Can insoles be used to improve postural stability and gait of community-dwelling older adults? A systematic review on recent advances and future perspectives

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Authors' contributions

CZHM carried out literature searches, quality assessments, data extraction and statistical analysis, and drafted the manuscript. WKL also carried out quality assessments and reviewed the manuscript. BCC reviewed the manuscript and provided academic support throughout. WCCL was responsible for supervision, including interpretation of data and critical revision of the manuscript. All authors read and approved the final manuscript.

Abstract

This systematic review investigated the effects of orthopaedic, vibrating, and textured insoles on postural balance of community-dwelling older adults. Articles published in English from 1999 to 2019 investigating the effects of 1) orthopaedic, 2) vibrating and 3) textured insoles on static and dynamic balance in community-dwelling older adults were considered. Twenty-five trials with totally 634 older adults were identified. Gathered information generally supported the balance improving effects of orthopaedic, vibrating, and textured insoles in both static and dynamic conditions among community-dwelling older adults. Further examination found that rigidity, texture patterns, vibration thresholds, and components like arch supports and heel cups are important factors determining whether insoles can improve balance. This review highlights the potential of insoles in improving static and dynamic balance of community-dwelling older adults. Good knowledge in insole designs and understanding of medical conditions of older adults is required, when attempt is made to improve postural balance using insoles.

Keywords: Falls; gait; postural balance; plantar sensation; elderly.

Introduction

Falls and associated injuries have been major public health problems globally. Approximately 30%-50% of community-dwelling older adults aged 65 and over experienced falls (Kannus et al., 2005; Kwan et al., 2011; Tinetti, 2003). In addition to reduced muscle strength and coordination of movements (Toraman & Yıldırım, 2010), age-related declines in vision (Dhital et al., 2010), proprioception (Corriveau et al., 2004) and vestibular functions (Marchetti et al., 2011) have been found to be linked to increased chance of falls. Restorations of sensory functions are usually difficult (Lacour, 2006; Riemann & Lephart, 2002). However, it has been suggested that the brain is able to interpret and integrate the signals from different senses, and enhancement of one single sensory input could compensate the deficits of other sensory functions (Sienko et al., 2012; Tyler et al., 2003). While plantar sensation is an important component of proprioceptive sensation for maintaining balance control (Meyer et al., 2004; Speers et al., 2002), some recent studies have investigated if insoles could improve postural balance by enlarging the sensory input at plantar surface of the foot.

Changing the mechanical properties and shapes of insoles alters the force distribution between foot and ground, which may potentially improve balance. **Orthopaedic insoles** with arch supports, metatarsal pads, and heel cups are conventionally prescribed to correct/compensate foot deformity (Takata et al., 2013) and relieve pain (Gross et al., 2002; Whittaker et al., 2019). They change the contact area between the foot and support surfaces (T.-h. Chen et al., 2014; Gross et al., 2012; C. Z.-H. Ma, Wong, et al., 2018) and re-distribute plantar loadings (Hennig & Sterzing, 2009). Studies have also suggested that that such design could provide supplemented information about the relative position of foot to ground for users during walking (Perry et al., 2008). **Vibrating insoles** produce vibration stimulation to the plantar foot. While some vibrating insoles are designed to massage the feet, some studies have found that some vibration (the so-called 'noise'), which is usually below the sensory threshold, could enhance the mechanical stimulation that produced during standing and walking at plantar foot through stochastic resonance (SR) (A. Priplata et al., 2003; A. A. Priplata et al., 2006). These different types of insoles magnify the mechanical input signals at plantar foot via giving different contours and vibration. **Textured insoles** are another type of insoles, which have some tiny flexible/semi-rigid plastic/rub cylinders or tubes (Anna L Hatton et al., 2019; Kenny et al., 2019). Some textured insoles may also use harder insole materials (Qu, 2015). They originally aimed to provide massage and acupressure to the foot. As both orthopaedic and textured insoles change the sensory input at plantar surface of the foot, some studies have looked into their effects on postural balance recently. It has been suggested that the hardness of insoles and insole textures may influence the mechanical stimulations at plantar foot and affects postural stability, and adding various textures to insoles has been demonstrated to increase sensory afferent feedback via enhanced tactile stimulation of plantar cutaneous mechanoreceptors (Anna Lucy Hatton et al., 2011). Varying the design of each type of insoles could have different effects on static and dynamic balance of older people.

A couple of reviews have been conducted to evaluate the effects of footwear on balance. Hijmans *et al*. (2007) comprehensively reviewed the effects of vibrating insoles and textured insoles, that were studied prior to 2004, on static and dynamic balance (Hijmans, Geertzen, Dijkstra, et al., 2007). However, most studies investigating balance improving effects of insoles were conducted after 2004. There were more updated reviews, however, they placed emphasis on static balance (Christovão et al., 2013; Kenny et al., 2019) and shoe designs (Aboutorabi et al., 2015; Davis et al., 2019; Wylie et al., 2019). Effects of insoles on balance of adults with sensory perception loss have been reviewed more recently (Bagherzadeh Cham et al., 2016). However, many community-dwelling elderly fallers do not have diabetic sensory neuropathy (Dhital et al., 2010), and insoles could still have positive effects on balance of people without any sensory perception loss. In addition, while orthopaedic, textured and vibrating insoles have different mechanisms in changing the sensory input at the plantar foot, most of these previous reviews (Aboutorabi et al., 2015; Christovão et al., 2013; Hijmans, Geertzen, Dijkstra, et al., 2007; Paton et al., 2016) did not separately evaluate the effects of each type of insoles on balance. An updated review evaluating the effects of each of the three types of insoles on both static and dynamic balance of community-dwelling older people is needed.

The potential effects of insoles on postural balance are usually overlooked, as they are originally designed for other purposes, such as treating foot deformity and relieving pain (Gross et al., 2002; Takata et al., 2013). The most common foot deformities among the older population that can be treated with orthopaedic insoles have been flat foot and hallux valgus (Luo et al., 2017). Due to aged degeneration, many community-dwelling older people without any known diseases causing balance problems are prone to falls (Rubenstein & Josephson, 2002). A quality review paper looking into the balance improving effects of insoles among community-dwelling older people can attract attention to the clinical application and future investigations, which potentially give them significant health benefits. This paper reviews the effects of orthopaedic, textured and vibrating insoles separately on static and dynamic balance of community-dwelling older people, and identifies the key design features of insoles that are related to postural balance improvement. It gives consolidated analysis of existing evidence in an attempt to support decision-making regarding the use of insoles in improving balance of community-dwelling older people, as well as to inspire future research.

Methods

Inclusion criteria

Types of participants and interventions

This review included studies that recruited community-dwelling older people aged 65 and over (Crocker et al., 2019). Subjects who had neuropathy, pathologically reduced tactile sensation over the feet, or any known diseases leading to balance problems were not included. When a paper involved subject samples with other characteristics, only the findings from participants fulfilling the inclusion criteria were reviewed and reported. It reviewed studies that have evaluated the balance effect of orthopaedic insoles, vibrating insoles, and textured and harder insoles.

Types of insoles

This review categorized insoles into three types: 1) orthopaedic insoles (custom-made/fitted insoles with heel cups, metatarsal pads, and/or medial arch support); 2) vibrating insoles (insoles embedded with vibrators); and 3) textured insoles (insoles with textured patterns or insoles fabricated by materials with various hardness).

Types of intervention outcomes and studies

This review considered studies that included instrumented and non-instrumented outcome measures related to static and dynamic balance (C. Z.-H. Ma et al., 2016). Instrumented tests involved using force plates, motion capture systems, and in-shoe plantar pressure measuring systems to measure the movements of center of pressure (COP) and center of mass (COM) during standing/walking, and gait variabilities (C. Z.-H. Ma et al., 2016). Non-instrumented tests involved clinical functional tests, balance assessment scales and questionnaires assessing postural balance (C. Z.-H. Ma et al., 2016).

This review considered randomized controlled trials (RCT), non-RCTs, before and after studies, prospective and retrospective cohort studies, and case-control studies.

Search strategy and selected publications

This review was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, as outlined at http://www.prisma-statement.org/PRISMAStatement/Checklist.aspx. This review employed a three-step search strategy aiming to find published relevant studies. An initial search of MEDLINE was undertaken, followed by analysis of the keywords contained in the title, abstract, and indexed terms using to describe articles (Step 1). A second search was then undertaken across all included databases using all identified keywords (Step 2). Thirdly, the reference lists of all identified articles were searched for additional relevant studies (Step 3).

Studies published in English from 2000 to 2020 were considered for inclusion in this review. Databases been searched included: Web of Science, MEDLINE, and Google Scholar. Keywords been used for the search were: insole, foot orthosis/orthoses, foot insert, balance, static balance, dynamic balance, postural stability, and postural control. A completed PRISMA flow diagram showing the searching strategy and results is attached as Figure 1. As shown in Figure 1, the three-step literature search yielded 129 publications after removing the duplicated publications. Of these, twenty-five publications met the inclusion criteria and were included in this review (Figure 1). The latest literature search was conducted in March 2020 to ensure that the latest publication matching the inclusion criteria was involved in this review.

