

Fontys Paramedic University of Applied Sciences

Physiotherapy English Stream

Balance Training versus Stretching in Fall Prevention.

A Systematic Review

Selina Schmid

Student Number: 2160141

E-Mail: s.schmid@student.fontys.nl

Phone number: +31 624 795 604

Version: 1.1

Date: 03-06-2014

Supervisor: Anke Lahaije

E-Mail: a.lahaije@fontys.nl

Preface

This paper is the final product for my study at Fontys University of Applied Sciences in Eindhoven, the Netherlands. In order to complete my Bachelor degree in Physiotherapy this systematic review about the effects of balance training and stretching interventions on the risk of falling in elderly people was written.

I decided to write about the elderly population since it is growing and people get older compared to 20 years ago. Therefore it is important to conduct research on this age group and to deal with the consequences of getting older.

The completion of this work would not have been possible, if it was not for some special people in my life. I would like to thank my family and my boyfriend for their help and assistance during this period of my study.

Furthermore, I would like to thank my supervisor Anke Lahaije for her support, and Saskia Boer and Valentina Senoner for peer reviewing.

Eindhoven, 03-06-2014

Abstract

Background With ageing not only the body, but also the gait pattern of an elderly person is changing. This can result in a higher risk of falling. Apart from other factors, decreased balance function or reduced mobility of the lower limb joints can be a reason for a changed gait pattern. The hypothesis is that with either balance training or stretching these parameters can be improved and thus also the gait pattern is improved. This results in the following research question:

Objective “Which training program is improving the gait pattern and the risk of falling more in elderly people, balance training or a stretching program?”

Method A systematic review after using Pubmed, Medline and PEDro was done. Subjects were elderly aged 60 years and older and included outcome measurements were “gait velocity”, “stride length” and “cadence”. The articles were checked for methodological quality using the PEDro score and a best evidence synthesis was performed.

Results There was no study found that compared balance training with a stretching intervention so the research question cannot be answered directly. For this reason, two best evidence syntheses were done, one for the studies conducting balance training and one for studies with a stretching program. Resulting in two statements:

- 1) There is conflicting/insufficient evidence on the effect of balance training on the parameters “gait velocity”, “stride length” and “cadence” of the human gait.
- 2) There is strong evidence for the effect of stretching on the parameters “gait velocity” and “stride length” of the human gait and conflicting evidence for its effect on “cadence”.

Conclusion There is sufficient evidence for the effect of stretching on gait and this again implicates a positive effect on fall risk. However, no direct evidence for that was found in this review.

Table of Content

Preface	2
Abstract.....	3
Table of Content	4
1. Introduction	5
2. Method	8
2.1 Search Strategy	8
2.2 Study Selection.....	8
2.3 Assessment of Methodological Quality.....	9
2.4 Data Analysis.....	10
3. Results	11
3.1 Result Search Strategies and Study Selection.....	11
3.2 Results Data Extraction	13
3.3 Result Methodological Quality Assessment	16
3.4 Best Evidence Synthesis	17
4. Discussion	19
5. Conclusion	23
6. References	24
7. List of tables.....	27
8. List of figures	27
9. Appendices	I
Appendix I: Search Strings	I
Appendix II: PEDro Scale	II

1. Introduction

Worldwide ca. 28-35% of elderly over 65 years of age have a history of at least one fall a year. The World Health Organization defines a fall as “an event, which results in a person coming to rest inadvertently on the ground or floor or other lower level”. Since there is a broad interpretation of what falls are, it is important to have a clear definition. Elderly for example also describe loss of balance as a fall, whereas health care professionals often see it as an event leading to an injury. The injuries resulting from falling are amongst others hip fracture, traumatic brain injury or upper limb injuries (World Health Organization [WHO], 2007).

At risk of falling are often elderly with an altered gait, since this is one of the biggest risk factors for falls. Even though causes for falling also contain other factors, the majority of falls occur when walking (Bridenbaugh & Kressig, 2011).

