That's no trouble. ... I've got all the time." (Q06, male, 76 years)*

For the majority of the participants, working through the training sessions had become a routine activity where they felt familiar with. Some eventually found working through the program enjoyable, or even felt a sense of pride. Some had implemented their own creative solutions to ease the counting of repetitions, showing their accommodation with the program. Frequently, participants experienced the training sessions as an ordinary activity in their everyday lives.

> *"Really with pleasure, yes, it becomes a part of your life, you know? Whether it's breakfast or these exercises, it eventually fits into the system." (Q02, male, 74 years)*
>
> *"If you enjoy something, it comes naturally." (Q11, female, 76 years)*
>
> *"There were exercises that you had to do 10 times, for example, with one foot and then the other. And yeah, then I came up with a system… a cabinet with doors, and I would count the doors 1, 2, 3, and then back again 1, 2, 3. And then I would move a row, and that way I knew the number…" (Q08, male, 87 years).*

In the rare case that the rhythm was not reached, it remained quite an effort to adhere to the program until the end.

> *"Well, think about it like when you have to study and you don't feel like it. It's kind of like that." (Q01, male, 91 years)*

"I found it all a bit boring and also really long. It's about 30 hours of work altogether." (Q07, male, 81 years)

Perceiving health benefits is the ultimate

This theme highlights the range of health benefits perceived by the participants and the consequences of these benefits on the training period and the retention of exercising afterwards.

Almost all participants noticed improvement on one or more aspects of their health. Benefits that were mentioned were improved stability, improved gait/mobility, increased confidence about physical abilities, less fear of falling, better control over the feet, less neuropathic foot pain and compensation for disabilities (see Supplementary Material 7B for the richness in expressions). The point in time when awareness of the benefits arose differed from roughly halfway through the program to after the program had ended.

"...especially because I have that dizziness, I was really unsure and fell a lot, you know... I thought, yeah, I could try to get a bit more stability and become a bit more confident in myself. And that made a difference, because in all that time, I only fell once, you know? So yeah, yeah, I think that's really good, because I used to be flat on the ground all the time." (Q04, female, 73 years)

"Well, uh, very positive, very positive. Because what I thought would happen mostly did. Yeah, that you're just a bit freer in your mind. That you dare to walk." (Q06, male, 76 years)

Awareness that the training truly effected aspects of their health caused a substantial shift in participants' attitude towards the program. Perceiving the benefits made the program more enjoyable for the participants who were neutral up to that point, as well as for those who already experienced some fun. While the training was initially obeyed routinely, noticing the benefits was the ultimate reward, enhancing the intrinsic motivation to complete the training period.

"When you see, you still have so many weeks to go, for example, you know... But then you think, yeah, I'm not doing this for nothing. It has its purpose, and then, yeah, that little bit of frustration fades away." (Q08, male, 87 years).

"The 'yay' feeling never faded, especially because I could feel the improvement. So that motivates you, right? When you feel that it's doing something, like you're stepping onto that stool more easily, going down the curb more easily, walking down the stairs without holding the railing... That's what gave me the motivation to keep going." (Q09, female, 73 years).

Even when the program was perceived as demanding and it was hard to find the rhythm of the training, noticing improvement in a particular aspect of their health caused a shift in the perception of the training.

"Yeah, what kept me going was that around 2/3 or 3/4 of the way through, I started to notice it was helping, even outside of the exercises, you know, that I was becoming more stable. Well, and then the last third was actually doable." (Q07, male, 81 years)

Perceiving benefits also made participants profit from opportunities presented throughout the day to do additional exercises during the training period. It also encouraged to continue doing exercises after the intervention period had ended. However, the way participants intended to do this differed from what was prescribed by the study. This is because the prescribed training has a certain duration and requires full attention. Additionally, tools are needed to complete some of the exercises.

"Yeah, so not the whole program, because with that band and all, you really have to sit or stand for it, you know?" (Q03, female, 69 years)

"I still do the exercises once or twice a day. If you're busy in the kitchen with something, it's really easy to do." (Q08, male, 87 years)

"I just keep doing it, yeah, not with that towel anymore. I don't do that now, but I still do the arch exercise, …,and walking on my toes, and standing on one leg. I always brush my teeth on one leg." (Q11, female, 76 years)

Not all participants reported improved health benefits. Despite this, they completed the program, primarily because they had promised to do so. The participants who had settled into the rhythm stayed tuned routinely, whereas the participants who had not settled had to force themselves to complete each training session.

DISCUSSION

In this qualitative study, we presented how adherence of older adults to an intensive foot strengthening program is influenced, not only by listing barriers and facilitators, but by mapping overarching themes onto the timeline of the intervention. Four themes evolved: "Getting started", "Hanging in", "Settled into the rhythm", "Perceiving health benefits is the ultimate". These in-depth insights into participants' perspectives in relation to adherence and how the perspectives change over time, provide guidance to physiotherapy or geriatric practice, and inform researchers to set up similar intervention studies for older adults.

The results show that the overall positive experiences of participants throughout each identified phase of the foot strengthening program contributed to their adherence to the program. This confirms that our intervention met the needs of the participating older adults well. Their positive experience is likely attributable to the design of the intervention being based on the proposed behavior change techniques (BCTs) [29]. After conducting this interview study, a selection of BCTs was recommended to promote adherence to exercise intervention in specifically older adults [33]. Among this selection, the BCTs appreciated by our sample were: the exercise program being tailored to preferences and capabilities, the appropriateness of the exercise environment, guidance by the trainer (e.g., social support, providing feedback on progression, education, enhancing self-efficacy), flexibility (i.e., autonomy) in timing and content of the training. Conflicting with the recommended BCTs [33] was that the exercise diary seemed to have no motivational value, prompting was not needed and assistive technologies such as apps or wearables were not suggested. In addition, social support from relatives was not needed, which may be explained by the high level of intrinsic motivation of our sample. Moreover, and most surprising, negative emotions provoked by challenging exercises did promote exercise adherence. However, this may require supervision from a professional (e.g., physiotherapist), as was the case in our intervention, to coach expectations of the individual on the outcome. These insights emphasize the need to consider the identified factors in the design of a foot exercise program for older adults to maximize adherence.

Our results also highlight the importance of facilitating individuals to settle into an exercise program early to promote adherence. Once started, settling in may not happen automatically, especially if intrinsic motivational factors (e.g., positive expectations, self-efficacy, goal setting skills) are lacking. Then, a greater role is reserved for the therapist. The therapist may promote self-management skills, focus on small successes, emphasize the benefits of training, and adjust expectations. In a home-based exercise setting without visits from a therapist, which is often the case in health care, following up by telephone calls may be recommended [18]. The therapist could also anticipate on motivating aspects, for example by providing proper (written) guidance in advance. Digital technology may be another solution. However, our sample appreciated the written instructions and rarely used the instructional videos. In addition, a need for supportive technology was not indicated.

Perceiving health benefits was the ultimate motivational factor and experienced by a large proportion of our sample. Once settled in the program, at some point in time most participants found something stronger than just the rhythm, which encouraged them to continue doing the training or to not have the feeling that one is wasting time. The exact point in time when this occurred varied between individuals: for some it occurred during the training period and for others after the training had finished. Our analysis revealed that perceiving a health benefit surpassed any other enabler and was the ultimate facilitator in making exercise an automated behavior. This is consistent with the literature, which most

frequently cites health benefits as a reinforcer of adherence to an exercise intervention by older adults [33]. It is also the most powerful experience that made people build in a training or its exercises into their daily lives [34], which in turn promotes long-term adherence [35]. The frequency and richness with which health benefits were expressed by the participants exceeded our expectations and underscores the appropriateness of our foot strengthening program to improve mobility. However, an experimental design is needed to demonstrate its effectiveness.

Since it took some time before health benefits were perceived by the participants, keeping the individual motivated up to that point should be key in the design of exercise interventions. Although most participants felt empowered and healthy by doing the exercises of our program, they typically did not find the exercises enjoyable. Moreover, a few participants found the exercising boring or tedious. The immediate reward of feeling pleasured by exercising is a strong predictor of persistence in exercising to pursue long-term goals [36], as was, for instance, improving mobility in our population. Hence, intrinsic motivation may be enhanced by redesigning the foot exercises to make them more enjoyable. The first draft of the training program was based on the exercises used in scientific research. By several feedback rounds, both the perspective from healthcare professionals as well as the opinions of older adults were incorporated in the design of the training program. To fully respect the needs of older adults, a participatory design process is needed and may be recommended as the next step, while taking into account the findings of this study. The results of this study can also be used to build personas to inform the design process.

This study provides insight into how factors influence adherence to a foot strengthening intervention in older adults and how this interplay changes along the course of the intervention. This overview may aid health professionals to be sensitive to the position of an individual in this process and its associated factors. The professional can adapt one's strategy accordingly to promote adherence to the prescribed program. The findings of this study are limited to our foot strengthening program and the sample to which the training was delivered. Our sample consisted of older adults who were already enrolled in an exercise class to improve and maintain mobility and who volunteered in our intervention study. This indicates high levels of motivation which suggest high self-control skills among these individuals [37]. The extent to which the proposed timeline applies to other interventions or programs and to different populations needs to be validated.

This study had both strengths and limitations. One strength was that selection bias was minimized, because only one participant declined the interview, and the reason was not related to the intervention. Another strength was that the interviewers were familiar with the intervention, which enabled an in-depth conversation. At the same time, being interviewed by the primary investigator may also have promoted socially desirable answers. However, the interviewees were instructed that being honest would be most

helpful to this research which is expected to limit this source of bias. In addition, as the primary investigator designed the intervention, this may have introduced subjectivity in the data collection and analysis beyond what is expected in qualitative research. However, the researcher, assisted by the observer during the data collection, was extra sensitive for expressions that were against preconceptions, contributing to reflexivity. Another limitation was that the perspectives of the participants on the foot strengthening program originated from taking part in a research project. This may have shaped their perspective on the training. Different themes may result from future research in a clinical practice setting.

In conclusion, adherence to a foot strengthening program is influenced by changing factors over the course of the intervention. These factors are linked in this study to typical phases encountered consecutively by the participants and evolved from "getting started", through "Hanging in", "Settled into the rhythm" to "Perceiving health benefits is the ultimate". The last phase involves the exercises becoming habitual practice, which is, like the second-to-last phase, not reached by every participant. This timeline as well as the factors that are presented for each phase offers professionals a tool to approach individuals appropriately to maximize adherence to a foot strengthening training program. It also guides the development of similar interventions.

LIST OF ABBREVIATIONS

STIFF: STrengthening Intrinsic Foot Flexor muscles; EARS: Exercise Adherence Rating Scale; BCT: behavior change technique.

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DECLARATIONS

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Statement of Ethics

This study protocol was reviewed and approved by the medical research ethics committee of Maxima Medical Center, Veldhoven, The Netherlands (CCMO nr. NL80110.015.21). All participants provided written informed consent.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

All authors have made substantial contributions to the conception of the study. LW and EW designed the methodology of the study and analyzed and interpreted the data. LW collected the data. LW drafted the manuscript and BV, EW, and MP critically reviewed the manuscript. All authors read and approved the final manuscript and are accountable for all aspects of the work.

Data Availability Statement

The data that support the findings of this study are not publicly available as they are context-dependent and therefore not suitable for reuse. However, the data are available upon request from the corresponding author (LW).

SUPPLEMENTARY MATERIALS

Supplementary Material 7A: Interview guide

Adjustments to the interview guide are indicated by [a] (2023-12-14) and (2024-2-26) [b]

Introduction
Before we begin the interview, I would like to thank you for participating. Next to me is ..., and he/she will assist with the interview where necessary. The purpose of this interview is to understand what made the training doable and what aspects may not have been helpful. Based on the findings, we aim to gain a better understanding of how we can improve this training and similar programs. You will be most helpful to the research by sharing your experiences as honestly as possible. Feel free to be critical. The interview will last about 30 minutes.

On the table is a voice recorder, which will record the interview. After the interview, we will transcribe the interview literally. This forms the input for further analysis. The recording will be destroyed at the end of the project. Nowhere will the data be linked to you personally.

Do you have any questions before I start the recorder?

[start audio recorder]

Note for the interviewer: try to determine the impact that mentioned factors have had on adherence. [a]

Introductory questions
- What motivated you to participate in the study? [b]
- What was your initial reaction when you heard that you were assigned to the training group?
- How did you experience following the exercise program?
- Can you walk me through how you approached doing the training?