Assessment of methodological quality

The level of evidence and grade of recommendation of each included study were accessed by two independent reviewers, using the scoring protocol of the Oxford Centre for Evidence-based Medicine (Supplemental file 1 & 2) (Interval, 2009). The reporting quality, methodological design, external and internal validity, and power of all included studies were assessed using the Downs and Black quality list (Supplemental file 3) (Downs & Black, 1998). Any disagreements of assessing results that arose between two reviewers were resolved through discussion with a third reviewer.

Results

Methodological quality

As shown in Table 1, three publications were considered to be with level 1B of evidence (de Morais Barbosa et al., 2018; de Morais Barbosa et al., 2013; Perry et al., 2008), and with recommendation of grade A (strong recommendation that is expected to be followed, unless there are compelling reasons to deviate from the recommendation in an individual). The remaining twenty-two publications were considered to be with level 3B of evidence, and with recommendation of grade B (weak recommendation that consideration should be given to follow the recommendation). These twenty-five studies had some methodological weaknesses, including lack of randomization and double-blindness. Only three of them incorporated blindness of subjects and/or assessors (de Morais Barbosa et al., 2018; Qiu et al., 2013; Stephen et al., 2012). As shown in Table 2, most included studies revealed high levels of reporting quality, but with relatively low internal and external validity, and power.

Sample characteristics

Table 3 illustrates the characteristics of the elderly subjects recruited in the included studies. The sample size ranged from 12 (Lipsitz et al., 2015; Simeonov et al., 2011) to 91 (de Morais Barbosa et al., 2018), and the age of participants ranged from 51 to 85. All studies suggested that they recruited community-dwelling older people as subjects, who did not have any known diseases that might cause balance problems. In addition, sixteen studies specifically clarified that their recruited subjects did not have neurological disorders (Antonio & Perry, 2014; de Morais Barbosa et al., 2018; Galica et al., 2009; Gross et al., 2012; Anna L Hatton et al., 2012; Iglesias et al., 2012; Li et al., 2019; Lipsitz et al., 2015; C. Z.-H. Ma, Wong, et al., 2018; Palluel et al., 2008; Palluel et al., 2009; Perry et al., 2008; A. Priplata et al., 2003; A. A. Priplata et al., 2006; Samimi et al., 2014; Stephen et al., 2012), two studies recruited subjects with no reduced tactile sensitivity only (de Morais Barbosa et al., 2018; de Morais Barbosa et al., 2013), and the rest of the studies suggested their subjects did not have a medical condition that may affect postural balance. Most studies required the subjects to be able to walk 10 meters without assisting devices and follow the study instructions. The self-reported history of falls was specified in nine publications: three claimed that the subjects shall have no history of falls (Palluel et al., 2008; Palluel et al., 2009; A. A. Priplata et al., 2006), two claimed subjects shall experience at least one fall (Gross et al., 2012; Wang & Yang, 2012), three claimed subjects shall experience at least two falls (Galica et al., 2009; Anna L Hatton et al., 2012; Wei et al., 2012), and another one study have documented the number of falls ranging from 0 to 5 (de Morais Barbosa et al., 2018) before the experiment (Table 3). The majority (64.4%) of the participant were women for studies that have reported the gender distribution. However, most studies did not report the distribution of race of the participants. Only two studies reported that approximately 64.5% of participants were Caucasian, 22.6% were African American, and 12.9% were Mullato (de Morais Barbosa et al., 2018); and also 81% of participants were Caucasian and the rest of them were African American as specified in (de Morais Barbosa et al., 2013).

Balance outcome measurements

Various balance outcome measures were adopted in the selected twenty-five studies (Table 4): fourteen assessed static balance only (Bae et al., 2016; T.-h. Chen et al., 2014; Iglesias et al., 2012; C. Z.-H. Ma, Wong, et al., 2018; Palluel et al., 2008; Palluel et al., 2009; A. Priplata et al., 2003; A. A. Priplata et al., 2006; Qiu et al., 2012; Qiu et al., 2013; Samimi et al., 2014; Simeonov et al., 2011; Wang & Yang, 2012; Wei et al., 2012), five assessed dynamic balance only (Antonio & Perry, 2014; Galica et al., 2009; Perry et al., 2008; Qu, 2015; Stephen et al., 2012), and the remaining six assessed both static and dynamic balance (de Morais Barbosa et al., 2018; de Morais Barbosa et al., 2013; Gross et al., 2012; Anna L Hatton et al., 2012; Li et al., 2019; Lipsitz et al., 2015). Most studies evaluated the immediate effect of insoles by comparing balance performance pre- and post- intervention. Only six of them evaluated the long-term effect, with intervention duration ranged from 1 day to 12 weeks (T.-h. Chen et al., 2014; de Morais Barbosa et al., 2018; de Morais Barbosa et al., 2013; Gross et al., 2012; Lipsitz et al., 2015; Perry et al., 2008).

Both instrumented and non-instrumented tests were used to quantify the balance performance. Of the studies incorporating instrumented tests, fifteen assessed static postural stability during standing using force plates (Antonio & Perry, 2014; Bae et al., 2016; T.-h. Chen et al., 2014; Anna L Hatton et al., 2012; Iglesias et al., 2012; Lipsitz et al., 2015; C. Z.-H. Ma, Wong, et al., 2018; Palluel et al., 2008; Palluel et al., 2009; Qiu et al., 2012; Qiu et al., 2013; Qu, 2015; Samimi et al., 2014; Wang & Yang, 2012; Wei et al., 2012), and another three used motion capture systems (A. Priplata et al., 2003; A. A. Priplata et al., 2006; Simeonov et al., 2011); three assessed dynamic balance during walking using in-shoe plantar pressure measurement insoles (Galica et al., 2009; Li et al., 2019; Stephen et al., 2012), and another six used motion capture systems (Antonio & Perry, 2014; Anna L Hatton et al., 2012; Lipsitz et al., 2015; Perry et al., 2008; Qu, 2015; Stephen et al., 2012). Of the studies incorporating non-instrumented tests, the clinical functional tests, including Berg Balance Scales (BBS), Time Up and Go test (TUG), 1-leg stance, tandem stance, tandem gait, and alternating step test, were used (de Morais Barbosa et al., 2018; de Morais Barbosa et al., 2013; Gross et al., 2012; Lipsitz et al., 2015). Generally, non-instrumented tests were used as a secondary assessment of balance, except three studies that adopted functional tests only (de Morais Barbosa et al., 2018; de Morais Barbosa et al., 2013; Gross et al., 2012).

Effectiveness of insoles of various design features on static and dynamic balance

The insoles were categorized as orthopaedic insoles, vibrating insoles, and textured and harder insoles. An overview of the effectiveness of insoles, within each category, on static and dynamic balance is summarized in Figure 2. The detailed design features together with their reported effects on postural balance are summarized in Table 3 and Table 4.

Orthopaedic insoles

Six reviewed studies evaluated the effect of orthopaedic insoles on **static balance**. One study found that insoles with a medial arch support only did not enhance postural stability in healthy older adults (Samimi et al., 2014). Another study found that insoles with medial arch supports only and insoles with heel cups only did not enhance static balance in healthy older adults (Bae et al., 2016). The remaining four studies found that the orthopaedic insole with 1) a medial arch support, a metatarsal pad and a heel cup (C. Z.-H. Ma, Wong, et al., 2018), 2) a medial arch support and a heel cup (T.-h. Chen et al., 2014), 3) a medial arch support and a metatarsal pad (de Morais Barbosa et al., 2013), as well as 4) a custom-fabricated medial arch support, metatarsal pad and heel cup (Gross et al., 2012) significantly improved static balance in healthy older adults.

Three reviewed studies evaluated the effect of orthopaedic insoles on **dynamic balance**. These studies used the orthopaedic insole 1) with a medial arch support and a heel cup (height: 15mm) (Qu, 2015), 2) with both a medial arch support and a metatarsal pad (de Morais Barbosa et al., 2013), and 3) made from total casting technique with components of a medial arch support, a metatarsal pad and a heel cup (used in 1 study) (Gross et al., 2012). Healthy older adults (de Morais Barbosa et al., 2013; Qu, 2015) and recurrent elderly fallers (Gross et al., 2012) were recruited, and all these three studies revealed significantly improved dynamic balance while wearing these orthopaedic insoles in participants.