Other risk factors for falling include fear of falling (Halvarsson, Olsson, Farén, Pettersson, & Ståhle, 2011) previous falls, strength and balance impairments and the use of special medication, which can for example have dizziness as a side effect (Tinetti & Kumar, 2010). Falls in general have been associated with reduced physical activity and impaired mobility measurements (Rodacki, Souza, Ugrinowitsch, Christopolski, & Fowler, 2009).

As the body changes with age, the gait pattern is changing, too. There are some important differences compared to the standard gait pattern of an adult below the age of 65. These are a slower walking velocity ranging from < 70 cm/s to 70 - 100 cm/s, compared to standard values of 1,54 m/s for men and 1,31 m/s for women (Murray, Drought, & Kory, 1964; Murray, Kory, & Sepic, 1970), a worse performance on the swing phase, the double support phase, swing time variability and shorter stride length (Verghese, Holtzer, Lipton, & Wang, 2009; Kimura, Kobayashi, Nakayama, & Hanaoka, 2007). Gait speed is composed of cadence and stride length, which makes them dependent on each other and are therefore all three focused on in this review (Sutherland, Olshen, Biden, & Wyatt, 1988).

Not only the gait is different of that of an adult it also differs between elderly who already experienced a fall and elderly who did not fall before.

When comparing the gait patterns of elderly fallers with elderly non-fallers, the following changes can be observed. Fallers have a higher stride frequency, decreased stride length, decreased ankle plantar flexion, decreased hip extension, decreased lateral body sway, an increased hip flexion at a higher walking speed and a greater variability in their walking pattern and thus a more unstable gait, which in turn is increasing the fall risk (Barak, Wagenaar, & Holt, 2006).

It can be speculated that these changes might be due to some general physiological changes that occur with aging: muscle atrophy, reduced capacity of healing, diminished capillary blood supply, reduced amounts of mesenchymal stem cells, loss of elasticity in soft-tissue matrices, and an increased muscle and joint stiffness with increased amounts of fibrous connective tissue (Feland, Myrer, Schulthies, Fellingham, & Measom, 2001).

Balance itself is a “task-specific multi-joint skill that relies on the interaction of several physiological sensory systems including the neuromuscular, visual, vestibular and somato-sensory ones (Spirduso, Francis, & MacRae, 2005). As functional mobility is provided by postural stability and dynamic balance (Jacobson, Thompson, Wallace, Brown, & Rial, 2011), a good balance is required to remain functionally mobile. As there is a progressive loss of functioning of systems required for balance with age this could contribute to the seen balance deficits, as we get older. The mentioned systems are vision, vestibular sense, proprioception, muscle strength and reaction time. (Sturnieks, St George, & Lord, 2008)

In one study the researchers found out that balance training decreases the fear of falling, it shortens the time to take a fast step during a dual task and that it increases the walking speed (Halvarsson et al., 2011). Another study comes to the conclusion that improving balance skills is a way to decrease the number of falls and fall-related injuries (Melzer & Oddsson, 2013). This also allows a greater personal independence for elderly.

The muscle – tendon unit and the surrounding tissue is getting stiffer when aging, resulting in a decreased range of motion, which has a relation to fall incidence (Miguez, Guimaraes, Tarso de, & Farinatti, 2005).

The fact that stretch training has a chronic effect on increasing range of motion (ROM) (Knudson, 2006) leads to the assumption that with, for example a supervised hip-flexor stretching program, some gait parameters that are related to the aging process can be reversed (Cristopolski, Barela, Leite, Fowler, & Rodacki, 2009). The following important gait parameters can be significantly improved: stride length, cadence and the self-selected comfortable walking speed. The improvements lead to an easier adaption of persons to their walking environment. It enables them to rapidly change stride length or walking speed when an obstacle occurs or when the ground is uneven (Watt, Jackson, Franz, Dicharry, Evans, & Kerrigan, 2011b). Not only these parameters can be enhanced with stretching. As mentioned before a decreased ankle plantar flexion and hip extension are characteristics that are present in elderly fallers and can thus be interpreted as a risk of falling (Barak et al., 2006). With stretching these characteristics can be improved, too.