Capability
- How did you manage to follow the instructions? What did you find difficult, and why?
- What did you think of the instructions you received (training log and instructional videos)? How supportive did you find them?
- Can you tell me how the program fit with your abilities and preferences [a]?
- How did you manage to physically keep up with the exercises? What challenges did you encounter?
- Where did you carry out the exercises? Can you describe what it was like to do the exercises there? How did you adapt the environment for this?
- What do you think is needed to be able to perform the exercises properly?

Opportunity
- Who or what convinced you to follow the exercise program?
- How did friends, family, or other people around you influence your adherence to the program?

- Were there other people in your environment who also participated in the program? How did this motivate you to continue doing the exercises?
- How did the exercise program fit into your daily routine? How did you manage that?
- Can you give an example of a time when you didn't have time to do the exercises? What caused that? How did you feel about it?
- Can you give an example of a time when you didn't feel like doing the exercises? What caused that? How did you feel about it? What would have helped you to do them anyway? [a]
- Are there any tools or methods you came up with to help you follow the program better (e.g., smartphone apps, reminder notes, etc.)?

Motivation
- What made it possible (or not) for you to adhere to the program? What were your thoughts?
- Can you talk about the effort it took for you to adhere to the program?
- Were there any specific goals you set for yourself? How did that help you?
- What role had the trainer in helping you adhere to the program?
- What role had the training guide in helping you adhere to the program?
- What emotions did you experience while following the program?
- Were there any circumstances that made it difficult for you to commit to the training? How did you handle that?
- We sometimes hear people say, "Phew, do I really have to do this again?" How was that for you?
- Can you talk about…
  - …how important you find doing these exercises?
  - …the benefits you think you gained from the program?
  - …the challenges you encountered while following the program? [a]
  - …the concerns you had that were related to the program?
- What was the most important factor for you in deciding whether or not to do the exercises? [a]
- What ways can you think of that the program could have better supported you in adhering to the prescribed exercises?

Questions related to specific exercises
- Which exercises did you find the most challenging? Why? How did you deal with this?
- Which exercise did you dread the most? Why? How did you handle this?

Closing questions
- What were your thoughts when the program ended?
- How do you look back on it now?
- What would you recommend to improve the program?

- Do you think you will continue doing the exercises now that the program has ended? Why/why not? Which exercises, and how often? What would help you with that?
- Would you recommend the program to others?
- Is there anything else you would like to add that we haven't discussed?

[stop recorder]

Closing

We would like to thank you for your participation in the study. We will start analyzing the data we have collected. The data will be protected in the same way as outlined in the information letter you received at the start of the study. We will provide you with a summary of the interview. If there is anything in it that you disagree with, please let us know. If you think of anything later that is important or if you have any questions regarding the research, we would also be happy to hear from you.

Supplementary Material 7B: Themes, codes and illustrative data extracts

More than one data extracts per code is provided to demonstrate richness among the dataset.

Codes	Illustrative data extracts
Theme: Getting started	
Wanting to maintain/improve stability/mobility	"Well, I had noticed for a while that my balance was getting worse, or was bad, and then I thought, well, this is an opportunity to do something about it." (Q07, male, 81 years)
Wanting to maintain independence	"Yeah, I really dread the thought that as I get older—I'm already 87—I'll need a walker or, even worse. So, I try to push that as far away from me as possible. That's why those exercises seemed like a good idea." (Q08, male, 87 years)
Positive expectations about the benefits of the training	"From the very beginning, I saw the benefit of it." (Q08, male, 87 years)
Will the training help me?	"In the beginning, I also thought, I can't imagine that just having strong muscles in your foot would actually stop you from losing your balance." (Q02, male, 74 years)
	"I mean, I come from the healthcare field, so, well, I've seen so many people fall, unstable, this and that, and all sorts of exercises are done, but not this one. So I thought, yeah, that's... it's really nice to try and see if this actually contributes." (Q03, female, 69 years)
	"Well, that's very important. Otherwise, I don't think you'd keep going. There has to be curiosity, of course, about what it will bring." (Q06, male, 76 years)
Wanting to prove oneself	"To be completely honest… I even showed it to my daughters, and they were like, 'Mom, what are you getting yourself into!' I said, well, listen, it can't hurt. So despite their cynicism, I stuck with it… bring it on!" (Q05, female, 84 years)
Theme: Hanging in	
Positive beliefs about the benefits of the training	"It was actually really good, those exercises where you... do things you'd never normally do, you know? Like how much your toes move, and I thought that was really good." (Q10, female, 85 years)
Doable exercises are motivating	"Maybe I'm a bit performance-oriented, because everything that went well, yeah, I liked doing that." (Q05, female, 84 years)
Challenging exercises are motivating	"If you put that elastic band around your big toe, you can pull as hard as you want. Well, then I'd be curious to see what the hardest pull was and if I could still manage that." (Q07, male, 81 years)
I'm going to get this exercise right!	"I thought it was really fun to see—why can I do it on the left? Why can't I do it on the right? But it remained a challenge for me, like, it has to work eventually." (Q02, male, 74 years)
I nailed this exercise!	"Then I see it more as a challenge, like, I have to get this done. And I did. ... Well, see? You can do it!" (Q09, female, 73 years)

Supplementary Material 7B: Continued

Codes	Illustrative data extracts
Progression in execution is motivating	"… and also that you could actually see your toes spreading apart. At first, it was barely noticeable, but as you go on, even my two 'Siamese twins' (toes) that are usually stuck together started to join in!" (Q09, female, 73 years)
Those who say A must also say B	"If I start something, I finish it. You know, that's just a fact. I mean, otherwise, you shouldn't even start in the first place." (Q03, female, 69 years)
Loyal to the research(team)	"I didn't want to let the whole organization down, so I, I, I did my exercises not just for myself, but also for you all, you know? I mean, you could say, well, it doesn't do much for me, but I wanted to show solidarity with you all, and with [trainer's name] too. I couldn't let myself down — or let you down either." (Q02, male, 74 years)
Trainer encourages	"Well, yeah, it keeps you going, more than anything else, yeah." (Q07, male, 81 years)
Theme: Settled into the rhythm	
Training integrated into daily/weekly routine	"That actually went pretty automatically, you know? And mainly, I did it either in the morning or in the evening, because then I'd take off my shoes … that's the easiest way, so I wouldn't have to deal with other shoes ... Yeah, in the morning or evening, that was the easiest. Otherwise, I'd have to keep taking my shoes on and off." (Q03, female, 69 years)
	"Because I have to take off my socks and shoes, I did it after showering." (Q09, female, 73 years)
Training has become a routine	"And after a few weeks, it could just be done in 20 minutes, and then you get into a rhythm, and I could do it almost, yeah, thoughtlessly—not completely, you still have to concentrate on the exercises... So, well, but still, you know exactly what you need to do." (Q03, female, 69 years)
Training has become a habit	"Really with pleasure, yes, it becomes a part of your life, you know? Whether it's breakfast or these exercises, it eventually fits into the system." (Q02, male, 74 years)
	"I didn't really think about it." (Q10, female, 85 years)
Training is an enjoyable experience	"Just thinking, oh, now I'm going to do this (exercise), do that, put on some music." (Q09, female, 73 years)
	"If you enjoy something, it comes naturally." (Q11, female, 76 years)
Theme: Perceiving health benefits is the ultimate	
Balance/stability	"Well, sometimes I walk, say, along a long sidewalk, like from the bus stop in [place] to here. And then I try to walk along the edge of the sidewalk tiles, and I notice that it goes much better now than 3 months ago. Yeah, much less wobbling." (Q07, male, 81 years)
Mobility	"Well, I still walk over uneven ground sometimes, and that goes so much better... I can walk much more easily over bumpy terrain now than before." (Q07, male, 81 years)

Supplementary Material 7B: Continued

Codes	Illustrative data extracts
Self-confidence about physical abilities	"Well, uh, very positive, very positive. Because what I thought would happen mostly did. Yeah, that you're just a bit freer in your mind. That you dare to walk." (Q06, male, 76 years)
	"The sidewalk there is a bit uneven and not very comfortable. My wife always had trouble with that stretch when she was still alive... Yeah, and now I notice that I handle it better too. I don't know, can I say I was uncertain there before? But at least now, I'm definitely more confident there." (Q08, male, 87 years)
Less fear of falling	"But that really helped, so you're a bit less afraid of falling flat... That was one of the benefits I've experienced." (Q02, male, 74 years)
Control over the feet	"In daily activities, yeah, you also become more aware of using your toes, I think, and because of that, it also becomes more stable." (Q12, female, 72 years)
Less neuropathic pain	"Well, my left foot, I have neuropathy in it, and that has become much better. Yeah, so the pain in my left foot has really, really improved." (Q03, female, 69 years)
Compensation for disabilities	"...especially because I have that dizziness, I was really unsure and fell a lot, you know... I thought, yeah, I could try to get a bit more stability and become a bit more confident in myself. And that made a difference, because in all that time, I only fell once, you know? So yeah, yeah, I think that's really good, because I used to be flat on the ground all the time." (Q04, female, 73 years)
Exercises have become habitual practice	"I'll walk on my toes for a bit longer. Yeah, I do that whenever I can, whether it's a good moment or not." (Q03, female, 69 years)
	"I always have to go to the bathroom at night, and I still have little rugs on the bathroom floor. And, I was sitting on the toilet, and I was still trying with my toes." (Q05, female, 84 years)
	"I still do the exercises once or twice a day. If you're busy in the kitchen with something, it's really easy to do." (Q08, male, 87 years)
	"You just sit there, and then either I lift my heel like this, you just do that automatically when you're relaxing after dinner and cleaning up, then you just do it without thinking." (Q09, female, 73 years)
	"I just keep doing it, yeah, not with that towel anymore. I don't do that now, but I still do the arch exercise, … ,and walking on my toes, and standing on one leg. I always brush my teeth on one leg." (Q11, female, 76 years)
	"I even do it while showering, lifting my big toes up, and yeah, you're then still thinking about it in your head, you know." (Q12, female, 72 years)

General Discussion

8

The overall aim of this doctoral project was to improve fall prevention by gaining insight into the trainability of the PIMs and their role in gait and balance in older adults. We hypothesized that the PIMs adapt in response to training in older adults. We further hypothesized that training the PIMs results in improved gait and balance, thereby contributing to reducing fall risk. In line with this project's conception, this chapter discusses three main themes: (i) the extent to which the results confirm the trainability of the PIMs in older adults, (ii) the extent to which the results confirm the role of the PIMs in gait and balance in older adults, and (iii) the contribution of PIM training to reducing fall risk. The first two theme discussions begin with a summary of the corresponding key findings from the previous chapters. To substantiate the discussion, additional data not reported in the previous chapters is presented where applicable. In each section, findings are interpreted and recommendations for further research are presented. Subsequently, clinical implications are elaborated and a r eflection upon the generalizability of the findings is provided. The discussion section ends with a conclusion addressing the general project's aim.

THE EXTENT TO WHICH THE RESULTS CONFIRM THE TRAINABILITY OF THE PIMS IN OLDER ADULTS

Summary of key findings

Several project findings support the trainability (i.e., adaptive response to a given exercise load [1]) of the PIMs in older adults. The instrument we used to investigate the trainability of the PIMs was a PIM strengthening intervention study, of which the protocol is presented in Chapter 5. The training program included both isolated foot exercises and functional exercises, since we demonstrated in Chapter 4 that both types of exercises similarly activated the PIMs. For a training program to be effective, participants should adhere to the program, which requires that the program fits their preferences. The randomized controlled trial, reported in Chapter 6, showed that participants completed almost all prescribed sessions (group median: 99%). In addition, the maximum score (group median: 23.5) on the six items of the Exercise Adherence Rating Scale (EARS), which was evaluated as part of the qualitative interview study (Chapter 7), revealed that participants highly adhered to the prescribed home exercises. The same study additionally discovered that this was the result of participants' positive experiences with the program. Additional analysis of the ten items of the EARS assessing reasons for adherence/non-adherence, not presented in previous chapters, further supported the fit of the program with the preferences of the participating older adults. The main findings of this project, concerning the trainability of the PIMs in older adults, originated from the RCT. This study showed that, in response to the PIM strengthening program, hallux flexor force increased. In addition, the flexor digitorum brevis hypertrophied, reflecting increased capacity of the muscle to produce force. The reliability study concerning the ultrasound assessment of PIM morphology, presented in Chapter 2, provided the minimal detectable changes

for the ultrasound assessment of PIMs' morphology, allowing us to conclude that this hypertrophy was real and not attributable to measurement error.