Vibrating insoles

A total of six reviewed studies investigated the effect of vibrating insoles on **static balance**. Except for one study which found vibrating insoles providing supra-threshold (120% of subjects' plantar sensory threshold values) vibration not to be able to reduce postural sway in older adults (Simeonov et al., 2011), all the other five studies reported that vibrating insoles providing sub-threshold vibrations (up to 90% of subjects' plantar sensory threshold values) significantly improved static balance in healthy older adults (Lipsitz et al., 2015; A. Priplata et al., 2003; A. A. Priplata et al., 2006), and elderly fallers (Wang & Yang, 2012; Wei et al., 2012). In all these five studies, four studies put three vibrators at the first and fifth metatarsal heads, and heel of each foot (A. Priplata et al., 2003; A. A. Priplata et al., 2006; Wang & Yang, 2012; Wei et al., 2012); and the remaining one study put two vibrators at the lateral longitudinal arch region (Lipsitz et al., 2015). Most studies provided non-stop vibrations to subjects consistently throughout the experiment (A. Priplata et al., 2003; A. A. Priplata et al., 2006; Simeonov et al., 2011; Wang & Yang, 2012); except for one study which asked subjects to wear vibrating insoles for a while, before evaluating the balance without the vibrating insoles (Wang & Yang, 2012).

Totally three studies evaluated the effect of vibrating insoles on **dynamic balance**. The vibrators were put at the first and fifth metatarsal heads, medial arch, and heel. Different modes of vibrations were given. Stephen *et al*. (2012) provided sub-threshold vibrations (70%, 85%, or 90% of plantar sensory threshold values) to subjects throughout the entire walking trials. Wei *et al*. (2012) and Galica *et al*. (2009) provided vibrations only during the stance phase of gait, as detected by a touch-type switch or force sensors at the plantar foot. The batteries in vibrating insoles could last for about 8 hours (Lipsitz et al., 2015). Healthy older adults (Galica et al., 2009; Lipsitz et al., 2015; Stephen et al., 2012) and healthy older people with a history of recurrent fall (Galica et al., 2009) were recruited, and both subject groups revealed significant reductions of gait variability and improvement of dynamic balance while wearing the vibrating insoles. The dynamic balance improvement in recurrent fallers (6.3%) was higher than non-fallers (5.8%) (Galica et al., 2009). In one study, attempt was made to reduce the sub-threshold vibration from 90% to 70% and 85% of the individual plantar sensory threshold, and has found that the positive effects in dynamic balance retained(Lipsitz et al., 2015).

Textured insoles

A total of seven reviewed publications studied the effect of textured insoles on **static**

balance. One study found no improvement in postural stability in older people, who had prior history of falls, after wearing insoles that were attached with equally distributed (2.5mm center-to-center distance) small pyramidal peaks made of medium density Ethylene Vinyl Acetate (EVA) (Anna L Hatton et al., 2012). The remaining six studies concluded that textured insoles improved the static balance of healthy older adults who reported no history of falls. Textured insoles with medium and rigid hardness (Shore value A50 or 270-320 density (kg/m^3) EVA) reduced postural sway significantly (Iglesias et al., 2012; Qiu et al., 2012; Qiu et al., 2013). One study revealed that the more rigid the insoles were, the more postural sway were reduced in subjects (Iglesias et al., 2012). Some studies also found positive outcomes of balance improvement upon using insoles with different upper surface textures, including equally distributed granulations (height: 3.1 mm; diameter: 5mm) made of 270 density (kg/m^3) EVA, compliant ridges (height: 3.1 mm; width: 3.1mm) located at lateral perimeter around the heel (Qiu et al., 2013), and spikes (density: 4 spikes/cm^2; height: 5mm; diameter: 3mm) made of semi-rigid polyvinyl chloride (PVC) (Palluel et al., 2008; Palluel et al., 2009). Healthy older adults (Iglesias et al., 2012; Palluel et al., 2008; Palluel et al., 2009; Qiu et al., 2012; Qiu et al., 2013) were recruited, and they exhibited significant reductions of postural sway while wearing these textured insoles.

Totally four reviewed studies investigated the effect of textured insoles on **dynamic balance**. One study found that elderly fallers wearing insoles attached with equally distributed (2.5 mm center-to-center distance) small pyramidal peaks made of medium density EVA did not reveal better balance than those wearing smooth insoles (Anna L Hatton et al., 2012). The remaining three studies found that insoles with a raised ridge (height:2.5mm) around the perimeter (Perry et al., 2008) and with semi-rigid materials (Antonio & Perry, 2014; Qu, 2015) enhanced dynamic balance of healthy older adults who reported no history of falls, with significantly improved postural stability during walking and reduced gait variability. More rigid insoles were also associated with better dynamic balance (Qu, 2015).

There were two studies investigated the effect of textured insoles on **static and dynamic balance** (de Morais Barbosa et al., 2018; Li et al., 2019). These studies found that textured insoles with medium hardness (Shore A 35) and those with small equally distributed (2 mm center-to-center distance) pyramidal peaks made of medium density EVA (Shore A 40) (de Morais Barbosa et al., 2018) and with raised nodules (density: 1.12 g/cm^3; height: 5mm; diameter: 15mm) (Li et al., 2019) on upper insole surface enhanced both static and dynamic balance of community-dwelling older people (Li et al., 2019) and those with number of falls ranged from 0 to 5 (de Morais Barbosa et al., 2018).

Discussion

Insoles are commonly used to treat foot disorders. This review extensively examines the effect of insoles on static and dynamic balance of the community-dwelling older adults, which has received much less attention. Twenty-five clinical studies evaluating the effectiveness of various types of insoles with a total of 634 participants were reviewed. It can be seen that providing additional/enhanced mechanical stimulation at plantar surface of the foot, through the use of insoles with appropriate physical designs, has great potential of improving postural balance in older adults.

Quality of reviewed papers

The methodological quality of some involved studies was not very high, only three of the twenty-five reviewed studies provided level 1b evidence. Common existing methodological weaknesses included lack of randomization and double-blindness, and relatively lower level of internal and external validity and power. It should be noted that the relatively small sample size of some reviewed papers (<20) lowered the statistical power and may limit the generalizability of the findings to a wider population. The experimental protocols and balance outcome measurements assessing the effectiveness of insoles varied among the studies. This restricted the ability to perform cross-study comparisons, leading to difficulty for this review in identifying an optimal insole design for balance improvement. Parametric studies investigating effects of different design features of insoles are scarce in previous studies. In addition, all included studies did not take any measurements to monitor the compliance of insole-usage, which should be one important factor determining the long-term intervention outcome. Most studies only investigated the immediate effect, leading to insufficient evidence about the long-term effect of insoles on balance.

Relevant design features of insoles that contribute to improvement in postural balance

Except for four studies (Bae et al., 2016; Anna L Hatton et al., 2012; Samimi et al., 2014; Simeonov et al., 2011) showing no positive outcomes in postural balance, information gathered from the remaining twenty-one studies supported the effectiveness of orthopaedic insoles, vibrating insoles, and textured insoles in enhancing static and dynamic balance of healthy older adults and elderly fallers.

Among the twenty-five studies, three studies with high level of evidence and recommendation strongly supported the effectiveness of 1) orthopaedic insoles with medial arch supports and metatarsal pads in enhancing static and dynamic balance in older adults (de Morais Barbosa et al., 2013), 2) textured insoles with raised ridges around the perimeter in enhancing dynamic balance (Perry et al., 2008), and 3) textured insoles made of medium hardness materials and with pyramidal peaks on upper insole surface in enhancing both static and dynamic balance (de Morais Barbosa et al., 2018). The intensity of mechanical stimulations provided by insoles appears to be important in influencing balance in older adults. While providing appropriate mechanical stimulation could improve postural balance, too much mechanical stimulation may cause adverse effects by inducing pain or discomfort in users.

Orthopaedic insoles

Previous studies reported that the **orthopaedic insole** with 1) a medial arch support, a metatarsal pad and a heel cup (C. Z.-H. Ma, Wong, et al., 2018), 2) a medial arch support and a heel cup (T.-h. Chen et al., 2014; Qu, 2015), 3) a medial arch support and a metatarsal pad (de Morais Barbosa et al., 2013), and 4) a medial arch support, a metatarsal pad and a heel cup (Gross et al., 2012) all enhanced static and dynamic balance in older adults. The major reasons could be that such design could increase the contact area between foot and ground, providing supplemented information about the relative position of foot to ground for users during walking (Perry et al., 2008). These strategies would be helpful for improving the balance of older adults. However, two studies reported that the orthopaedic insole with a medial arch support only and with a heel cup only did not enhance static balance (Bae et al., 2016; Samimi et al., 2014). This may imply that orthopaedic insole with a single component only might not be sufficient enough to enlarge contact area and enhance plantar sensory input, which are important to improving postural balance. Totally three studies investigated and reported the positive long-term balance improving effects of orthopaedic insoles in older adults (T.-h. Chen et al., 2014; de Morais Barbosa et al., 2013; Gross et al., 2012). It is still necessary to continue the studies of this research segment in order to find out the most appropriate design of orthopaedic insoles.