Furthermore, stretching allows the elderly to present a gait and movement pattern that is more similar to that seen in healthy adults. The modifications in gait parameters are suggestive that stretching depicts an attractive way to improve the influence of aging on some functional characteristics applied to fall risk during walking (Rodacki et al., 2009).

Since the group of elderly in our population is growing faster than any other age group (WHO 2007), there are consequently also more elderly people who visit a physiotherapist. For the high amount of elderly experiencing a fall it is necessary for the physiotherapist to engage in minimizing the fall risk for his or her patients. Two inexpensive methods are balance training, either in a group or individually, or stretching exercises.

As balance training is challenging for the whole body and also involving more coordination than stretching, the hypothesis is that balance training will improve the gait pattern more than stretching exercises.

In order to find out if this hypothesis is true there are some sub questions that will be answered previous to the research question. It is interesting to find out, if balance training is improving the gait pattern and thus minimizing the fall risk. The same is looked for when conducting a stretching training and as well what effect stretching the lower extremity has on the gait pattern in the elderly.

Finally there are two questions that resemble the research question. First it is interesting to find out, what is more effective in improving the gait pattern: balance training or stretching and second which one is more effective in decreasing the fall risk.

This leads to the following research question:

Research Question

Which training program is improving the gait pattern and the risk of falling more in elderly people, balance training or a stretching program?

2. Method

2.1 Search Strategy

The search in several electronic databases was performed in April 2014. The included databases were PubMed, Medline and PEDro. To obtain the latest evidence on the subject only studies that have been published between the years 2003 and 2013 were taken into account.

The search terms were first entered into PubMed using Booleans (and, or) and Medical Subject Headings (MeSH terms). Also the selection filter for full text articles was applied. Afterwards the search was adapted to the databases Medline and PEDro.

The keywords used to find the articles in combination or alone and using Booleans were namely: elderly, training program, exercise, balance, stretching, gait improvement, risk of falling. Since the search was also conducted with synonyms, Table 1 presents the used equivalents.

Table 1 Keywords and Synonyms

Search Term/Keyword	Synonym
Elderly	Older People Senior 65 and older
Mobility	Stretching
Training Program	Exercises Training Exercise Program
Balance	Equilibrium
Gait Improvement	Walking Better gait Gait Training Gait Parameters Gait Pattern
Risk of Falling	Fall Risk Falling

Specific Search Strategy used to identify relevant articles

The combination of keywords and synonyms resulted in two search strings that were used for exploring the databases. For the different databases the search strings were slightly adapted. In Appendix I the exact search strings are described.

2.2 Study Selection

After searching for studies in databases the found articles were selected starting with screening the title for the keywords and synonyms according to Table 1.

The abstracts of the selected studies were then read and inclusion and exclusion criteria, as well as keywords were applied.

Only studies that have been conducted on elderly people were included. Furthermore the studies had to be published in English and be available in full text. After the relevant articles were identified, their references were screened and the same selection procedure was applied to those articles.

Design

To maintain a high level of evidence only randomized controlled trials (RCT) and controlled clinical trials (CCT) were included in this systematic review. Since there might not have been enough studies, if exclusively RCTs were included, also CCTs were included in the search.

Population

Studies including male and/or female participants were included. Furthermore, it was obligatory that the subjects had a minimum age of 60 years. Patients did not necessarily have to experience a previous fall.

Intervention and Control Group

Studies, which conducted either a stretching or balance training program or comparing both were included. Studies that performed a strength program, other kinds of training, a combination of different kinds of exercise or multifactorial interventions were excluded.

Outcome Measures

Studies had to measure gait parameters, including preferred gait velocity, stride length and/or cadence. Gait velocity is measured in cm/s or m/s, stride length in cm or m and cadence in steps/min. Since one stride is two steps, studies that measured either step or stride length both were included. For simplicity reasons the term “stride length” was used in this review.

To be able to assess statistical significance a p-value of $p \leq 0.05$ is considered to describe a statistically significant outcome.

2.3 Assessment of Methodological Quality

Once the articles have passed the inclusion and exclusion criteria, the studies were scanned through the 10 point PEDro Score for Randomized Controlled Trials (PEDro Scale, 1999). The scale was used on RCTs and CCTs and is considered a reliable (Maher, Sherrington, Herbert, Moseley, & Elkins, 2003) and valid (de Morton, 2009) tool to assess the methodological quality of a trial.