Strengthening the PIMs with a combination of isolated and functional foot exercises

To strengthen the PIMs in older adults, we recommend a combination of isolated foot exercises and functional foot exercises. We eventually used this combination in our PIM strengthening program to examine the trainability of the PIMs in older adults. However, we first validated the ability of the proposed exercises for this PIM strengthening program to activate the PIMs. For this purpose, we compared the ability of functional exercises to activate the PIMs with isolated foot exercises, since functional exercises have various advantages (e.g., task-specificity, habitual motor control) over the frequently applied isolated foot exercises. Our results showed that the functional foot exercises activated the PIMs at least to the same degree as the most activating isolated foot exercise. This was a promising finding, since the task-specificity of functional exercises and the underlying habitual motor control favor this type of exercise. It was also a remarkable finding, since isolated foot exercises are most frequently applied to strengthen the PIMs, as shown by our systematic literature review (Chapter 3) and a systematic literature review by others [2]. In accordance with our findings on the ability of functional exercises to activate the PIMs, recent studies support the usefulness of functional exercises in training the foot muscles [3,4]. A comparable cross-over experiment [4] confirmed that their functional exercise (i.e., swinging the non-stance leg back and forth) was at least as effective as isolated PIM exercises in activating the abductor hallucis muscle, which is one of the largest PIMs. In addition, another study [3] – aimed at developing a foot and ankle strengthening program for the treatment of plantar heel pain –incorporated increased functionality of exercises in their sequence of progression levels. Since isolated foot exercises are still effective in engaging the PIMs and given there are situations in which isolated foot exercises are more appropriate (e.g., when full weight-bearing is not possible), our proposed PIM strengthening program combined both functional and isolated foot exercises.

Adherence to and suitability of the PIM strengthening training

The rate of completed sessions of the PIM strengthening program, participants' adherence behavior and their perspective on the program and its exercises, support the fit of the program with the preferences and abilities of older adults. This match is essential to achieving a training effect and, in that sense, contributing to the trainability of the PIMs. The rate of prescribed sessions that were completed (a group median of 99% of the supervised and unsupervised training sessions) is higher than the rate of 83% reported in a comparable study with respect to the intervention and the study population [5]. It also largely exceeds the rate reported for general exercise interventions in older adults [6]. Likewise, the almost maximum achieved score on the EARS [7] demonstrated optimal adherence to the home exercises of the PIM strengthening program. This confirmed that

the participants not only adhered to the prescribed number of sessions, but that they also adhered to the agreed content of the sessions. This occurred to a larger extent in our project than among a similar population participating in the 6-months evidence-based Otago fall prevention exercise program [8], in which the group mean score on the EARS reached 20 out of 24 [9]. This indicates that the content of our PIM strengthening program effectively encouraged adherence behavior.

The qualitative interview study revealed reasons for this high level of adherence. It turned out that the participants appreciated the clear trainer's instructions, supportive materials, the flexibility of the training in timing and content, and the home setting in which the training took place. With the guidance of the trainer, the exercises appeared to be a good fit with the physical capabilities of the participants. It is further exemplified that the functional exercises were integrated in daily-life activities without the need for supervision. This suggests that PIM exercises may also be accepted when supervision becomes less frequent, which is often the case in clinical practice. This idea is supported by the previously cited study [9], which had less frequent face-to-face supervision, but still an acceptable adherence behavior (i.e. EARS > 17 [10–12]). Analysis of a subset of relevant additional items of the EARS, addressing reasons for adherence/non-adherence, revealed that participants had positive beliefs about the exercises from the PIM strengthening training (Figure 1). This further explains the high adherence rate and confirms the suitability of the PIM strengthening program for older adults.

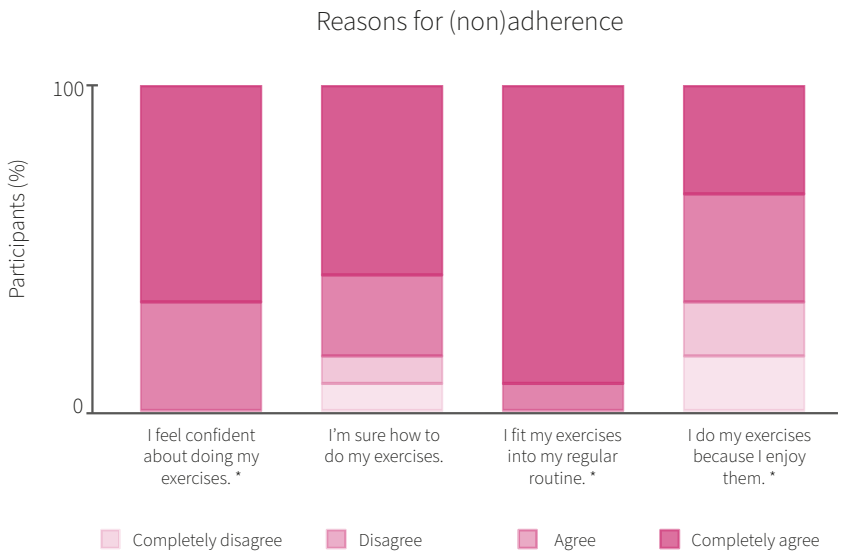

Figure 1. The scores on a selection of relevant items from the Exercise Adherence Rating Scale (EARS) showing that the exercises from the PIM strengthening program suit the preferences and capabilities of the participating older adults. Scores are recoded for items indicated by * and the remaining item is rephrased into a positive statement such that a higher score indicates a positive belief for all items.

Trainability of the PIMs from the perspective of motor skill acquisition

Although functional foot exercises, such as toe walking and single-leg stance, are habitual movements, isolated foot exercises require a period of familiarization allowing the establishment of neural adaptations. The literature has already recognized that isolated foot exercises are difficult to perform in healthy younger volunteers [13,14], but the extent to which older adults are able to acquire the required motor skills was still unknown. As part of our PIM strengthening intervention study, the trainer graded the motor performance for each of the exercises on a weekly basis. Figure 2, which is the result of additional analysis, demonstrates that participating older adults progressively improved their performance of the exercises over the course of the program. To illustrate the diversity among the exercises, the figure displays the motor performance for an exercise that was difficult at the start, but was mastered by all participants by the end of the intervention period (Figure 2 , left-hand side: lesser toes flexion against resistance) and for an exercise which remained difficult over time (Figure 2 , right-hand side: toe press). These data illuminate that isolated foot exercises are difficult in execution, primarily at the start when these are new to the older participants. Although some participants learned the required motor skills in a few weeks, others failed to master these skills before the end of the intervention. However, all participants were able to perform at least one of the isolated exercises after 8 weeks of training, confirming the trainability of the PIMs from the perspective of neural adaptations.

Our results extend the literature, which showed that a considerable subset of healthy younger individuals seemed incapable to perform isolated foot exercises after two weeks of daily practicing [13]. A more recent study concluded that 4 weeks of daily training would be sufficient for healthy active individuals to perform the isolated PIM exercises satisfactorily from the perspective of a clinician [15]. Our findings revealed that, when treating older adults, a period of at least 8 weeks should be accounted for the acquisition of new motor skills needed to perform isolated foot exercises. In contrast, the majority of the participants were able to execute the functional exercises satisfactorily from the start of the program. Therefore, the functional exercises may be used to complement the isolated exercises to achieve effective training volumes.

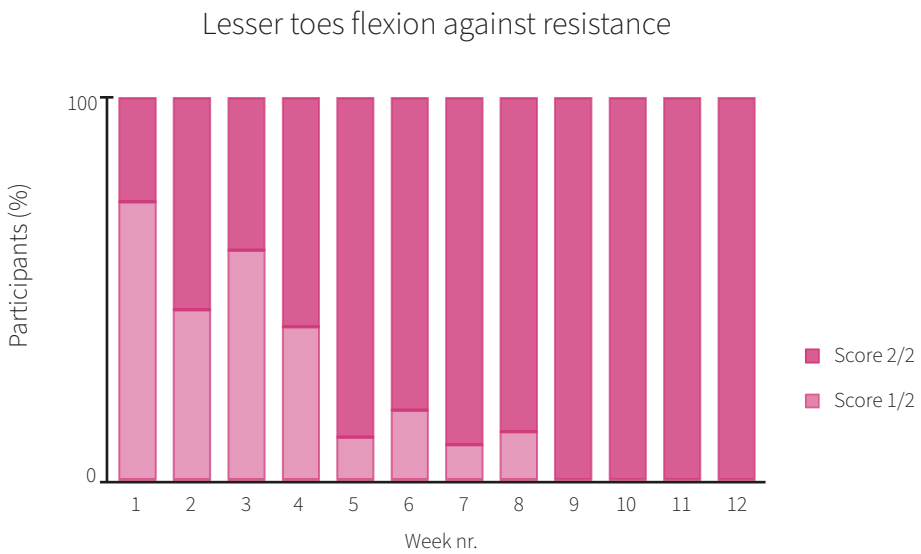

Figure 2. Motor performance of two isolated foot exercises from the PIM strengthening program: lesser toes flexion against resistance and toe press. A higher score indicates better performance with a maximum of 2.

Trainability of the PIMs in terms of muscle strength increments and hypertrophy

Increased hallux flexor strength and hypertrophy of the flexor digitorum brevis in the group of older adults who followed the 12-week PIM training program was the main finding supporting the hypothesis that the PIMs are trainable in older adults. Flexor strength was assessed for both the hallux and the lesser toes by measuring the pressure

under these regions while the participants pushed their toe(s) against the pressure plate as hard as possible [16]. The same task was also included as one of the exercises in the PIM strengthening program. During this task, the PIMs are highly activated as shown by the electromyography recordings, Supplementary Material 4D). Although hallux flexor strength increased, no hypertrophy was observed for the involved PIMs (i.e., abductor hallucis and flexor hallucis brevis). This implies that hallux flexor strength gains originated from improved motor control, which may be the expression of a learning effect. Such neural adaptation typically precedes hypertrophy and may dominate for a longer period for unfamiliar exercises, such as the hallux press exercise, particularly in older adults [17]. Another explanation lies in the fact that evaluating individual muscles does not do justice to their functional redundancy and may therefore not be sensitive enough to detect a training response. Nevertheless, even without hypertrophic changes, increased hallux flexor strength is associated with better functioning [18] and reduced risk and likelihood of falling [19,20].

The opposite pattern was found for the flexor strength of the lesser toes, which remained unchanged while the flexor digitorum brevis increased in size. This is unlikely explained by a high baseline level of lesser toes flexor force as this was 2-3 times less compared to the hallux. Therefore, exercises other than the lesser toe press – most likely the functional exercises – may be responsible for the hypertrophy of the flexor digitorum brevis observed in our study. Furthermore, it seems that the isolated lesser toe press may not be appropriate to evaluate flexor strength of the lesser toes. Nevertheless, the hypertrophic response of the flexor digitorum brevis is promising as it may contribute to postural balance during challenging tasks [21]. However, isolated lesser toe flexor strength also appeared to be an important determinant for balance in older adults [18] and, in addition, distinguishes non-fallers from fallers [20,22]. When improving isolated lesser toe flexor strength is the goal of treatment, it must be considered that this may require a training period lasting longer than 12 weeks.

Future research

Given the apparent challenges associated with the isolated evaluation of toe flexor strength with respect to motor control, it is recommended that future research utilizes functional assessment for this purpose. For instance, advanced analysis of center of pressure trajectories during balance tasks may enable relating functional performance to the contribution of the PIMs [23]. To further distinguish between improvement in motor control and hypertrophy, we suggest assessing the morphological changes of the involved PIMs together in a composite measure [24], rather than assessing individual PIMs. This is due to the observation that certain PIMs exhibit functional redundancy. For example, contraction of the abductor hallucis and flexor digitorum brevis both resist MTP joints extension [25]. Additionally, it is reasonable that, when training the PIMs, the interplay between agonistic muscles differs between individuals. Consequently, a composite morphological measure that combines individual PIMs, may be more suitable

and more sensitive to change when evaluating the effects of an intervention such as our PIM strengthening training program.