Vibrating insoles

All studies of **vibrating insoles** providing sub-threshold vibrations reported positive results of improved postural balance, however, they provided level 2b evidence only. The intensity of vibrations is rather important in affecting balance performance. This review identifies that while sub-threshold vibration consistently enhanced balance, one study which used supra-threshold vibration did not produce any positive outcome in balance (Simeonov et al., 2011). The possible reason could be that sub-threshold vibration could enhance plantar sensory input through SR without notice of users, while continuously providing supra-threshold vibrations may negatively affect balance by interfering with individual's detection of mechanical input signals produced from the stepping on the floor. Continuous supra-threshold vibration may also cause discomfort or increase subject's consciousness by interfering the automaticity of balance control (Wulf et al., 2001). Attention needs to be paid to the fact that none of the studies about vibrating insoles involved a subject control group or investigated the long-term effect.

Textured insoles

It has been generally reported that **textured insoles** can enhance the balance of older adults (Antonio & Perry, 2014; de Morais Barbosa et al., 2018; Iglesias et al., 2012; Li et al., 2019; Palluel et al., 2008; Palluel et al., 2009; Perry et al., 2008; Qiu et al., 2012; Qiu et al., 2013; Qu, 2015). One possible reason could be that the hardness of insoles and insole textures influences mechanical stimulations at plantar foot and affects postural stability. Adding various texture patterns to insoles was demonstrated to increase sensory afferent feedback via enhanced tactile stimulation of plantar cutaneous mechanoreceptors (Anna Lucy Hatton et al., 2011). However, the sparsely distributed textured patterns may not be able to provide sufficient sensory augmentation for balance improvement, as one reviewed study found that the small pyramidal peaks distributed 2.5mm center-to-center distance did not enhance neither static nor dynamic balance of the elderly fallers (Anna L Hatton et al., 2012). Wearing more rigid insoles, without causing discomfort, also contributed to greater postural stability in older adults (Iglesias et al., 2012). Possible underlying mechanism could be that more rigid insoles tend to provide more mechanical stimulations and place the foot in a more neutral position, while softer insoles tend to accommodate the foot posture (Iglesias et al., 2012). Special attention should be paid that excessive rigid insoles induced discomfort (Perry et al., 2008), which may impair balance, as better comfort perception might allow for better postural and balance control in individuals (Nigg, 2010). While textured insoles could improve balance of elderly non-fallers, they may not be helpful for elderly fallers as Hatton et al (2012) found no balance improvement of textured insoles in elderly recurrent fallers. While insoles with medium hardness and appropriate texture patterns generally improve the balance in older adults, an optimal design providing best balance outcomes still remains unclear. Totally two studies investigated the long-term effect of textured insoles and supported the long-term effect of textured insoles in older adults (de Morais Barbosa et al., 2018; Perry et al., 2008).

Decision-making when attempting to use insoles to improve balance of healthy community-dwelling older adults

While further studies are warranted to increase the level of evidence and to identify an optimal insole design, the evidence we have so far supports the efforts to use insoles to improve balance of healthy older people who had no known diseases affecting their postural balance. However, good knowledge in insole designs is important, as different design features could have different effects on postural balance as detailed above. It should also be understood that special care has to be taken in some medical conditions.

Good knowledge in insole designs and understanding of medical conditions of older adults is required when the attempt is made to improve postural balance using insoles. Several factors affected the effect of insoles on improving balance, including rigidity, texture patterns, vibration thresholds, and types of added components like arch supports and heel cups. The essential factors determining the improved balance by insoles are different among different insoles designs. For the orthopaedic insoles, a design with at least two components of medial arch support, a metatarsal pad and a heel cup is important, preferably with all three components. When choosing vibrating insoles, sub-threshold vibrations are suggested to be provided. When it comes to the textured insoles, materials with medium and rigid hardness and texture patterns made of semi-rigid materials shall be considered. The fitting of insoles shall also be customized, taking into consideration of the shoe designs of the potential users.

Some potential side effects of using insoles have to be noted. It needs to be aware that some textured insoles (Perry et al., 2008) and vibrating insoles (de Morais Barbosa et al., 2013) may cause pain and discomfort after long-term use. Rigid textures could induce excessive local pressure to the feet, which might damage the skin and soft tissue. If they are used in patients with neuropathy which significantly reduces the tactile sensation of the feet, patients may not be able to notice the excessive pressure. After prolonged usage, this potentially leads to development of pressure sores (Wu et al., 2007). These people should seek professional medical advice in choosing appropriate footwear. Many older people have foot deformities, and the abnormal bony prominence could also lead to abnormally high pressure (Menz & Morris, 2006; Wu et al., 2007), which requires special care. Orthopaedic insoles could be a good option for older people with foot deformities and pain, and expertise in orthotics is required in dealing with such cases. In addition to the potential effects of balance improvement, the arch supports of orthopaedic insoles could relieve pain associated with plantar fasciitis by supporting the longitudinal arch and relieving soft tissue stretch (Conceição et al., 2014). Metatarsal pads of orthopaedic insoles can also relieve pain over the metatarsal heads by redistributing loadings to the metatarsal shafts (Lee et al., 2014). Heel cups help to grasp the heel in a more neutral position (T.-h. Chen et al., 2014). Vibrating insoles need to be powered by batteries. They might not be good options for older people who may get their shoes wet and those with memory problems, such as dementia, who may easily forget to charge/replace the batteries.

The findings from the reviewed papers of this systematic review suggested that insoles with some particular design features were not effective in improving balance. Specifically, textured insoles with sparsely distributed textured patterns (Anna L Hatton et al., 2012) and orthopaedic insoles with single component of a medial arch support or a heel cup only (Bae et al., 2016; Samimi et al., 2014) could not improve balance. Attention should also be paid to the physical and psychological conditions of community-dwelling older adults, as one study reported that while textured insoles could improve balance of non-fallers, they could not improve balance of recurrent fallers (Anna L Hatton et al., 2012). There were studies investigating both static and dynamic balance. Those studies found that the insoles that could effectively improve dynamic balance generally could also improve static balance, however, the reverse might not be true.

Insoles may not be effective in improving balance of individuals in some special conditions. Slippery floor and poor lighting can contribute to fall of older people (Aizen et al., 2007; Eriksson et al., 2009). These environmental factors cannot be addressed by the use of insoles. Some medical problems, such as hypotension and complications from medication, can impose balance problems (Y.-C. Chen et al., 2009; Rubenstein & Josephson, 2002; von Heideken Wågert et al., 2009). There is a lack of evidence supporting whether insoles can improve postural balance of people with such medical conditions. In addition, some neuromuscular disease, such as stroke, may require physiotherapy and more extensive orthotic treatments to achieve better postural balance. It should also be noted that while there is evidence supporting the balance improvement effects of vibrating insoles and orthopaedic insoles among healthy older people with and without a fall history, textured insoles were found to be ineffective in improving balance in older people who had a history of fall. Prescribing insole intervention only may not be able to replace balance training programs in improving functional ability and in fall prevention.

Future research directions

This review highlights several issues that merit further investigation. Firstly, RCTs with double blindness of both subjects and experimenters should be conducted. Clinical trials with large sample size should also be conducted in the future. This helps enhance the trial’s methodological quality and evidence level. Some standard experimental protocols and balance outcome measurements assessing the effectiveness of insoles shall be adopted to facilitate future cross-study comparisons. Further studies about the long-term effect of the insole intervention shall also be conducted.

Secondly, comparisons of different types and designs of insoles should be conducted to allow better identification of the balance improving mechanisms and optimization of the insole designs. Several possible explanations regarding the positive balance improving effects of insoles have been proposed, including 1) orthopaedic insoles enlarging the contact area between foot and support surface (T.-h. Chen et al., 2014) and redistributing force to more force-sensitive areas (C. Z.-H. Ma, Wong, et al., 2018); 2) vibrating insoles increasing the sensory input via the SR mechanism (A. A. Priplata et al., 2006); and 3) the recesses and stretching of skin caused by textured insoles allowing better detection of the spacing, roughness and direction of the texture patterns (Palluel et al., 2009). However, there was a lack of evidence directly supporting these propositions. Investigations into the effects of systematically modified designs of one type of insoles on balance would help confirm the underlying mechanisms, and contribute to knowledge for even better insole designs and prescriptions in the future. Considerations could be putting the vibrators, textures, and pads at different plantar sites, and producing customized stimulation intensity through different specific characteristics of each insole component, including size, hardness and distribution density. A recent study has also suggest that the thickness of insoles might also change postural stability (Büyükturan et al., 2018). In addition, the relationship among the individualized sensory threshold, the intensity of provided sensory stimulations (magnitude and duration), and the outcome balance performance could and shall be carefully examined in the future. Meanwhile, comparisons among different insoles in same subjects may also identify which type or design feature of insoles offers the best positive outcomes in balance. Future attempts can also evaluate if combining two elements, e.g. orthopaedic/textured insoles together with vibrators, could further enhance balance.