Through this, the reader can estimate the credibility of results in comparison with other studies. A PEDro Score of 4 on a RCT was considered as “sufficient” and a score of 3 points or lower was considered as “insufficient” (van Peppen, Kwakkel, Wood-Dauphine, Hendriks, van der Wees, & Dekker, 2004). To have been able to compare all studies there was no change in the PEDro score for the use with CCTs, even though a CCT is always scoring 2 points less than an RCT. Thus in this study, for CCTs a score of 3 points was considered to be “sufficient”.

The PEDro Scores was not used as an in- or exclusion criterion, but for data-analysis and when discussing the strengths and weaknesses of this review.

The PEDro Scale is added in Appendix II.

2.4 Data Analysis

To compile the evidence on balance training and stretching a best-evidence synthesis was performed, based on the criteria by Steultjens, Dekker, Bouter, van Schaardenburg, van Kuyk, & van den Ende (2003). For the best evidence synthesis the PEDro score of the trials and the significance of their results was taken into account. Each outcome measurement has been analyzed separately.

3. Results

3.1 Result Search Strategies and Study Selection

Figure 1 represents the result of the search strategy and selection procedure. After removal of the duplicates, 125 potentially relevant articles were identified. When screening the titles another 31 were excluded and 93 studies remained. These article's abstracts were scanned and again 86 studies were excluded, 29 based on the outcome measures and 58 based on the intervention. The main reasons were that these studies did not measure gait parameters or that they carried out combined or different interventions than stretching or balance training. One study was excluded for the best-evidence synthesis, since it only carried out a long-term follow-up assessment of a trial that was already included in the analysis. This specific study was included in the interpretation of results of this review. Finally seven studies remained to be included.

The reference lists of these seven articles were then screened as well, to identify possible relevant articles, but no additional articles were found.