THE EXTENT TO WHICH THE RESULTS CONFIRM THE ROLE OF THE PIMS IN GAIT AND BALANCE IN OLDER ADULTS

Summary of key findings

Chapter 3 demonstrated that the literature provides, at best, low-certainty evidence supporting the effectiveness of PIM strengthening exercises with respect to gait and balance. This conclusion was based on a limited number of high-quality studies, primarily conducted in small samples of younger adults. Our RCT, reported in Chapter 6, did not show an effect of our 12-week PIM strengthening training program on gait and balance as measured in a laboratory setting. However, the PIM strengthening program reduced concerns about falling, though this was not associated with the observed adaptations of the PIMs. On the other hand, the qualitative interview study, presented in Chapter 7, elucidated that health benefits (e.g., improved gait, enhanced self-confidence in walking, increased stability) were perceived by a large proportion of the participants.

The role of the PIMs in gait and balance in older adults

Since laboratory-based gait and balance improvements were not demonstrated, and the reduction in concerns about falling lacked an association with observed PIM adaptations, the exact role of PIMs in gait and balance remains unclear. Nevertheless, a potential beneficial role of PIM strengthening in older adults in relation to gait and balance was indicated by the finding that concerns about falling were reduced to a greater degree in the group that followed the PIM strengthening program and by gait and balance improvements as perceived by the participants.

The absence of an improvement in the laboratory-based gait analysis might mean that (i) gait and balance were not affected by the PIM strengthening training or that (ii) gait and balance were improved, but that we were not able to measure this by performing this type of gait analysis. The former suggestion (i) might be supported by the possibility that the structures and function of the older feet are too severely affected by the ageing process. This would impede any muscle adaptation to translate into functional improvement. Another explanation is that 12 weeks of training may be too short for PIM's adaptations to translate into changes in a habitual functional ability, such as walking [26]. Improvements in gait and balance might only begin to emerge with a longer training duration. Regarding the latter suggestion (ii), a lab setting induces an unnatural gait pattern due to, for instance, walking barefoot, wearing sensors, and the experimental setting. Particularly in older adults, this might provoke a cautious gait pattern, which prevents us from detecting gait and balance adaptation. An alternative explanation is that the variable we used to evaluate gait and balance was not sensitive enough in this population. We used gait speed as a metric reflecting both propulsive capacities and postural balance

capabilities [27], and as a proxy for fall risk [28]. The literature suggests a cut-off value of <0.8 m/s to discriminate between low fall risk and increased fall risk [29]. The average preferred gait speed in our sample at baseline was 1.1 m/s. This indicates normal gait ability and may have precluded an effect to occur. The limitations with respect to the intervention duration, the lab setting and the metric for evaluation may be addressed in future research.

Concerns about falling were assessed using the FES-I scale, which addresses 16 everyday activities, 4 of which explicitly involve walking [30]. Additional analysis, depicted in Figure 3, showed that improvements were most obvious (i.e., proportion of participants with decreased concerns about falling outweigh proportion of participants with increased concerns with > 15%) for 3 of these explicit walking activities (i.e., walking around outside, walking on a slippery surface, walking on uneven surface) and 1 activity that implicitly involves walking (i.e., going to a place with crowds). This reflection suggests that the reduction in concerns about falling might be associated with improved gait. The literature supports this suggestion by indicating that having fewer concerns about falling is associated with better gait performance [31]. Moreover, an experimental study [32] suggested that improved gait might be the consequence of reduced concerns about falling. However, the absence of laboratory-based gait and balance improvements does not support a direct objective association between the PIM strengthening training and gait and balance.

In addition to using validated questionnaires (e.g., FES-I), the PIM training was also subjectively evaluated by interviewing the participants. The interview study was intended to investigate how factors influenced adherence to the PIM training. Surprisingly, many participants began the interviews by sharing perceived health benefits without prompts from the interviewer. Most of these health benefits were related to gait or balance. Participants provided detailed narratives, emphasizing the extent and the importance of the perceived improvement.

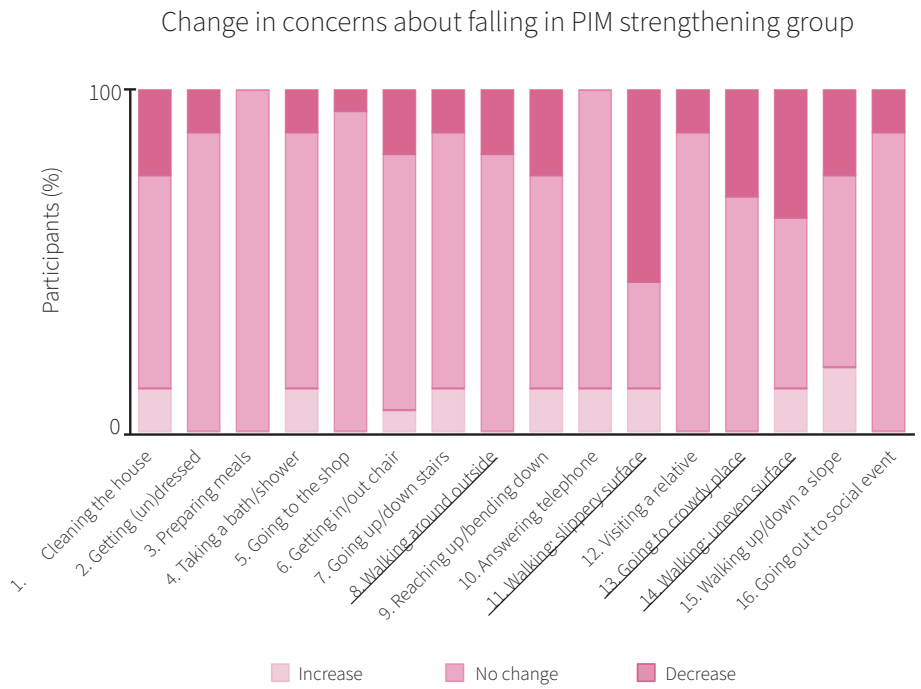

Figure 3. Frequency plot displaying the proportion of participants from the PIM strengthening group which have increased (blue), unchanged (orange), and decreased (green) concerns about falling at post-intervention compared to baseline for the 16 items of the Falls Efficacy Scale (FES-I). The items are slightly rephrased for clear presentation. It shows that improvements were most obvious (i.e., proportion of participants with decreased concerns about falling outweigh proportion of participants with increased concerns with > 15%) for 8. walking around outside, 11. walking on a slippery surface, 13. going to a place with crowds, and 14. walking on uneven surface.

Thus, while we did not find direct and objective evidence that training the PIMs improved gait and balance, improvements in perceived gait and balance may have resulted from – or preceded – reduced concerns about falling. The positive effect of PIM strengthening training on perceived gait and balance is novel in its field, since this project is the first to demonstrate that the effect of PIM strengthening training in older adults goes beyond the previously observed muscle adaptations [5,33,34] and static balance [5]. As our systematic literature review revealed, some evidence already existed for the effect of PIM strengthening training on gait and balance in younger adults. Considering that gait and balance impairments are a common threat, particularly in older adults [35], improvements in perceived gait and balance in older adults resulting from PIM strengthening training encourages further investigation into the beneficial effects of strengthening the PIMs in this population.

Despite the uncertainty about the objective improvement in gait and balance as a result of the PIM strengthening training, reduced concerns about falling and the perception

of improved gait and balance allude to increased confidence in gait and balance. This is equally important, since self-reported measures have been acknowledged as being complementary to performance-based measures in the assessment of function and health in older adults [36]. The clinical importance of confidence in gait and balance is further emphasized by the development of scales to assess these confidence constructs [37–39]. It is proposed that improved confidence in gait and balance precedes the actual behavior [40]. This explains that that improved confidence might translate into improved quality of life [41] and increased physical activity levels [42], which may benefit gait and balance in the longer term [43,44].

Future research

Future research may address the limitations put forward above regarding the objective evaluation of gait and balance improvement in response to a PIM strengthening program. To make sure that the intervention period is long enough, the duration may need to be doubled to 24 weeks. Although 12 weeks is already on the upper limit of a typical duration for foot and ankle training in older adults [45], an intervention that effectively reduced the rate of falls included a foot and ankle exercise program that lasted 6 months [46]. Even with a longer intervention period, laboratory-based gait analysis may still fail to detect modifications due to factors contributing to cautious gait (e.g., walking barefoot, wearing sensors, experimental setting). Additionally, lab-based gait analysis is a time-intensive method, particularly when the focus is on foot and ankle biomechanics, as was in our project. This focus requires a multi-segment foot model with precise and extensive marker placement on anatomical landmarks.

To overcome the limitations of a lab-based analysis that may contribute to cautious gait and to prevent the potentially unnecessary use of this time-consuming procedure, an initial step in the evaluation of a future PIM strengthening training program could be assessing daily-life gait. This can be achieved by trunk accelerometry in combination with an algorithm to estimate stride length, which allows to determine daily-life gait quality characteristics (e.g., gait speed, gait consistency, local instability, gait variability, gait intensity, smoothness) [47,48]. Subjects who respond positively to any of the daily-life gait quality characteristics may subsequently undergo lab-based gait analysis including multi-segment foot modelling. This enables the acquisition of foot and ankle biomechanics (e.g. joint power, foot arch kinematics), which is necessary for an in-depth investigation of the role of the PIMs. Walking in shoes is then preferred to minimize the probability of a cautious gait pattern. Alternatively, by the time such an intervention study is conducted, new techniques may be available to perform biomechanical analysis of the foot and ankle during daily-life shod walking [49].

CONTRIBUTION OF PIM TRAINING TO REDUCING FALL RISK

PIM strengthening training appeared to positively affect a selection of fall risk factors, as described in the previous section, and thereby contribute to fall prevention. Falling is a geriatric syndrome that can be prevented by treating modifiable risk factors [29]. Among these factors, lower extremity muscle strength, self-perceived gait and balance impairments and having concerns about falling are most frequently and strongly associated with falling [35,50,51]. These were also the factors that were improved by the PIM strengthening training, suggesting a potential role in fall prevention.

Although the literature shows associations between outcome measures that were positively affected by our PIM training and fall risk, we did not actually evaluate fall risk or fall incidence. Nevertheless, we took an additional step compared to a previous study in older adults [5] with a similar foot strengthening intervention in terms of the comprehensive and progressive nature of our intervention. Besides evaluating toe flexor strength, which increased to an extent akin to what was observed in that study [5], we also evaluated measures that were more clearly identified as fall risk factors in the literature, such as self-perceived gait and balance impairments and having concerns about falling. By doing this, we extended the findings of the previous study [5] and accommodated its recommendation to determine the effect of such an intervention on fall risk.

Concerns about falling

Among the variety of fall risk factors that were evaluated in our project, having concerns about falling was the most notable factor impacted by our PIM training. This is because our RCT, the study with the highest level of evidence in this project, showed a large reduction in concerns about falling. This is a promising finding as having concerns about falling is a strong predictor of falling [51] and, as such, included in the common set of risk factors that requires clinical assessment when someone is at high risk of falling [29].

Our project is the first to show that PIM strengthening training effectively lowers concerns about falling. This finding is distinctive from previous studies on PIM strengthening training, which failed to reduce concerns about falling [46,52–55] as was confirmed by a systematic review [45]. The superior results of our project may be explained by the progressive nature of our intervention, which aligns with the recommendations for exercise interventions to prevent falls proposed by the World Falls Guideline [29]. In addition, the large positive effect of our PIM training program on having concerns about falling was more convincing than the small to moderate effect that was shown for general physical exercise interventions [56] or any other type of intervention aimed at reducing fear of falling [57]. The observed reduction in concerns about falling is considered clinically important as it exceeded the difference between multiple-fallers vs. non-multiple fallers, as well as between high versus low physical fall risk that was revealed by a prospective study in a similar sample with a comparable level of concerns about falling [30].

Apart from the likelihood that reduced concerns about falling will lead to reduced risk of falling [51], the benefits may go beyond fall prevention. Fewer concerns about falling is identified in the World Falls Guideline (74) as contributing to healthy aging. This is because reduced concerns about falling lead to increased physical activity and physical functioning, decreased risk for depression or for declines in quality of life [58,59]. These factors, in turn, further decrease the risk of falling.