Thirdly, the effects of insoles on balance in populations with different characteristics shall be studied. It is generally suggested that insoles could improve the balance of community-dwelling older people, further efforts are still needed to investigate the effect of insoles in older people with various aged degenerations and medical conditions. Future studies shall evaluate the participant's condition more comprehensively and recruit subjects with more specific characteristics. This could help further determine and identify if insoles are not beneficial for some specific populations, and facilitate evidence-based clinical application in the future. Efforts could also be put to optimize the design of insoles to compromise different medical conditions of the users. It is also suggested that future studies shall report the distribution of race of the participants, which is important regarding the interpretation and generalization of the findings among different populations globally.

Finally, efforts are still needed to facilitate the long-term use of each type of the insoles in daily life. Some insole components may lead to discomfort, pain and even side effects after long-term use, such as the small rigid nubs in textured insoles (Perry et al., 2008) and vibrators in vibrating insoles (de Morais Barbosa et al., 2013). The diameter, height, hardness, and distribution of those components shall be more carefully chosen and determined to avoid possible discomfort/pain in users upon long-term usage. Some silicon materials enabling long-term usage in older people (Mustafa Mohamed Osman Elhadi et al., 2018; M.M.O. Elhadi et al., 2017) could also be considered as a potential option of insole materials in the future. So far, only two or three vibrators were put at the plantar foot, mainly metatarsal heads and heel (Hijmans, Geertzen, Schokker, et al., 2007; Lipsitz et al., 2015). Future attempts may consider to selectively putting more vibrators and textures at plantar areas experiencing lesser loads during standing and walking, such as the medial longitudinal arches, and evaluating its effect on balance. The vibrators may also be put on the other body parts to provide sensory augments to remind users of the degree of body sway (C. Z.-H. Ma & Lee, 2017; C. Z.-H. Ma et al., 2015;

C. Z.-H. Ma et al., 2016; C. Z.-H. Ma, Zheng, et al., 2018; C. Z. Ma et al., 2014; Wan et al., 2016). With current state-of-the-art wearable smart product technologies (Khanuja et al., 2018; C. Z.-H. Ma, Chung, et al., 2019; C. Z.-H. Ma & Lee, 2017; C. Z.-H. Ma, Ling, et al., 2019; C. Z.-H. Ma et al., 2015; C. Z.-H. Ma et al., 2016; C. Z.-H. Ma, Zheng, et al., 2018; C. Z. Ma et al., 2014; Ren et al., 2019; Wan et al., 2016), vibrating insoles could be developed smarter with custom on/off function, cheaper, smaller, lighter, and with higher power capacity to facilitate future long-term daily and therapeutic usage. More long-term studies including falls and falls-related injuries as outcome measures shall also be conducted. To monitor and guarantee the compliance of insole usage during long-term follow-up, researchers could also consider to embedding some force sensors and wireless connection modules into insoles in future studies.

Conclusions

This review examines the effects of orthopaedic insoles, vibrating insoles, and textured insoles on static and dynamic balance performance of community-dwelling older adults. The evidence gathered generally supports the effectiveness of these insoles in improving the postural balance of healthy older people. Good knowledge in insole designs and understanding of medical conditions of community-dwelling older adults is required, when attempt is made to improve postural balance using insoles. Specifically, insoles with more rigid materials, insoles with texture patterns, orthopaedic insoles with arch supports and heel cups, and vibrating insoles delivering sub-threshold vibrations have gained evidence supporting that they are effective in enhancing postural balance in community-dwelling older adults. History of falls of an older person appears to be an important factor in determining which type of insoles to be chosen. Meanwhile, cares should be taken in users with some medical conditions, such as people with foot deformities requiring attention to avoid excessively high pressure at the abnormal bony prominence areas. Clinical trials with high quality should be conducted to further strengthen the evidence. Future research could employ randomized controlled trials and comprehensive parametric analysis to study the effects of various insole designs on balance of older people with wider ranges of physical capability after both short and long time periods of using the insoles.

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Figure captions

Figure 1. Flow chart of searching strategy and results

Figure 2. Overview of each type of the effective insole in enhancing static and dynamic balance

Tables

Table 1. Levels of evidence and grades of recommendation (n=25)

Table 2. Assessing results of the Downs and Black Quality List (n=25).

Table 3. Study characteristics (n=25)

Table 4. Study outcomes (n=25)

Supplemental files

Supplemental file 1. Levels of Evidence (Oxford Centre for Evidence-based Medicine – March 2009) (Interval, 2009)

Supplemental file 2. Grades of Recommendation (Oxford Centre for Evidence-based Medicine – March 2009) (Interval, 2009)

Supplemental file 3. The Downs and Black Quality List (Downs & Black, 1998)