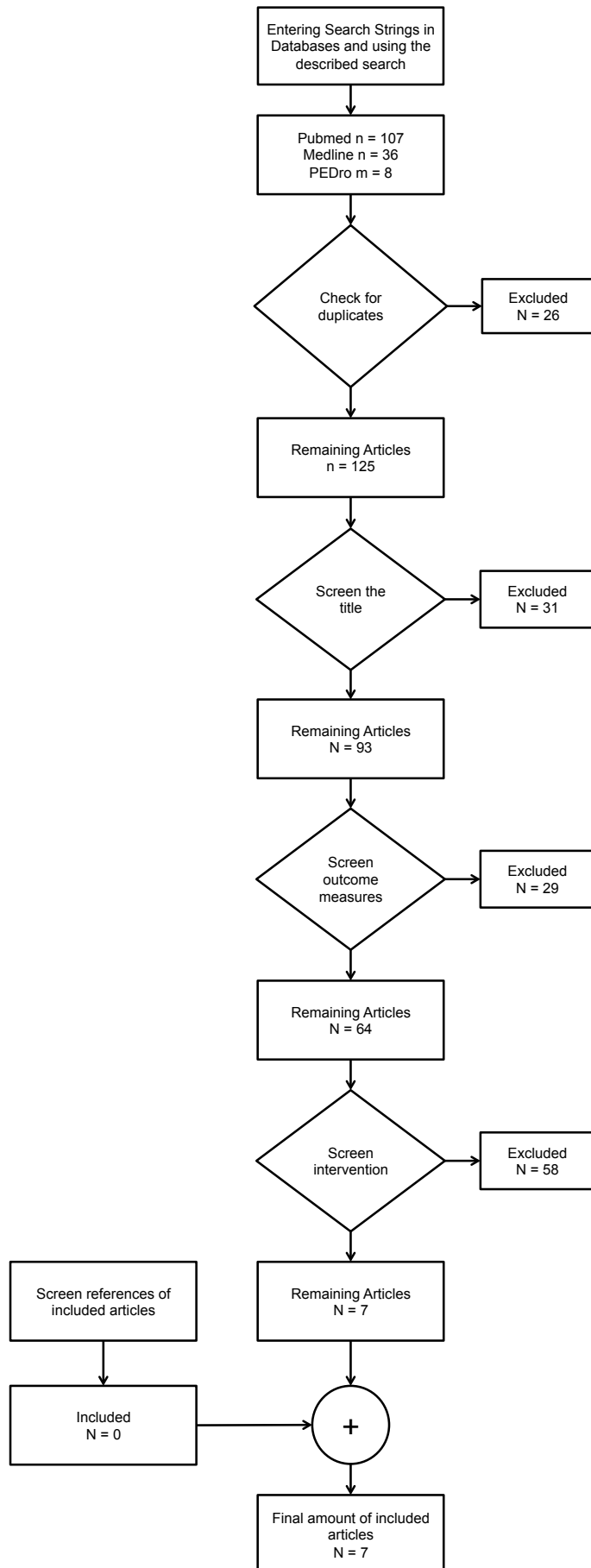


Figure 1 Flow Chart of the Selection Procedure

3.2 Results Data Extraction

Design

Seven trials were included in this systematic review (Halvarsson et al., 2011; Trombetti, Hars, Herrmann, Kressig, Ferari, & Rizzoli, 2011; Watt, Jackson, Franz, Dicharry, Evans, & Kerrigan, 2011a; Watt et al., 2011b; Rodacki et al., 2009; Cristopolski et al., 2009; Christiansen, 2008). The publication dates ranged from 2008 to 2013.

Population

The number of included participants per trial ranged from 15 to 134. In total 421 elderly people were included in this review. 89 subjects were male and 332 of female sex. The subjects' mean age was 72 years.

In all trials the baseline characteristics of the subjects were similar comparing control group with intervention group. Tables 2 and 3 show the characteristics of the participants of each study.

Table 2 Baseline Characteristics of Participants in Studies conducting a Balance Program

Author	N (I/C)	Gender	Age (years)
Halvarsson et al. 2011	59 (38/21)	Male: 17 Female: 42	Mean: 77 Range: 67 - 93
Trombetti et al. 2010	134 (66/68)	Male: 5 Female: 129	Mean: 76 SD: 7

I = Intervention Group; C = Control Group; SD = Standard deviation

Table 3 Baseline Characteristics of Participants in Studies conducting a Stretching Program

Author	N (I/C)	Gender	Age (years)
Watt et al. 2011a	82 (43/39)	Male: 25 Female: 57	Mean: 73 Range: 65 - 87
Watt et al. 2011b	74 (33/41)	Male: 34 Female: 40	Mean: 77 Range: 65 - 87
Rodacki et al. 2008	15 (15/n/a)	Male: 0 Female: 15	Mean: 65 SD: 3
Cristopolski et al. 2009	20 (12/8)	Male: 0 Female: 20	Mean: 66 SD: 4
Christiansen 2008	37 (18/19)	Male: 8 Female: 29	Mean: 72 SD: 5

I = Intervention Group; C = Control Group; SD = Standard deviation

Intervention and Control Group

The studies on balance training used either an individually adjusted, progressive and specific balance group training (Halvarsson et al., 2011) or music-based balance exercises (Trombetti et al., 2011). The duration of the program was in one study three (Halvarsson et al., 2011) and in the other six months (Trombetti et al., 2011). Furthermore the training was carried out at least once a week.

Each study conducted an assessment previous to the intervention and one assessment directly after the intervention period. The control group subjects were encouraged to continue their normal activities and were offered the same training after the follow-up assessment and thus end of the study.

Table 4 shows the details about the interventions used in studies carrying out balance training.

Table 4 Details about Intervention and Follow-up in Balance Studies

Author	Type of Intervention	Amount of sessions	Follow-Up
Halvarsson et al. 2011	Individually adjusted, progressive and specific balance group training	45 min per session 3x per week, 3 months 36 sessions	T0: before intervention T1: after 3 months
Trombetti et al. 2010	Music-based balance exercises; Group training	1x per week 60 min 6 months 24 sessions	T0: before intervention T1: after 6 months

All studies, which used a stretching intervention performed stretching programs for the hip joint and two also included the ankle joint (Cristopolski et al., 2009; Christiansen, 2008). The stretches were held between 45 and 60 seconds and repeated for two to four times per limb. Both limbs were stretched in all studies and the limbs were alternated. As for the balance studies, all stretching studies assessed the participants before and directly after completing the intervention program.