Self-perceived balance and gait abilities

The perceived improvements in gait and balance, and the confidence in these abilities, discussed in the previous section, are particularly relevant in the context of reducing fall risk. To illustrate this, in practice, self-perceived balance and gait abilities are evaluated in initial fall risk screening and – together with fall history and having concerns about falling – this discriminates between low fall risk and possibly increased fall risk [29]. Furthermore, a systematic review emphasized the importance of self-reported mobility problems (including gait and balance problems) to predict falls [50]. The importance of confidence in gait and balance is additionally demonstrated by a prospective cohort study that found superior ability for confidence in balance to predict falls compared to physical measures [60]. These studies suggest that when older adults perceive improvements in gait and balance or gain confidence in these abilities – as observed in our project – their fall risk may also decrease.

Lower extremity muscle strength

As described earlier, our RCT showed a significant improvement in hallux flexor strength in participants who followed the PIM strengthening program. This is relevant, since previous research suggests that this increase may reduce fall risk by approximately 15% [19]. More generally, lower extremity disability (i.e., reported problems with strength, sensation, or balance) and muscle weakness have also been identified as fall risk factors [35,61]. Although hallux flexor strength represents only one component of lower extremity strength and function, its improvement indicates that PIM strengthening may play a role in mitigating fall risk.

Future research

Although not explicitly hypothesized, in addition to PIM adaptations, we observed reduced concerns about falling in response to the PIM training. This novel insight supports further investigation into the integration of PIM exercises in existing fall prevention programs. This is particularly relevant because concerns about falling is often a target for exercise interventions for older adults, due to the extensive and impactful consequences of these concerns [56].

We suggest evaluating the integration of PIM exercises in existing fall prevention exercise programs by not only assessing concerns about falling, but also by objectifying gait and balance improvements (as discussed in the previous section), quantifying confidence

in gait and balance and expanding the evaluation of lower extremity function. Since the PIM strengthening program seemed to improve confidence in gait and balance, we recommend quantification of these constructs using validated instruments, such as the Activities-specific Balance Confidence (ABC) Scale [37] and the modified Gait Efficacy Scale [38,62]. This aligns with the recommendation to assess these constructs to determine fall risk [63]. Second, we recommend using the function component of the Late-life Functioning and Disability Instrument [64] to evaluate the effect of PIM strengthening on lower extremity functions. Surprisingly, a few participants in the PIM strengthening group showed increased scores on the physical functioning domain of the SF36, which is limited to ten items and not solely reflects lower extremity function. The Late-life Functioning and Disability Instrument is expected to be more precise and more sensitive to changes in lower-extremity functions in older adults living in the community than the physical functioning domain of the SF36 [64,65] and is able to prospectively discriminate between fallers and non-fallers [66].

In addition to assessing relevant fall risk factors, we propose evaluating the integration of PIM exercises in existing fall prevention exercise programs by assessing fall incidence rates. The rationale for this recommendation is twofold. First, the fall incidence rate is the preferred outcome measure for developing evidence-based strategies to prevent falls [67]. Second, this approach aligns with the need to generate concrete, actionable results.

CLINICAL IMPLICATIONS

In our project, as proof of concept, we intensively trained the foot muscles and we inferred the beneficial contribution of the training program to reducing fall risk. However, we believe that PIM strengthening training should not be introduced as a stand-alone program when the aim is to reduce fall risk. This is because other exercise programs have proven to directly reduce fall risk or fall rate [67], whereas our effect is limited to fall risk factors (e.g., having concerns about falling, self-perceived gait and balance abilities, lower-extremity muscle strength). Therefore, we propose to further investigate the beneficial value, concerning fall risk and falls, of integrating PIM strengthening exercises into these exercise programs. However, when the aim is to reduce concerns about falling, the PIM strengthening program may be offered as a stand-alone program or its exercises may be directly incorporated into existing exercises programs to further improve its effectiveness on concerns about falling. In addition, incorporation of the PIM exercise may also apply to general exercise programs for older adults that aim to preserve mobility and therefore indirectly contribute to fall prevention. For each of these three directions, it is essential to align our recommendation with global and national approaches in the field of fall prevention. To put forward sensible recommendations for research and practice, these approaches will be outlined first hereafter.

The global and national approach to prevent falls

Falling in older adults is a worldwide issue that becomes increasingly urgent to defeat. This urgency is underscored by the recent publication of the World Falls Guidelines [29], a global initiative to address the need for clinical practice guidelines that offer consistency between national guidelines and between guidelines by specialist associations. This guideline advocates national implementation of the global guidelines in alignment with the current healthcare system.

In the Netherlands, fall prevention has taken off rapidly over the past couple of years. This started with the 2021-2025 coalition agreement, a government policy document, in which fall prevention was identified as a priority. It announced that municipalities would be assigned the responsibility of offering fall prevention programs to their residents aged 65 years and older. Subsequently, The Healthy and Active Life Agreement (In Dutch: Gezond en Actief Leven Akkoord (GALA)[68]) was established, which unifies the national government, municipalities, and health insurers to pursue several cross-sectoral societal goals, including fall prevention. These parties agreed on an integral approach to prevent falls (in Dutch: Ketenaanpak Valpreventie [68]), which aligns seamlessly with the World Falls Guidelines [29]. The Dutch government provides specific financial support to municipalities for the implementation of this approach and for promoting physical activity programs for older adults. On behalf of the Ministry of Health, Welfare and Sport (VWS), the knowledge center for injury prevention “VeiligheidNL”, in collaboration with the National Institute for Public Health and the Environment (in Dutch: Rijksinstituut voor Volksgezondheid en Milieu (RIVM)), supports municipalities with knowledge on how to operationalize the approach to prevent falls effectively. The workflow of the approach to prevent falls starts with classifying older adults in either the category of low fall risk or increased (i.e., intermediate or high) fall risk. Older adults with low fall risk are referred to an ongoing exercise program. Those with increased risk and mobility impairments are first referred to a fall prevention exercise intervention. In addition, older adults who are at high risk for falls undergo a multifactorial fall risk assessment to tailor interventions to individual needs. If this fall risk assessment identifies concerns about falling, an additional exercise intervention is recommended.

Recommendations for exercise programs targeting older adults at low fall risk

With the appropriate strategy, integration of PIM exercises in exercise programs for older adults at low fall risk may enhance their effectiveness on fall risk factors. The World Falls Guideline emphasizes that “low risk” does not mean “no risk” as 19-36% of the older adults who were initially identified as being at low risk will fall in the subsequent year [50]. Older adults at low risk for falls are therefore recommended to participate in exercise programs for older adults to preserve functional mobility and to prevent becoming at increased risk for falls [29,68]. Although our project does not provide strong evidence for the contribution of the PIM strengthening exercises to mobility or fall prevention, the observed benefits – reduced concerns about falling, improved self-perceived gait and

balance abilities and increased muscle strength – suggest that the PIM exercises may be a valuable addition to exercise programs for older adults in supporting their intended goals.

Noteworthy, the structure and content of our PIM exercises align well with existing exercise programs for older adults. These programs are typically ongoing and consist of exercises that challenge the postural system similar to daily life tasks and may include strength exercises. Our PIM strengthening exercises, consisting of both functional exercises with a narrowed base of support and isolated exercises (e.g., resistance exercises), are thus an appropriate fit with the content of these programs. At the same time, individual physical capabilities may favor one type of foot exercises (i.e., functional or isolated) over the other. These insights highlight the importance of offering both types of foot exercises in programs for older adults.

Implementation should consider the need for supervision. The interview study emphasized that the performance of and adherence to isolated PIM exercises merit supervision, whereas functional exercises can be done independently during daily activities at home. Therefore, in ongoing exercise programs, isolated exercises may be preferably integrated as supervised strength exercises, whereas the instructor may stimulate participants to integrate the functional foot exercises into their daily life activities. This dual approach extends the impact of training beyond the scheduled classes.

Recommendations for exercise programs targeting older adults at increased fall risk

Since we have not provided strong and direct evidence that the PIM strengthening training improves gait and balance or fall outcomes, we recommend further investigating the effect of integrating PIM exercises in existing programs on these outcomes first. The alignment of the nature of our PIM exercise program with the recommendations for exercise interventions for older adults at increased fall risk [29] facilitates smooth integration. These recommendations emphasize the necessity of progressive exercise programs, tailored to the individual's physical capabilities, that include at least balance-challenging and functional exercises and when feasible tai chi and/or resistance strength exercises. The exercise programs can be delivered group-based, home-based, or a combination of both and should preferably continue after the minimum duration of 12 weeks. The match between our program and these recommendations is illustrated by several aspects. First, our foot exercises are provided with different difficulty levels, such that individuals can progress based on their own performance. This facilitates offering challenging exercises that are still achievable, which promotes adherence and enjoyment – an insight revealed by our interview study. Second, the isolated foot exercises allow various positions, ranging from seated to standing on one leg, making the exercises suitable for participants with diverse physical capacities. Third, a selection of exercises from our program, primarily the functional exercises, is appealing to be performed

at home and do not require supervision. This supports sustained exercise after an intervention ends to avoid losing the health benefits gained.

In addition to the match between our PIM exercises and the global recommendation for fall prevention exercise interventions, the exercises are also a good fit with the interventions endorsed by VeiligheidNL (i.e., the knowledge center for injury prevention) in the Netherlands: 'In balans' (22), 'Otago' (21), and 'Vallen verleden tijd' [69]. The nature of each of these programs may make one type of exercise (e.g., functional or isolated) preferable, but overall, these interventions allow integration of at least a selection of the PIM exercises with relative ease.

Recommendations for exercise programs targeting older adults at high fall risk and having concerns about falling

The clinically relevant reduction in concerns about falling suggests that our PIM strengthening training may be a promising stand-alone program for older adults having concerns about falling, as indicated by the multifactorial fall risk assessment. Alternatively, its exercises could be integrated into current interventions targeting concerns about falling. However, replication of our study findings is needed to support these recommendations.

In The Netherlands, two interventions are currently recommended for older adults to reduce concerns about falling: 'a matter of balance' (in Dutch: 'zicht op evenwicht') [70] and 'Zeker Bewegen'. The latter focuses primarily on fall techniques and is, therefore, not matching our PIM exercises. In contrast, 'Zicht op evenwicht' [70] is a multicomponent cognitive behavioral group intervention that includes two sessions of low-intensity physical exercise, among which resistance band training, along with take-home assignments. This structure provides opportunities for feasible integration of our PIM exercises, which are in accordance with the recommendations originating from our interview study. First, group sessions could incorporate selected isolated PIM exercises using resistance bands, which benefit from available supervision. Second, home assignments could promote regular practice of functional PIM exercises in daily life.

Future opportunities may include combining PIM training with holistic interventions. A recent systematic review identified routines from, for instance, tai chi, pilates, or yoga as the most effective exercise components to reduce concerns about falling [57], with tai chi also being associated to reduced probability of falling [67]. The potential of PIM training in combination with the proposed benefits of holistic approaches may open new avenues for addressing concerns about falling and improving fall prevention outcomes.

Concluding remarks

Although replication of our findings is merited, the benefits of PIM strengthening training on having concerns about falling advocate for early referral to such a program when someone is worried about falling. This may not be limited to older adults at increased

fall risk. The initial fall risk stratification starts with asking if someone is worried about falling, next to two other questions (i.e., falls in the past year and difficulties when moving, walking, or remaining balanced). Ironically, the fall risk classification leaves the possibility open that an individual who indicates having concerns about falling is eventually classified as being at low fall risk in the absence of additional indications (e.g., injurious fall, more than one fall, frailty) and consequently – following the decision tree – is only referred to an ongoing exercise program. At this point, the decision tree may be improved by referral to an appropriate intervention, such as our PIM strengthening training, based on a positive answer to the initial question about being worried about falling.

Future research

A successful implementation of the recommendations outlined above necessitates interactions and engagement with key stakeholders, which may be addressed in a future project. Key stakeholders who should at least be involved in the implementation process include (i) the owners of the exercise programs acknowledged by the National Institute for Public Health and the Environment and opted by VeiligheidNL, (ii) organizations that provide ongoing exercise programs for older adults, (iii) instructors, including physiotherapists who deliver exercise programs to older adults and (iv) older adults participating in or referred to these exercise programs. Identifying barriers and facilitators may support this iterative process of refining the incorporation of PIM exercises in existing programs or integrating the PIM exercise training program in the current approach to prevent falls. A possible direction to incorporate the PIM exercises into existing programs may be to provide them in existing publicly available online sources, such as 'MijnZorgApp' or exercise cards provided by VeiligheidNL.