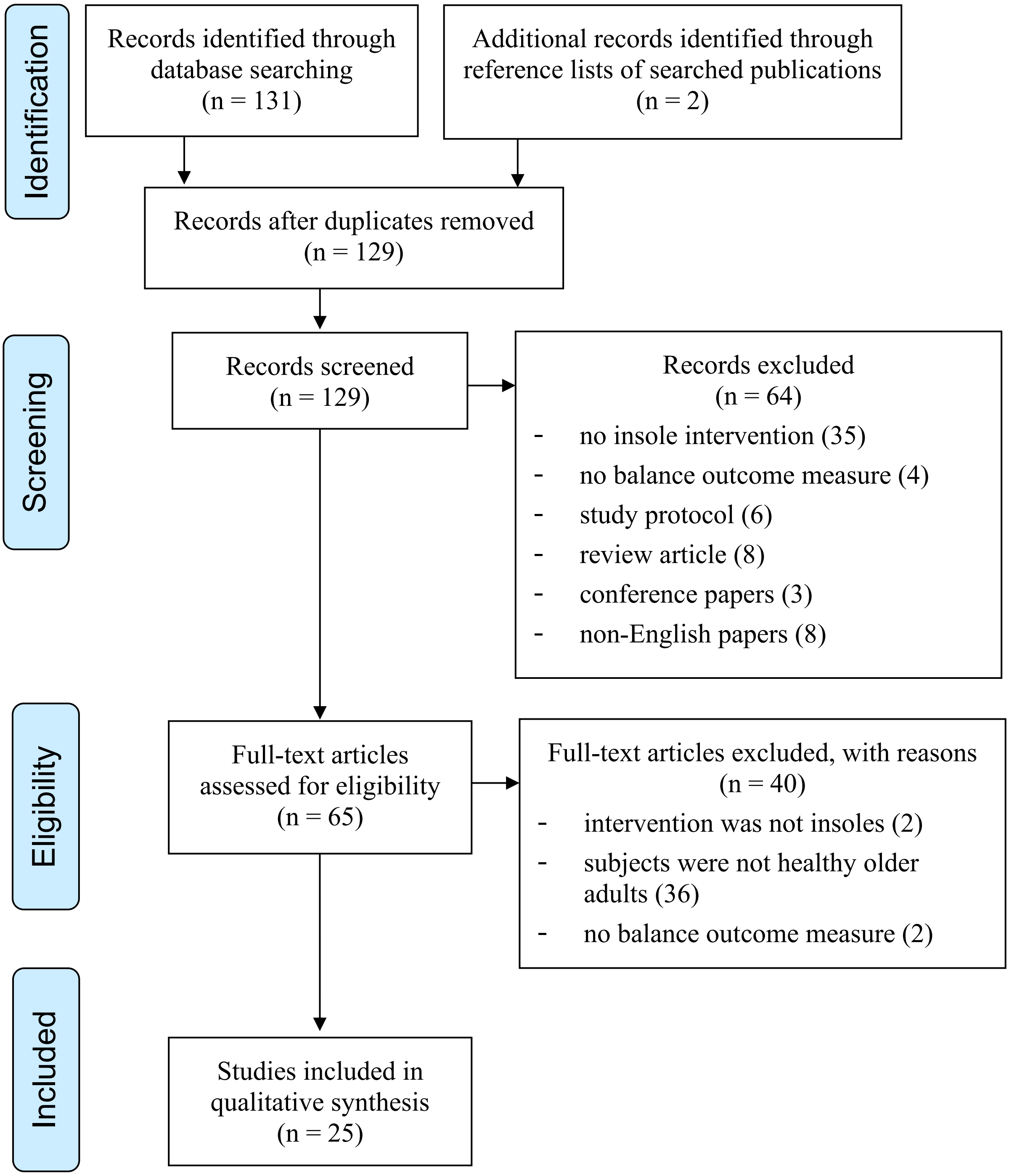

Figure 1. Flow chart of searching strategy and results

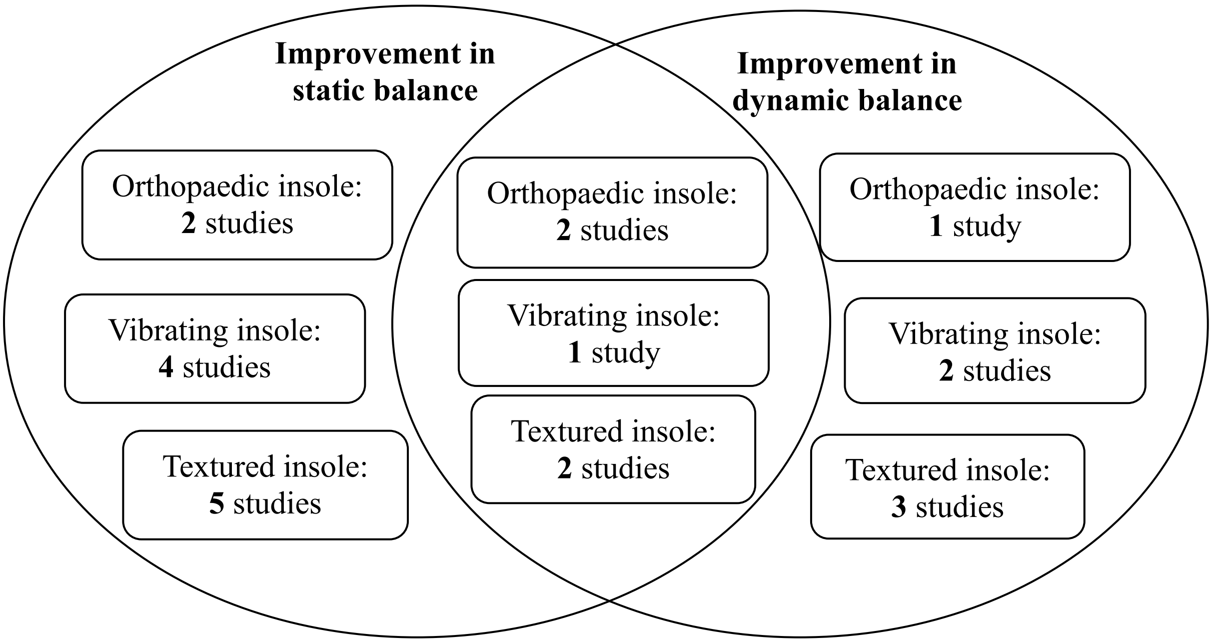

Figure 2. Overview of each type of effective insole in enhancing static and dynamic balance

Table 1. Levels of evidence and grades of recommendation (n=25)

Study	Levels of Evidence	Design	Grades of Recommendation
Li et al 2019 (Li et al., 2019)	3B	Individual Case-Control Study	B
de Morais Barbosa et al 2018 (de Morais Barbosa et al., 2018)	1B	Individual Randomized Clinical Trial (single-blinded)	A
Ma et al. 2018 (C. Z.-H. Ma, Wong, et al., 2018)	3B	Individual Case-Control Study	B
Bae et al. 2016 (Bae et al., 2016)	3B	Individual Case-Control Study	B
Qu 2015 (Qu, 2015)	3B	Individual Case-Control Study	B
Lipsitz et al. 2015 (Lipsitz et al., 2015)	3B	Individual Case-Control Study	B
Samimi et al. 2014 (Samimi et al., 2014)	3B	Individual Case-Control Study	B
Chen et al. 2014 (T.-h. Chen et al., 2014)	3B	Individual Case-Control Study	B
Antonio and Perry 2014 (Antonio & Perry, 2014)	3B	Individual Case-Control Study	B
Qiu et al. 2013 (Qiu et al., 2013)	3B	Individual Case-Control Study (single-blinded)	B
de Morais Barbosa et al 2013 (de Morais Barbosa et al., 2013)	1B	Individual Randomized Clinical Trial	A
Wei et al. 2012 (Wei et al., 2012)	3B	Individual Case-Control Study	B
Wang and Yang 2012 (Wang & Yang, 2012)	3B	Individual Case-Control Study	B
Stephen et al. 2012 (Stephen et al., 2012)	3B	Individual Case-Control Study (double-blinded)	B
Qiu et al. 2012 (Qiu et al., 2012)	3B	Individual Case-Control Study	B
Iglesias et al. 2012 (Iglesias et al., 2012)	3B	Individual Case-Control Study	B
Hatton et al. 2012 (Anna L Hatton et al., 2012)	3B	Individual Case-Control Study	B
Gross et al. 2012 (Gross et al., 2012)	3B	Individual Case-Control Study	B

Study	Levels of Evidence	Design	Grades of Recommendation
Simeonov et al. 2011 (Simeonov et al., 2011)	3B	Individual Case-Control Study	B
Palluel et al. 2009 (Palluel et al., 2009)	3B	Individual Case-Control Study	B
Galica et al. 2009 (Galica et al., 2009)	3B	Individual Case-Control Study	B
Perry et al. 2008 (Perry et al., 2008)	1B	Individual Randomized Clinical Trial	A
Palluel et al. 2008 (Palluel et al., 2008)	3B	Individual Case-Control Study	B
Priplata et al. 2006 (A. A. Priplata et al., 2006)	3B	Individual Case-Control Study	B
Priplata et al. 2003 (A. Priplata et al., 2003)	3B	Individual Case-Control Study	B

1

Table 2. Assessing results of the Downs and Black Quality List (n=25).

Study	Score of Subscale and Index																											
	Reporting										External Validity			Internal Validity-Bias							Internal Validity-Confounding (Selection Bias)						Power	Total
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	
Li et al 2019 (Li et al., 2019)	1	1	1	1	1	1	1	1	1	1	0	0	0	0	0	1	1	1	1	1	1	1	0	0	0	1	0	18
de Morais Barbosa et al 2018 (de Morais Barbosa et al., 2018)	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	26
Ma et al. 2018 (C. Z.-H. Ma, Wong, et al., 2018)	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0	1	1	1	1	1	1	1	1	0	0	1	0	21
Bae et al. 2016 (Bae et al., 2016)	1	1	1	1	1	1	1	0	1	1	1	0	0	0	0	1	1	1	1	1	1	1	0	0	0	1	0	18
Qu 2015 (Qu, 2015)	1	1	1	1	1	1	1	0	1	1	0	0	0	0	0	1	1	1	1	1	1	1	0	0	0	1	0	18
Lipsitz et al. 2015 (Lipsitz et al., 2015)	1	1	1	1	1	1	1	1	1	1	1	0	1	0	0	1	1	1	0	1	1	1	0	0	0	1	0	20
Samimi et al. 2014 (Samimi et al., 2014)	1	1	1	1	1	1	1	0	1	1	0	0	0	0	0	1	1	1	1	1	1	1	0	0	0	1	0	17
Chen et al. 2014 (T.-h. Chen et al., 2014)	1	1	1	1	1	1	1	0	1	1	1	1	1	0	0	1	1	1	1	1	1	1	0	0	0	1	0	20
Antonio and Perry 2014 (Antonio & Perry, 2014)	1	1	1	1	1	1	1	0	1	1	1	0	1	0	0	1	1	1	1	1	1	1	0	0	0	1	0	19
Qiu et al. 2013 (Qiu et	1	1	1	1	1	1	1	0	1	1	1	0	1	0	1	1	1	1	1	1	1	1	0	0	0	1	0	20

Study	Score of Subscale and Index																											Total
	Reporting										External Validity			Internal Validity-Bias							Internal Validity-Confounding (Selection Bias)						Power	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	
al., 2013)																												
de Morais Barbosa et al 2013 (de Morais Barbosa et al., 2013)	1	1	1	1	1	1	1	0	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	1	0	1	0	22
Wei et al. 2012 (Wei et al., 2012)	1	1	1	1	1	1	1	0	1	1	1	1	1	0	0	1	1	1	1	1	1	1	0	0	0	1	0	20
Wang and Yang 2012 (Wang & Yang, 2012)	1	1	1	1	1	1	1	0	1	0	1	0	0	0	0	1	1	1	1	1	1	1	0	0	0	1	0	17
Stephen et al. 2012 (Stephen et al., 2012)	1	1	1	1	1	1	1	0	1	1	1	0	0	1	1	1	1	1	1	1	1	1	0	0	0	1	0	20
Qiu et al. 2012 (Qiu et al., 2012)	1	1	1	1	1	1	1	0	1	0	1	0	1	0	0	1	1	1	1	1	1	1	0	0	0	1	0	18
Iglesias et al. 2012 (Iglesias et al., 2012)	1	1	1	1	1	1	1	0	1	1	1	1	1	0	0	1	1	1	1	1	1	1	0	0	0	1	0	20
Hatton et al. 2012 (Anna L Hatton et al., 2012)	1	1	1	1	1	1	1	1	1	1	1	0	1	0	0	1	1	1	1	1	1	1	0	0	0	1	0	20
Gross et al. 2012 (Gross et al., 2012)	1	1	1	1	1	1	1	0	1	1	1	0	1	0	0	1	1	1	0	1	1	1	0	0	0	1	0	18
Simeonov et al. 2011 (Simeonov et al., 2011)	1	1	1	1	1	1	1	0	1	1	1	0	1	0	0	1	1	1	1	1	1	1	0	0	0	1	0	19
Palluel et al. 2009 (Palluel et al., 2009)	1	1	1	1	1	1	1	0	1	1	1	0	0	0	0	1	1	1	1	1	1	1	0	0	0	1	0	18