GENERALIZABILITY AND FUTURE RESEARCH

The findings of the current project are limited to the population of adults living in the community with a possibly increased risk of falling and who are involved in a functional exercise program. We deliberately selected this population to align with the practical setting in which we intended to integrate the PIM exercises. Furthermore, we expected the greatest impact of PIM exercises in individuals already adhering to an exercise program. This is because these participants are anticipated to exhibit high levels of self-efficacy, motivation, and goal-directed behavior in relation to exercising for health [6]. On the other hand, gait and balance impairments – the target of the PIM exercises – may be more severe in less physically active or untrained older adults living in the community, who may therefore benefit from the PIM strengthening exercises to a greater extent. Moreover, applying the PIM strengthening intervention in such a population would increase the contrast between the intervention group and the control group, since the intervention is anticipated to increase physical activity levels.

However, investigating the effect of the PIM strengthening program in less physically active individuals introduces other challenges. First, the generally low adherence to health-promoting behaviors in this population [71], would require the intervention to have enhanced focus on these aspects. For instance, the exercise program may then pay more attention to cognitive-motivational factors, such as through educational components that address health beliefs, facilitation of social support and reinforcement, and provision of reminders [6]. Second, medical conditions affecting gait and balance are more prevalent in less active older adults [72] and may interfere with the effects of PIM strengthening exercises. From this perspective, it is important to control the confounding effects of medical conditions when analyzing the intervention effect. Third, due to molecular and neurophysiological responses to training in untrained individuals [73,74], the onset of muscular and functional adaptation may take longer in less active older adults. Therefore, an intervention period longer than 12 weeks is needed to facilitate these adaptations. In summary, it is reasonable to investigate the effect of PIM strengthening training on gait and balance in less active older adults, but this necessitates a greater focus on adherence, control for medical conditions in the analysis and a longer intervention period.

Frail older adults living in care homes are another group that might particularly benefit from our PIM strengthening program to improve confidence in gait and balance. The number of falls is especially high in the care home setting [29], making this an important target for fall prevention. Moreover, compared with community-residing older adults, gait and balance impairments and physical inactivity are more prevalent among care home residents, particularly among those who are frail [75,76]. The identified mediating factor between frailty and falls is fall-related self-efficacy (i.e., someone's confidence in their ability to undertake activities of daily life without falling [77]) [78]. Therefore, it is important to improve confidence in gait and balance in frail older adults living in care homes. This will likely further facilitate the ability to perform functional exercises, increase overall physical activity and hence reverse the downward spiral in physical functioning that increases fall risk. Our PIM strengthening program showed, in particular, an effect on confidence in gait and balance, indicating its potential for this purpose. Most of the PIM exercises within our program are suitable for frail older adults, since they can be performed seated. A care home setting enables the delivery of a supervised exercise program within the institution, which facilitates social support and adherence to the program. The PIM strengthening program may thus be an effective first step to improve confidence in physical functioning of frail older adults living in care homes. However, this needs further investigation.

The effect of PIM strengthening training may have been different for certain subgroups within our study population. However, subgroup analysis was not performed due to the small sample sizes and the corresponding inadequate power. Although we selected a specific group among the older adults participating in a functional exercise program – people with a possibly increased fall risk – this resulted in a heterogeneous group

with respect to fall risk, gait and balance abilities, physical activity, and PIM strength. For example, one participant was included because of reporting a fall while ice skating in the previous year but exhibited no gait or balance impairments. Another participant was included after reporting difficulty with moving, walking, or remaining balanced, in addition to reporting an injurious fall in the previous year, and having concerns about falling. Both participants might be at increased fall risk, but they obviously differ with respect to actual fall risk, gait and balance abilities, physical activity, and possibly with respect to PIM strength. The PIM strengthening program was aimed at improving PIM strength and thereby contributing to improved gait and balance, and indirectly to a reduced fall risk. From this perspective, it is reasonable to suggest that older adults with gait and balance impairments would mostly benefit from PIM strengthening training. Therefore, we recommend that future research select a study sample with intermediate or high fall risk based on gait speed (≤ 1 m/s) according to the fall risk classification incorporated in the Dutch approach to prevent falls [79]. In the more distant future, digital twins technology may enable an even more individualized approach in the prevention of falls [80]. This technology encompasses a virtual representation of a person which allows simulations of potential treatment strategies to predict health outcomes, based on multi-scale modeling of multi-modal data, such as clinical, genetic, molecular, environmental, and social factors [80]. It is envisioned that digital twins technology will contribute to better treatment outcomes and less adverse effects [80].

Conclusion

In this project, we demonstrated that strengthening the PIMs contributes to increased confidence in gait and balance and leads to reduced concerns about falling in older adults who might be at increased fall risk. Although our findings support the trainability of the PIMs in older adults, this did not explain the observed improvements, and, therefore, the mechanisms behind the improvements are still to be unraveled. Further, the findings of this project do not confirm the contributing role of the PIMs in objective gait and balance performance, which needs to be addressed in future research by assessing daily life gait as opposed to lab-based gait assessment. Nevertheless, the improvements in response to PIM strengthening training advocate further research on the effect of integrating isolated and functional PIM exercises into current functional exercise programs for older adults on gait and balance performance – as a proxy for fall risk – and directly on falls. In addition, the PIM exercises appeared to be particularly beneficial for exercise programs aimed at reducing concerns about falling, which needs confirmation by subsequent studies.

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Samenvattingen

SUMMARY

Falling among older adults is a growing concern and requires optimal prevention. Incidence rates are rising as the population continues to age and because of the increasing prevalence of multimorbidity and frailty. Among the diverse fall risk factors, impaired gait and balance are, second to muscle weakness, the strongest predictors of falling. Effective fall prevention programs are those that contain physical exercise. More specifically, exercise programs are recommended to include at least balance and functional exercises to target impaired gait and mobility. The majority of existing fall prevention exercise programs are not focused on foot muscles. However, several studies have shown the importance of targeting foot muscles to treat gait and balance impairments in older adults. In addition, growing evidence highlights the key role of a specific group of foot muscles, the plantar intrinsic foot muscles (PIMs), in this context. If these muscles can be trained in older adults, and this results in improved gait and balance, this will benefit existing fall prevention programs. Therefore, the overall aim of this doctoral project is to improve fall prevention by gaining insight into the trainability of the PIMs and their role in gait and balance in older adults. We hypothesize that training the PIMs in older adults will increase their force capacity and, concomitantly, improve gait and balance. This is examined in a final intervention study investigating the effect of a PIM strengthening program on PIM force capacity, gait, and balance. This intervention study is preceded by several preparatory studies to substantiate choices in the design of the intervention study. Therefore, the methodological approach of this project consists of a chronological sequence of studies, each with its own methodology and purpose.

Chapter 2 presents the study investigating the intra-assessor reliability and measurement error of ultrasound-assessed morphology – an estimate of force capacity – of selected foot muscles in older adults using a tablet-based device. As a secondary aim, the measurement error was compared between older and younger adults and between the tablet-based device and a mainframe system. Ultrasound images were collected from 18 older and 10 younger adults on two occasions using the two ultrasound systems. In older adults, the standard error of measurement ranged from 2.8% to 11.9%, with most intra-class correlation coefficients being excellent. Although younger adults showed smaller error variance for six morphology measures, errors in older adults were small as well. The tablet-based device demonstrated superior repeatability compared to the mainframe machine. These findings suggest that a tablet-based ultrasound can be used to reliably assess foot muscle morphology in older adults and is suitable for detecting group-level hypertrophy following training. It presents a practical alternative to expensive mainframe systems, which often have limited access. In addition, the use of a tablet-based device enables the researcher or clinician to perform ultrasound measurements at any location, even at the home of older adults.

Chapter 3 reports the systematic literature review that examined the evidence on whether interventions anticipated to strengthen the PIMs improve dynamic balance control and foot function during gait in adults. Eleven studies were included, with the findings of five high- or moderate-quality studies synthesized. Most research involved younger populations and applied isolated foot exercises. Results showed low-certainty evidence that PIM exercises improve vertical ground reaction force – a measure for foot function during gait – and very low-certainty evidence for improved dynamic balance. No effect was found on medial longitudinal arch kinematics. Overall, findings suggest potential benefits of PIM strengthening for outcomes that are associated with falling in older adults. However, high-quality intervention studies targeting older adults are needed, using outcome measures related to fall risk and PIM function, such as propulsive forces and balance during gait, in addition to PIM strength or capacity measures.

Chapter 4 examines whether functional foot exercises can activate the PIMs to a comparable degree as isolated foot exercises. Although isolated exercises are traditionally used in clinical practice, they may be difficult for older adults to perform. Functional exercises, by contrast, are more accessible, but their effectiveness in specifically targeting the PIMs remains unclear. In this experimental study, surface electromyography was used in 29 younger adults to compare the activation of three PIMs during four functional exercises (normal and unstable toe stance, toe walking, and hopping) with the activation during the isolated foot exercise provoking the largest level of activation for the respective PIM. Results showed that functional exercises elicited similar or even greater muscle activation than the muscle-specific isolated exercise in all 12 comparisons. Specifically, functional exercises showed higher activation in 25% of the comparisons, with no significant differences in the remaining 75%. These findings suggest that functional exercises may serve as a viable alternative or as a complementary exercise mode to isolated foot exercises in rehabilitation or prevention programs targeting older populations.

Chapter 5 outlines the study protocol for a randomized controlled trial (RCT) designed to evaluate the effects of a 12-week PIM strengthening program on gait, dynamic balance and foot muscle function in older adults. Recognizing that effective fall prevention programs typically include exercise but still require enhancement, the study investigates whether targeted PIM training can improve gait and dynamic balance and, thereby contribute to reducing fall risk. The protocol describes that community-dwelling older adults (≥65 years) who participate in a group-based functional exercise program and have an indication of possibly increased fall risk are eligible. Participants are randomly assigned to either an intervention or control group. The intervention group follows a progressive 12-week training program combining isolated and functional foot exercises, to be performed five times per week at home of which one supervised by a trainer. The control group continues usual activities but keeps a diary. The primary outcome is the change in maximum gait speed, reflecting propulsive capacities and dynamic balance;

secondary outcomes include the change in PIM capacity and strength, foot and ankle biomechanics, and fall-related risk factors (e.g. concerns about falling). Data are collected at baseline and post-intervention in a laboratory setting, with between-group differences in change from baseline analyzed using ANCOVA. This protocol provides the foundation for determining whether PIM strengthening may enhance the effectiveness of existing fall prevention strategies for older adults.

Chapter 6 presents the results of the RCT introduced in Chapter 5. Thirty-three participants (15 men, 18 women) were randomly allocated to an intervention group receiving the PIM strengthening program (n = 16; median age: 78.4 years (IQR: 73.3 – 83.6)) or a control group (n = 17; median age 76.6 years (IQR: 71.3 – 82.1)). The median adherence to the prescribed number of training sessions was 99 % (IQR:97 % - 100%). While no significant between-group difference was found for the change in maximum gait speed, the intervention group demonstrated a larger reduction in concerns about falling. The reduction in concerns about falling was most notable for activities that involve walking. In addition, the intervention group showed increased capacity and strength for a selection of PIMs, affirming the trainability of the PIMs in this population. However, these muscle adaptations were not associated with other findings. The findings support further research on the benefits of integrating PIM strengthening exercises in physical exercise programs, including fall prevention programs, for mobility and fall risk. In addition, future studies are needed to unravel the mechanism behind the reduction in concerns about falling.