Study	Score of Subscale and Index																											Total
	Reporting										External Validity			Internal Validity-Bias							Internal Validity-Confounding (Selection Bias)						Power	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	
Galica et al. 2009 (Galica et al., 2009)	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0	1	1	1	1	1	1	1	0	0	0	1	0	21
Perry et al. 2008 (Perry et al., 2008)	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0	1	1	1	0	1	1	1	1	1	0	1	0	22
Palluel et al. 2008 (Palluel et al., 2008)	1	1	1	1	1	1	1	1	1	1	1	0	1	0	0	1	1	1	1	1	1	1	0	0	0	1	0	20
Priplata et al. 2006 (A. A. Priplata et al., 2006)	1	1	1	1	1	1	1	0	1	1	1	1	1	0	0	1	1	1	1	1	1	1	0	0	0	1	0	20
Priplata et al. 2003 (A. Priplata et al., 2003)	1	1	1	1	1	1	1	0	1	1	1	0	1	0	0	1	1	1	1	1	1	1	0	0	0	1	0	19

Table 3. Study characteristics (n= 25)

Author Year	Subjects	Sample size & Gender (EG/CG)	Mean age (years)	Fall history	Intervention	Shoe standardization (support surface)	Follow-up
Li et al. 2019	Community-dwelling women elderly (no neurological issues)	24 (24F)	65	Not specified	1) Flat insoles 2) Textured insoles	Yes	Immediate effect
de Morais Barbosa et al 2018	Community-dwelling elderly	60 (34F)/ 31 (15F)	70	0-5 falls	1) Flat insoles 2) Textured insoles	No	4 weeks
Ma et al. 2018	Community-dwelling elderly	14 (4F)	70	Not specified	Orthopaedic insole with an arch support, a metatarsal pad, and a heel cup and	Yes	Immediate effect
Bae et al. 2016	Community-dwelling elderly	13 (Gender N/R)	67	Not specified	1) Flat insoles 2) Insoles with medial arch support 3) Insoles with heel cup	No	Immediate effect
Qu 2015	Community-dwelling elderly (no medical condition)	13 (8F)	69	Not specified	1) Cupped insoles with medial arch supports 2) Textured insoles 3) Rigid hardness insoles 4) Soft hardness insoles	No	Immediate effect
Lipsitz et al. 2015	Community-dwelling elderly (no neurodegenerative conditions)	12 (11F)	74	Not specified	Vibrating insoles	No	1 day
Samimi et al. 2014	Community-dwelling elderly (no peripheral neuropathy)	15 (0F)	63	Not specified	1) Barefoot 2) Shoe only 3) Shoe with prefabricated arch supporting insoles	Yes	Immediate effect
Chen et al. 2014	-Community-dwelling elderly with good stability	25/20 (Gender	71	Not specified	Orthopaedic insole with a heel cup and an arch support	No	- Immediate effect

Author Year	Subjects	Sample size & Gender (EG/CG)	Mean age (years)	Fall history	Intervention	Shoe standardization (support surface)	Follow-up
	- Community-dwelling elderly with poor stability	N/R)					-8 weeks
Antonio and Perry 2014	Community-dwelling elderly (no neurological issues)	10 (5F)	73	Not specified	1) Barefoot 2) Soft hardness insoles 3) Medium hardness insoles 4) Rigid hardness insoles	Not specified	Immediate effect
Qiu et al. 2013	Community-dwelling elderly	20 (7F)	69	Not specified	1) Barefoot 2) Smooth insoles 3) Textured insoles	Yes	Immediate effect
de Morais Barbosa et al 2013	Community-dwelling elderly with osteoporosis (no reduced tactile sensitivity)	45/44 (94F in general)	72	Not specified	1) A medial arch support and a metatarsal pad 2) Conventional flat insole	Not specified	- Immediate effect -4 weeks
Wei et al. 2012	Community-dwelling elderly (no disease)	26 (Gender N/R)	59	⩾2 falls a year	Vibrating insoles	Yes	Immediate effect
Wang and Yang 2012	Community-dwelling elderly fallers	26 (Gender N/R)	83	Faller	Vibrating insoles	Yes	Immediate effect
Stephen et al. 2012	Community-dwelling elderly (no neurological condition)	29 (13F)	72	Not specified	Vibrating insoles	Yes	Immediate effect
Qiu et al. 2012	Community-dwelling elderly	7 (3F)	72	Not specified	1) Barefoot 2) Soft textured insoles 3) Rigid textured insoles	Not specified	Immediate effect
Iglesias et al. 2012	Community-dwelling elderly (no neurological disorders or diabetes)	22 (16F)	85	Not specified	1) Barefoot 2) Soft textured insoles 3) Rigid textured insoles	Not specified	Immediate effect
Hatton et al. 2012	Community-dwelling elderly (no	30 (21F)	79	⩾2 falls previously	1) Smooth insoles	Not specified	Immediate effect

Author Year	Subjects	Sample size & Gender (EG/CG)	Mean age (years)	Fall history	Intervention	Shoe standardization (support surface)	Follow-up
	peripheral neuropathy)				2) Textured insoles		
Gross et al. 2012	Community-dwelling elderly (no neurological condition)	13 (7F)	81	≥1 falls previously	Custom foot-orthosis	Yes	- Immediate effect -2 weeks
Simeonov et al. 2011	Community-dwelling elderly construction workers	6 (Gender N/R)	51	Not specified	Vibrating insoles	Yes	Immediate effect
Palluel et al. 2009	Community-dwelling elderly (no neurological condition with Monofilament test confirmed)	19 (11F)	69	No	Textured insoles with spikes	Yes	Immediate effect
Galica et al. 2009	-Community-dwelling elderly -Community-dwelling elderly fallers (no peripheral neuropathy)	18 (17F)/ 18 (17F)	77/78	≥2 falls previously	Vibrating insoles	Yes	Immediate effect
Perry et al. 2008	Community-dwelling elderly (no peripheral neuropathy)	20 (9F)/ 20 (10F)	70/69	Not specified	1) Textured insole with a small tube 2) Conventional flat insole	Yes	- Immediate effect -12 weeks
Palluel et al. 2008	Community-dwelling elderly (no peripheral neuropathy)	19 (11F)	69	No	Textured insoles with spikes	Yes	-Immediate effect -5 min
Priplata et al. 2006	Community-dwelling elderly (no diabetic neuropathy)	12 (8F)	73	No	Vibrating insoles	Yes	Immediate effect
Priplata et al. 2003	Community-dwelling elderly (no diabetic neuropathy)	12 (8F)	73	Not specified	Vibrating insoles	Yes	Immediate effect

Note:

EG: experimental group; CG: control group; F: female participants; N/R: not reported.

Table 4. Study outcomes (n=25)

Author Year	Outcome measures	Measurement tool	Results	Balance improvement
Li et al. 2019 (Li et al., 2019)	In-shoe force sensors	In-shoe force sensors	Significant reduction in postural sway, especially in the mediolateral direction during walking.	Yes, static and dynamic balance
de Morais Barbosa et al 2018 (de Morais Barbosa et al., 2018)	-BBS test -TUG test	Clinical functional tests	Significantly improved static and dynamic balance in the clinical functional test.	Yes, static and dynamic balance
Ma et al. 2018 (C. Z.-H. Ma, Wong, et al., 2018)	COP during standing	Force plate	Orthopaedic insole significantly reduced the postural sway.	Yes, static balance
Bae et al. 2016 (Bae et al., 2016)	COP during standing	Pressure mat	Insoles did not affect static balance significantly.	No, static balance
Qu 2015 (Qu, 2015)	-COP during standing -COM during walking	-Force plate -Motion capture system	-Cupped insoles improved dynamic postural stability; -The rigid insole was associated with better dynamic postural stability compared to soft insoles.	Yes, dynamic balance
Lipsitz et al. 2015 (Lipsitz et al., 2015)	-COP during standing -Gait parameters -TUG test	-Force plate -Motion capture system	-Improved performance on the TUG test, reduced the area of postural sway and reduced the temporal variability of walking at both 70% and 85% of the sensory threshold and during the course of a day. -Vibratory sensation thresholds remained relatively stable within and across study days.	Yes, static and dynamic balance