Chapter 7 presents a qualitative study exploring how adherence to a 12-week PIM strengthening program is experienced and influenced in older adults. Understanding their perspectives may improve adherence of the target population, which is generally low to moderate for foot exercise programs hampering the effectiveness Twelve participants (aged 69–91), all enrolled in the intervention arm of the randomized controlled trial reported in Chapters 5 and 6, were interviewed to gain in-depth insight into factors related to capabilities, opportunities, and motivation that shaped their adherence. The median total score on the six items of the Exercise Adherence Rating Scale (EARS) was 23.5 out of 24 (IQR: 20-24) and showed excellent adherence to the prescribed unsupervised home exercise session. Using reflexive thematic analysis with an inductive, experiential approach, four key themes were identified: “Getting started,” “Hanging in,” “Settled into the rhythm,” and “Perceiving health benefits is the ultimate.” These central themes were additional to the positive evaluation of intervention features: clear instructions from the trainer, supportive materials, and flexibility in timing and content of the training program. The identified phases reflect a temporal progression in participants’ perception and illustrate how the appearance of factors influencing adherence is dynamic and phase-dependent. Surprisingly, health benefits (e.g., improved gait, enhanced self-confidence in walking, increased stability) were spontaneously revealed by a large proportion of the participants. The findings underscore that a sense of benefit, combined with well-designed support and a personalized approach, support continued adherence. These

insights offer practical guidance for professionals designing and implementing foot strengthening interventions in older adults.

The Discussion Chapter, **Chapter 8**, elaborates on three main topics: (i) the extent to which the results confirm the trainability of the PIMs in older adults, (ii) the extent to which the results confirm the role of the PIMs in gait and balance in older adults, and (iii) the contribution of PIM training to reducing fall risk. Overall, findings confirm that PIMs are trainable in older adults through a program combining isolated and functional exercises. High adherence rates –confirmed by EARS scores – and qualitative evaluation, reflect the program’s alignment with older adults’ preferences and capabilities. Strength gains and muscle hypertrophy were observed for the PIMs, with different muscles responding via either neural adaptation or structural changes, supporting overall trainability of these muscles. Despite no objective improvements in gait and balance being observed in the movement analysis laboratory assessments, the role of PIMs in gait and balance remains potential due to reductions in concerns about falling and participants’ perceived improvements in gait and balance. Lab-based measures may have failed to detect changes due to the unnatural test setting, insensitive metrics, or the intervention’s limited duration. Qualitative and subjective data revealed perceived health benefits and reduced concerns about falling linked to walking activities. These improvements – indicating increased confidence in walking – could precede gains in function and participation.

The PIM strengthening training may contribute to fall prevention by improving key modifiable fall risk factors. Notably, the intervention significantly reduced concerns about falling – a strong predictor of falls – more effectively than previous PIM or general exercise programs. These perceived improvements may translate into reduced fall risk. Although the effect on falling was not evaluated, the findings support further investigation into integrating PIM exercises into broader fall prevention exercise programs. Future studies should assess fall incidence, confidence in gait and balance, and lower extremity function using validated tools. The clinical implication of this project is that, while PIM strengthening training seems promising in addressing fall risk factors, it should not replace existing evidence-based fall prevention exercise programs. Instead, PIM exercises may be integrated into current programs to enhance effectiveness for older adults at low or intermediate fall risk. For those with high fall risk ánd concerns about falling, PIM training may serve as a valuable supplemental intervention. Future implementation should align with national guidelines and involve collaboration with key stakeholders. The generalizability of this project is limited to physically active older adults participating in exercise programs, who likely show high motivation and self-efficacy. However, less active or frail older adults – particularly those in care homes – may benefit more from PIM strengthening due to greater gait and balance impairments. Future studies may target older adults with intermediate or high fall risk as indicated by a gait speed test.

In conclusion, we demonstrated that strengthening the PIMs contributes to increased confidence in gait and balance and leads to reduced concerns about falling in older adults who might be at increased fall risk. Although our findings support the trainability of the PIMs in older adults, this did not explain the perceived improvements, and, therefore, the mechanisms behind the improvements are still to be unraveled. Further, the findings of this project do not confirm the contributing role of the PIMs in objective gait and balance performance, which needs to be addressed in future research by assessing daily life gait as opposed to lab-based gait assessment.

SAMENVATTING

Vallen onder oudere volwassenen is een groeiende zorg en vraagt om optimale preventie. De incidentie neemt toe door de vergrijzing van de bevolking en de toenemende prevalentie van multi-morbiditeit en kwetsbaarheid. Van de vele risicofactoren voor vallen zijn, na spierzwakte, een verstoord looppatroon en verminderde balans de sterkste voorspellers. Effectieve valpreventieprogramma's bevatten bewegingsoefeningen, waarbij met name balans- en functionele oefeningen worden aanbevolen om beperkingen in de mobiliteit en het looppatroon aan te pakken. De meeste bestaande oefenprogramma's richten zich echter niet op de voetspieren, terwijl meerdere studies het belang laten zien van het trainen van voetspieren bij het behandelen van loop- en balansproblemen bij oudere volwassenen. In toenemende mate wordt een specifieke groep voetspieren in dit verband als essentieel gezien: de plantaire intrinsieke voetspieren ('Plantar Intrinsic Muscles', PIMs). Wanneer deze spieren bij oudere volwassenen getraind kunnen worden en dit leidt tot positieve effecten op het lopen en de balans, kan dit bestaande valpreventieprogramma's versterken. Het algemene doel van dit promotieonderzoek is dan ook om valpreventie te verbeteren door inzicht te verkrijgen in de trainbaarheid van de PIMs en hun rol in het lopen en de balans bij oudere volwassenen. De hypothese luidt dat training van de PIMs bij oudere volwassenen leidt tot een toename in spierkrachtcapaciteit en daarmee tot verbetering van lopen en balans. Dit wordt onderzocht in een afsluitende interventiestudie naar het effect van een PIM trainingsprogramma op spierkrachtcapaciteit, lopen en balans. Deze interventie wordt voorafgegaan door meerdere voorbereidende studies ter onderbouwing van de keuzes in het ontwerp van de interventiestudie. De methodologische aanpak van dit project bestaat uit een chronologisch opeenvolging van studies, elk met een eigen methode en doelstelling.

Hoofdstuk 2 beschrijft een studie naar de intra-beoordelaarsbetrouwbaarheid en meetfout van de door echografie bepaalde morfologie – een benadering van de spierkrachtcapaciteit – van geselecteerde voetspieren bij oudere volwassenen, met gebruik van een echo-apparaat met tablet. Als secundair doel werd de meetfout vergeleken tussen oudere volwassenen en jongeren en tussen het tabletsysteem en een traditioneel mainframe echo-systeem. Bij 18 oudere en 10 jongere volwassenen werden echo-beelden verzameld. Bij oudere volwassenen lag de standaardmeetfout tussen 2,8% en 11,9%, met overwegend uitstekende intra-class correlatiecoëfficiënten. Jongeren vertoonden bij zes metingen een lagere meetfout, maar ook bij oudere volwassenen waren de fouten gering. Het tabletsysteem liet een betere reproduceerbaarheid zien dan het mainframeapparaat. De bevindingen suggereren dat een echo-apparaat met tablet betrouwbaar voetspiermorfologie kan meten bij oudere volwassenen en geschikt is voor het detecteren van spierhypertrofie op groepsniveau na training. Het biedt een praktisch alternatief voor dure mainframe-systemen, die vaak moeilijk toegankelijk zijn. Bovendien

maakt het gebruik van een tablet-systeem het mogelijk voor onderzoekers of clinici om metingen op elke locatie uit te voeren, zelfs bij oudere mensen thuis.

Hoofdstuk 3 beschrijft een systematische literatuurstudie naar het bewijs in hoeverre interventies die gericht zijn op het versterken van de PIMs, leiden tot verbetering van dynamische balanscontrole en voetfunctie tijdens het lopen bij volwassenen. Elf studies werden geïncludeerd, waarvan de resultaten van vijf studies van hoge of matige kwaliteit werden gesynthetiseerd. De meeste onderzoeken zijn uitgevoerd in jongere populaties en pasten geïsoleerde voetoefeningen toe. De resultaten toonden bewijs met lage zekerheid dat PIM-oefeningen de verticale grondreactiekracht verbeteren – een maat voor voetfunctie tijdens het lopen – en bewijs met zeer lage zekerheid voor verbetering van dynamische balans. Er werd geen effect gevonden op de kinematica van de mediolongitudinale voetboog. Al met al suggereren de bevindingen mogelijke voordelen van PIM-versterkende training voor uitkomsten die samenhangen met vallen bij oudere volwassenen. Er is echter behoefte aan hoogwaardige interventiestudies bij oudere volwassenen, die uitkomstmaten gebruiken die verband houden met het risico op vallen en PIM-functie, zoals propulsieve krachten en balans tijdens het lopen, naast PIM kracht of capaciteit parameters.

Hoofdstuk 4 onderzoekt of functionele voetoefeningen de PIMs in vergelijkbare mate kunnen activeren als geïsoleerde voetoefeningen. Hoewel geïsoleerde oefeningen traditioneel worden gebruikt in de klinische praktijk, kunnen deze moeilijk uitvoerbaar zijn voor oudere mensen. Functionele oefeningen zijn daarentegen toegankelijker, maar hun effectiviteit in het activeren van specifiek de PIMs is onduidelijk. In deze experimentele studie werd bij 29 jongvolwassenen oppervlakte-elektromyografie gebruikt om de activatie van drie PIMs te vergelijken tijdens vier functionele oefeningen (normale en instabiele tenenstand, tenenlopen en huppen) met de activatie tijdens de geïsoleerde oefening die voor de betreffende PIM de hoogste activatie veroorzaakte. De resultaten toonden aan dat functionele oefeningen een vergelijkbare of zelfs hogere spieractivatie veroorzaakten dan de spier-specifieke geïsoleerde oefening in alle 12 vergelijkingen. In 25% van de vergelijkingen was de activatie bij functionele oefeningen zelfs hoger, en in de overige 75% waren er geen significante verschillen. Deze bevindingen suggereren dat functionele oefeningen een haalbaar alternatief of aanvullende oefenvorm kunnen zijn bij revalidatie- of preventieprogramma's voor oudere doelgroepen.

Hoofdstuk 5 beschrijft het studieprotocol van een gerandomiseerde gecontroleerde trial (RCT) om de effecten van een 12-weeks PIM trainingsprogramma op het lopen, dynamische balans en voetspierfunctie bij oudere volwassenen te evalueren. Gezien het feit dat effectieve valpreventieprogramma's doorgaans een beweegprogramma bevatten, maar nog verbetering behoeven, onderzoekt deze studie of gerichte PIM-training kan leiden tot een beter looppatroon en verbeterde balans, en daarmee bijdraagt aan vermindering van valrisico. Het protocol beschrijft dat zelfstandig wonende oudere

mensen (≥ 65 jaar) die deelnemen aan een groepsgewijs functioneel beweegprogramma en een mogelijk verhoogd valrisico hebben, in aanmerking komen. Deelnemers worden willekeurig toegewezen aan een interventiegroep of controlegroep. De interventiegroep volgt een progressief 12-weeks trainingsprogramma dat geïsoleerde en functionele voetoefeningen combineert, vijf keer per week thuis uit te voeren, waarvan één sessie onder begeleiding van een trainer. De controlegroep behoudt de gebruikelijke activiteiten maar houdt daarnaast een dagboek bij. De primaire uitkomstmaat is de verandering in maximale loopsnelheid, als weerspiegeling van de propulsieve capaciteit en dynamische balans; secundaire uitkomstmaten zijn de verandering in PIM-capaciteit en -kracht, voet- en enkelbiomechanica en valgerelateerde risicofactoren (zoals valangst). Gegevens worden verzameld bij aanvang en na afloop van de interventie in een laboratoriumsetting, waarbij verschillen tussen groepen in verandering ten opzichte van de beginwaarde worden geanalyseerd middels analyse van covariantie (ANCOVA). Dit protocol vormt de basis voor het bepalen of PIM oefeningen de effectiviteit van bestaande valpreventiestrategieën voor oudere mensen kan verbeteren.

Hoofdstuk 6 presenteert de resultaten van de RCT uit Hoofdstuk 5. Drieëndertig deelnemers (15 mannen, 18 vrouwen) werden willekeurig toegewezen aan een interventiegroep die het PIM-trainingsprogramma ontving (n = 16; mediane leeftijd: 78,4 jaar (IQR: 73,3 – 83,6)) of een controlegroep (n = 17; mediane leeftijd: 76,6 jaar (IQR: 71,3 – 82,1)). De mediane therapietrouw aan het voorgeschreven aantal trainingssessies was 99% (IQR: 97% – 100%). Hoewel er geen significant verschil werd gevonden tussen de groepen in verandering van maximale loopsnelheid, liet de interventiegroep een grotere afname zien in de bezorgdheid om te vallen. Deze afname was het grootst voor activiteiten met lopen. Daarnaast liet de interventiegroep een toename in capaciteit en kracht zien van een aantal PIMs, wat de trainbaarheid van deze spieren in deze populatie bevestigt. Deze spierveranderingen waren echter niet te associëren met andere bevindingen. De resultaten ondersteunen verder onderzoek naar de voordelen van het integreren van PIM-versterkingsoefeningen in beweegprogramma's, inclusief valpreventieprogramma's, gericht op mobiliteit en valrisico. Verder onderzoek is nodig om het mechanisme achter de afname in bezorgdheid om te vallen te achterhalen.