Author Year	Outcome measures	Measurement tool	Results	Balance improvement
Samimi et al. 2014 (Samimi et al., 2014)	COP during standing	Force plate	A medial arch support only increased the COP ranges.	No, static balance
Chen et al. 2014 (T.-h. Chen et al., 2014)	COP during standing	Force plate	Significantly better COP stability index.	Yes, static balance
Antonio and Perry 2014 (Antonio & Perry, 2014)	COM during walking up and down stairs	-Force plate -Motion capture system	-Barefoot condition increased the fall risk, as opposed to the other insole harnesses (soft, medium and hard); -Wearing textured insoles improved stability during stair gait	Yes, dynamic balance.
Qiu et al. 2013 (Qiu et al., 2013)	COP during standing	Force plate	Only the textured insole decreased medial-lateral sway, with and without visual input.	Yes, static balance
de Morais Barbosa et al 2013 (de Morais Barbosa et al., 2013)	-BBS test -TUG test	Clinical functional tests	Significantly improved static and dynamic balance in the clinical functional test.	Yes, static and dynamic balance
Wei et al. 2012 (Wei et al., 2012)	COP during standing	Force plate	The balance stability of 61.5% elderly subjects was improved after wearing vibrating shoes	Yes, static balance
Wang and Yang 2012	COP during standing	Force plate	Temporary use of vibratory insoles was essential for enhancing balance in elderly fallers, especially in the AP direction, for a short time duration (30 s).	Yes, static balance

Author Year	Outcome measures	Measurement tool	Results	Balance improvement
(Wang & Yang, 2012)				
Stephen et al. 2012 (Stephen et al., 2012)	-Spatial gait variability -3D position data of the feet	-In-shoe force sensors -Motion capture system	Applying stochastic-resonance mechanical vibrations on the plantar surface of the foot reduced gait variability	Yes, dynamic balance
Qiu et al. 2012 (Qiu et al., 2012)	COP during standing	Force plate	Both textured insole surfaces reduced postural sway for the older group especially in more challenging balance tasks (eyes closed on a foam surface).	Yes, static balance
Iglesias et al. 2012 (Iglesias et al., 2012)	COP during standing	Force plate	-Both hard and soft shoe insoles decreased postural sway compared with the barefoot condition. -The more rigid insole reduced more postural sway. -The hard insole was also effective when visual feedback was removed.	Yes, static balance
Hatton et al. 2012 (Anna L Hatton et al., 2012)	-Standing balance -Gait parameters	-Force plate -Motion capture system	-No significant differences in balance parameters between textured insoles and smooth insoles were found. -Wearing textured insoles significantly lowered gait velocity, step length and stride length.	No, static and dynamic balance
Gross et al. 2012 (Gross et al., 2012)	-1-leg stance time -Tandem stance time -Tandem gait -Alternating step tests	Clinical functional tests	-Significantly reduced one-leg stance times and tandem stance times after using orthopaedic insoles immediately and for 2 weeks. -Significantly increased steps taken for the tandem gait test and alternating step test after using orthopaedic insoles immediately and for 2 weeks. -Immediately and after 2 weeks measurements were not significantly different for any of the 4 outcome measures.	Yes, static and dynamic balance
Simeonov et al. 2011 (Simeonov	Trunk angular displacement during standing	Motion capture system	The supra-sensory vibration had a destabilizing effect significantly.	No, static balance

Author Year	Outcome measures	Measurement tool	Results	Balance improvement
et al., 2011)				
Palluel et al. 2009 (Palluel et al., 2009)	COP during standing	Force plate	-The elderlies were particularly perturbed when the textured insoles were removed. -Textured insoles led to a better postural control.	Yes, static balance
Galica et al. 2009 (Galica et al., 2009)	Stride, stance, and swing time variability	In-shoe force sensors	-Vibrating insoles significantly reduced stride, stance, and swing time variability measures for elderly recurrent fallers. -Elderly non-fallers also demonstrated significant reductions in stride and stance time variability. -Gait variability reductions with noise were similar between the elderly recurrent fallers and elderly non-fallers.	Yes, dynamic balance
Perry et al. 2008 (Perry et al., 2008)	-Lateral stability -Kinematic data	Motion capture system	-Textured insoles with a small tube significantly improved postural stability during gait immediately, and after 12 weeks of wearing the insole. -9 subjects who wore conventional insoles experienced one or more falls over the 12-week period, whereas only 5 subjects fell while wearing the textured insoles. -Initial reports of discomfort in 10 cases, all but one subject tolerated the textured insoles, and 17 of 20 indicated that they would like to continue wearing it on a long-term basis	Yes, dynamic balance
Palluel et al. 2008 (Palluel et al., 2008)	-COP during standing -Plantar sensation	-Force plate -Semmes–Weinstein monofilaments	Standing or walking for 5 min with spike insoles led to a significant improvement of quiet standing in elderly subjects.	Yes, static balance
Priplata et al. 2006 (A. A. Priplata et al., 2006)	Postural stability during standing	Motion capture system	-Statistically significant reduction in each of the eight sway parameters in the subjects with diabetic neuropathy and the elderly subjects. -Higher levels of baseline postural sway in sensory-impaired individuals were correlated with greater improvements in balance control with input noise.	Yes, static balance
Priplata et al. 2003 (A. Priplata et al., 2003)	Postural stability during standing	Motion capture system	Application of noise resulted in a reduction in all of the sway variables in elderly participants.	Yes, static balance

Supplemental file 1. Levels of Evidence (Oxford Centre for Evidence-based Medicine – March 2009) [29]

Level	Therapy/Prevention
1a	Systematic Review (with homogeneity) of Randomized Controlled Trials
1b	Individual Randomized Controlled Trial (with narrow Confidence Interval)
1c	All or none
2a	Systematic Review (with homogeneity) of cohort studies
2b	Individual cohort study (including low quality Randomized Controlled Trial; e.g., <80% follow-up)
2c	"Outcomes" Research; Ecological studies
3a	Systematic Review (with homogeneity) of case-control studies
3b	Individual Case-Control Study
4	Case-series (and poor quality cohort and case-control studies)
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"

Supplemental file 2. Grades of Recommendation (Oxford Centre for Evidence-based Medicine – March 2009) [29]

Grade	Contents
A	consistent level 1 studies
B	consistent level 2 or 3 studies or extrapolations from level 1 studies
C	level 4 studies or extrapolations from level 2 or 3 studies
D	level 5 evidence or troublingly inconsistent or inconclusive studies of any level

Supplemental file 3. The Downs and Black Quality List [30]

Subscale	Item	Index	Score					
			5	**4**	**3**	**2**	**1**	**0**
Reporting	**1**	Is the hypothesis/aim/objective of the study clearly described?	-	-	-	-	Y	N
	2	Are the main outcomes to be measured clearly described in the Introduction or Methods section?	-	-	-	-	Y	N
	3	Are the characteristics of the patients included in the study clearly described?	-	-	-	-	Y	N
	4	Are the interventions of interest clearly described?	-	-	-	-	Y	N
	5	Are the distributions of principal confounders in each group of subjects to be compared clearly described?	-	-	-	Y	P	N
	6	Are the main findings of the study clearly described?	-	-	-	-	Y	N
	7	Does the study provide estimates of the random variability in the data for the main outcomes?	-	-	-	-	Y	N
	8	Have all important adverse events that may be a consequence of the intervention been reported?	-	-	-	-	Y	N
	9	Have the characteristics of patients lost to follow-up been described?	-	-	-	-	Y	N
	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?	-	-	-	-	Y	N
External Validity	**11**	Were the subjects asked to participate in the study representative of the entire population from which they were recruited?	-	-	-	-	Y	N/UN

	12	Were those subjects who were prepared to participate representative of the entire population from which they were recruited?	-	-	-	-	Y	N/UN
	13	Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?	-	-	-	-	Y	N/UN
Internal Validity -Bias	**14**	Was an attempt made to blind study subjects to the intervention they have received?	-	-	-	-	Y	N/UN
	15	Was an attempt made to blind those measuring the main outcomes of the intervention?	-	-	-	-	Y	N/UN
	16	If any of the results of the study were based on "data dredging", was this made clear?	-	-	-	-	Y	N/UN
	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?	-	-	-	-	Y	N/UN
	18	Were the statistical tests used to assess the main outcomes appropriate?	-	-	-	-	Y	N/UN
	19	Was compliance with the intervention/s reliable?	-	-	-	-	Y	N/UN
	20	Were the main outcome measures used accurate (valid and reliable)?	-	-	-	-	Y	N/UN
Internal Validity - Confounding (Selection Bias)	**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?	-	-	-	-	Y	N/UN
	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?	-	-	-	-	Y	N/UN
	23	Were study subjects randomised to intervention groups?	-	-	-	-	Y	N/UN
	24	Was the randomised intervention assignment concealed from both patients and health care staff	-	-	-	-	Y	N/UN

		until recruitment was complete and irrevocable?						
	25	Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?	-	-	-	-	Y	N/UN
	26	Were losses of patients to follow-up taken into account?	-	-	-	-	Y	N/UN
Power	**27**	Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?	Size of smallest intervention group					
			$> n_8$	$n_7 - n_8$	$n_5 - n_6$	$n_3 - n_4$	$n_1 - n_2$	$<n_1$

-Note: Y: yes; P: partially; N: no; UD: unable to determine.