Hoofdstuk 7 presenteert een kwalitatieve studie naar hoe oudere volwassenen de therapietrouw aan een 12-weeks PIM-trainingsprogramma ervaren en wat hun therapietrouw beïnvloedt. Inzicht in hun perspectieven kan bijdragen aan het verbeteren van de therapietrouw van deze doelgroep, die bij voetoefenprogramma's doorgaans laag tot matig is, wat de effectiviteit belemmert. Twaalf deelnemers (leeftijd 69–91 jaar), allen uit de interventiegroep van de RCT beschreven in Hoofdstuk 5 en 6, werden geïnterviewd om dieper inzicht te krijgen in factoren die hun therapietrouw bepaalden, gerelateerd aan mogelijkheden, kansen en motivatie. De mediane totaalscore op de zes items van de Exercise Adherence Rating Scale (EARS) was 23,5 van de 24 (IQR: 20–24), wat een uitstekende therapietrouw aan de onbegeleide thuistrainingen representeert. Met behulp

van reflexieve thematische analyse, vanuit een inductieve, ervaringsgerichte benadering, werden vier centrale thema's geïdentificeerd: "Op gang komen," "Volhouden," "In het ritme zijn," en "Gezondheidsvoordeel is het ultieme." Deze thema's kwamen bovenop de positieve beoordeling van interventieaspecten: duidelijke instructies van de trainer, ondersteunend materiaal en flexibiliteit in tijdstip en inhoud van het programma. De geïdentificeerde fasen weerspiegelen een tijdsverloop in perceptie en laten zien hoe beïnvloedende factoren dynamisch en fase-afhankelijk zijn. Opvallend genoeg werden gezondheidsvoordelen (zoals verbetering van het lopen, meer zelfvertrouwen bij het lopen, toegenomen stabiliteit) spontaan benoemd door een groot deel van de deelnemers. De bevindingen onderstrepen dat een gevoel van vooruitgang, in combinatie met goede ondersteuning en een persoonlijke aanpak, aanhoudende therapietrouw bevordert. Deze inzichten bieden praktische handvatten voor professionals die voetversterkende interventies ontwerpen en implementeren voor oudere volwassenen.

Het discussiehoofdstuk, **Hoofdstuk 8**, gaat dieper in op drie hoofdthema's: (i) de mate waarin de resultaten de trainbaarheid van de PIMs bij oudere volwassenen bevestigen, (ii) de mate waarin de resultaten de rol van de PIMs in het lopen en de balans bij oudere volwassenen bevestigen, en (iii) de bijdrage van PIM-training aan het verminderen van valrisico. Over het geheel genomen bevestigen de bevindingen dat de PIMs trainbaar zijn bij oudere volwassenen met een oefenprogramma dat geïsoleerde en functionele oefeningen combineert. Hoge therapietrouw – bevestigd door EARS-scores – en kwalitatieve evaluaties laten zien dat het programma aansluit bij voorkeuren en mogelijkheden van oudere volwassenen. Krachttoename en spierhypertrofie werden waargenomen voor de PIMs, waarbij spieren ofwel reageerden met neurale aanpassing ofwel met structurele veranderingen, wat de algemene trainbaarheid van deze spieren ondersteunt. Hoewel geen objectieve verbeteringen in het lopen en de balans werden gemeten in het bewegingsanalyse laboratorium, blijft de rol van de PIMs in het lopen en de balans aannemelijk gezien de afname in bezorgdheid om te vallen en de door deelnemers waargenomen verbeteringen in het lopen en de balans. Mogelijk hebben laboratoriummetingen veranderingen niet gedetecteerd vanwege de onnatuurlijke testsituatie, ongevoelige meetmethoden of de korte duur van de interventie. Kwalitatieve en subjectieve data toonden gezondheidsvoordelen en minder bezorgdheid om te vallen aan, vooral bij loopactiviteiten. Deze verbeteringen – die wijzen op meer zelfvertrouwen tijdens het lopen – kunnen voorafgaan aan daadwerkelijke functionele vooruitgang.

PIM-versterkende training kan bijdragen aan valpreventie door belangrijke risicofactoren te beïnvloeden. Opmerkelijk is dat de training bezorgdheid om te vallen – een sterke voorspeller van vallen – effectiever verminderde dan eerdere PIM- of algemene oefenprogramma's. Deze ervaren verbeteringen kunnen zich vertalen in een lager valrisico. Hoewel het effect op vallen niet werd gemeten, ondersteunen de bevindingen verder onderzoek naar integratie van PIM-oefeningen in bredere valpreventieprogramma's. Toekomstige studies wordt aangereden om valincidentie, vertrouwen in het lopen en

de balans, en de functie van de onderste extremiteiten te meten met gevalideerde instrumenten. De klinische implicaties van dit project is dat PIM-versterkende training veelbelovend is voor het aanpakken van valrisicofactoren, maar niet ter vervanging kan dienen voor bestaande 'evidence-based' valpreventieprogramma's. In plaats daarvan kunnen PIM-oefeningen worden geïntegreerd in huidige programma's om hun effectiviteit te vergroten voor oudere volwassenen met een laag of gemiddeld valrisico. Voor oudere volwassenen met een hoog valrisico én valangst kan PIM-training een waardevolle aanvullende interventie zijn. Toekomstige implementatie dient aan te sluiten bij nationale richtlijnen en uitgevoerd te worden in nauwe samenwerking met relevante partijen. De generaliseerbaarheid van dit project is beperkt tot fysiek actieve oudere volwassenen die deelnemen aan oefenprogramma's en die waarschijnlijk een hoge motivatie en zelfeffectiviteit hebben. Toch zouden minder actieve of kwetsbare oudere mensen – met name zij in zorginstellingen – mogelijk juist méér baat hebben bij PIM-training vanwege grotere problemen met het lopen en de balans. Toekomstige studies zouden zich kunnen richten op oudere volwassenen met een matig of hoog valrisico, vastgesteld via een loopsnelheidstest.

Concluderend hebben we aangetoond dat het trainen van de PIMs leidt tot het krijgen van meer vertrouwen in het lopen en de balans en tot minder zorgen om te vallen bij oudere volwassenen met een mogelijk verhoogd valrisico. Hoewel onze bevindingen de trainbaarheid van de PIMs bij oudere volwassenen ondersteunen, verklaart dit niet de ervaren functionele verbeteringen, en moet het onderliggende mechanisme dus nog worden ontrafeld. Bovendien bevestigen de bevindingen niet dat de PIMs bijdragen aan objectief vastgestelde loop- en balansprestaties, wat in toekomstig onderzoek moet worden onderzocht door het lopen in het dagelijks leven te evalueren in plaats van in een laboratorium.

Appendices

USE OF AI

In the preparation of this dissertation, ChatGPT (OpenAI) was used as a writing assistant in Chapters 1, 6, 7, and 8. It supported the author in generating alternative phrasings, checking grammar and typographical errors, and processing reviewer feedback. In writing the general summary, generative AI was used more intensively to suggest larger pieces of text. All AI-generated suggestions were critically reviewed, adapted, and integrated by the author; no content was adopted without verification.

PHD PORTFOLIO

First Author Peer-Reviewed Publications

Willemse L, Wouters EJM, Pisters MF, Vanwanseele B. Effects of a 12-week intrinsic foot muscle strengthening training (STIFF) on gait in older adults: a parallel randomized controlled trial protocol. BMC Sports Sci Med Rehabil. 2024;16(158). DOI: 10.1186/s13102-024-00944-z

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Courses

Webinar Data publishing amd TiU Dataverse, Tilburg School of Social and Behavioral Sciences, Tilburg University, June 4 2024.

Webinar Publishing in Open Access, Tilburg School of Social and Behavioral Sciences, Tilburg University, May 13 2023.

Webinar Writing the PhD Dissertation, KU Leuven, June 8 2023.

Qualitative research techniques II, Tilburg School of Social and Behavioral Sciences, Tilburg University, 2022.

Academic Writing in English, Tilburg School of Social and Behavioral Sciences, Tilburg University, 2021.

MATLAB for Data Processing and Visualization, self-paced online training, Matlab Academy, MathWorks, 2021.

MATLAB Fundamentals, self-paced online training, Matlab Academy, MathWorks, 2020.

Course Scientific Integrity, KU Leuven, November 16 2020.

NFU eBROK with certificate. February 11 2020.

Educational Contributions

Client and supervisor for 54 students at Fontys Allied Health Professions during their graduation research project between 2018 and 2025.

Client for 6 student groups at Fontys Allied Health Professions during their minor project between 2019 and 2022.

Knowledge clips Fontys Allied Health Professions

- The human foot 1 – Intro
- The human foot 2 – Cardinal body planes
- The human foot 3 – Joint axes of the ankle complex
- The human foot 4 – Subtalar motion in weight-bearing
- The human foot 5 – Subtalar motion throughout the stance phase of gait
- The human foot 6 – Tarso-metatarsal joints
- The human foot 7 – MTP joints
- Ageing 1 – Muscular adaptations
- Ageing 2 – Neural adaptations

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Onderwijsactiviteiten opleiding oefen- en beweegdeskundige, Kennisinstituut Podotherapeutische Zorg, Eindhoven, 2022.

- Onderwijsactiviteit 1.5: functionele biomechanica en beoordeling van de voeten
- Onderwijsactiviteit 1.7: voetoefeningen
- Onderwijsactiviteit 6.4: beweegtherapie bij ouderen

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Blended refereeravond ‘Small is beautiful’, ofwel de kracht van de kleine voetspier. Event for professionals, Fontys Paramedisch, Eindhoven, 25 januari 2022.

ABOUT THE AUTHOR

Lydia Willemse holds a bachelor’s and a master’s degree in Human Movement Sciences from the University of Groningen. In 2009 she completed her two-year master’s specialization in Rehabilitation and Functional Recovery with graduation research at the University Medical Center Groningen. Supervised by Prof. J. Zwerver, she conducted a study on the diagnostic validity of instruments used in the assessment of jumper’s knee.

Following her master, Lydia volunteered at VU University Medical Center, where she did retrospective research on the reliability of lower extremity strength measurements in children with cerebral palsy. She was subsequently employed on a research project under supervision of Prof. J. Harlaar aimed at estimating muscle force during atypical gait using forward dynamic simulation techniques. From there, she developed her skills in performing gait analysis.

Since 2012, Lydia has worked at Fontys Allied Health Professions, primarily as a lecturer in research methodology and as a supervisor of student graduation research. She has been part of the team “Enabling People with Technology in the Context of Health” within the department of Health Innovations and Technology where her interest in the biomechanics of human movement continued and grew towards the function of foot and ankle muscles in the aging population in addition to the role of technology in supporting health.

In 2019, Lydia was awarded a “doctoral grant for teachers” by the Dutch Research Council (NWO). This grant enabled her to conduct doctoral research alongside her teaching activities, resulting in this dissertation. The project was supervised by Prof. E.J.M. Wouters, Prof. B.M.P. Vanwanseele, and Dr. M.F. Pisters, and led to a joint doctorate at Tilburg University and KU Leuven. Lydia was affiliated with the Human Movement Biomechanics Research Group of the Department of Movement Sciences at KU Leuven and the Academic Working Place ‘Technological and Social Innovation for Mental Health’ of Tranzo at Tilburg University. Her research was embedded within Fontys’ learning community “musculoskeletal projects”, where over 70 students contributed to the project either under her direct supervision or on her initiative. During her doctoral program, Lydia also contributed as a peer reviewer for journals including the Journal of the American Podiatric Medical Association, Journal of Foot and Ankle Research, Sports Biomechanics and Physical Therapy in Sport.

Currently, Lydia still works as a lecturer and researcher within Fontys Allied Health Professions, participating in various research projects. In the near future, she aims to further disseminate the findings of the doctorate project to strengthen fall prevention strategies and related education.

Dankwoord

DANKWOORD

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