The control group subjects of two studies participated in a shoulder abductor stretching program (Watt et al., 2011a; Watt et al., 2011b), and two studies requested the control group participants to maintain their normal daily activities (Cristopolski et al., 2009; Christiansen, 2008). One study (Rodacki et al., 2008) included a “group with equivalent physical characteristics” as control group from a different study. However, this subject group participated in the same gait assessment as the intervention group. Therefore, this study is treated as a controlled clinical trial (CCT) in this study.

In Table 5 the interventions are summarized.

Table 5 Details about Intervention and Follow-up in Stretching Studies

Author	Type of Intervention	Amount of sessions	Follow-Up
Watt et al. 2011a	8 min Hip flexor stretching per day; individual	2x per day, for 10 weeks 140 sessions	T0: before intervention T1: after 10 weeks
Watt et al. 2011b	8 min Hip flexor stretching per day; Individual	2x per day, for 10 weeks 140 sessions	T0: before intervention T1: after 10 weeks
Rodacki et al. 2008	4x 60 s Hip flexor stretching; both limbs; individual	One session	T0: before stretching T1: after stretching
Cristopolski et al. 2009	Hip flexor and extensor stretching; Ankle Plantar flexor stretching; Individual	3x per week for 4 weeks 12 sessions	T0: before intervention T1: after 4 weeks
Christiansen 2008	Hip and Ankle Stretching Program; Individual	2x per day for 8 weeks 58 sessions	T0: before intervention T1: after 8 weeks

Outcome Measures

The most commonly measured outcomes in the included studies were “gait velocity”, “stride length” and “cadence” (Table 6 and Table 7). Still only four out of seven studies measured “cadence”. All studies measured “gait velocity” and “stride length”.

Table 6 Outcome Measures of Balance Studies

Author	Gait velocity	Stride length	Cadence
Halvarsson et al. 2011	P > 0.05	P > 0.05	P < 0.05
Trombetti et al. 2010	P < 0.05	P < 0.05	P > 0.05

Table 7 Outcome Measures of Stretching Studies

Author	Gait velocity	Stride length	Cadence
Watt et al. 2011a	P > 0.05	P > 0.05	P > 0.05
Watt et al. 2011b	P < 0.05	P = 0.05	P < 0.05
Rodacki et al. 2008	P < 0.05	P < 0.05	P > 0.05
Cristopolski et al. 2009	P < 0.05	P < 0.05	-
Christiansen 2008	P < 0.05	P > 0.05	-

3.3 Result Methodological Quality Assessment

The results of the methodological quality assessment of the included RCTs and CCTs according to the PEDro scale are presented in Tables 8 and 9. According to van Peppen et al. (2004) six out of seven studies have sufficient quality (Halvarsson et al., 2011; Trombetti et al., 2011; Watt et al., 2011a; Watt et al., 2011b; Cristopolski et al., 2009; Christiansen, 2008). One study scored 3 points (Rodacki et al., 2009), but since it is a CCT this is interpreted as sufficient quality in this review.

Table 8 Methodological Quality according to the PEDro Scale in Balance Studies

Author	Item	1	2	3	4	5	6	7	8	9	10	11	Total	Quality
Halvarsson et al. 2011		1	1	1	1	1	0	1	1	1	1	1	9/10	Sufficient
Trombetti et al. 2010		1	1	1	1	0	0	1	0	1	1	1	7/10	Sufficient

* This item is not used to calculate the total PEDro Score

Table 9 Methodological Quality according to the PEDro Scale in Stretching Studies

Author	Item	1	2	3	4	5	6	7	8	9	10	11	Total	Quality
Watt et al. 2011a		1	1	0	1	0	0	1	0	0	0	1	4/10	Sufficient
Watt et al. 2011b		1	1	0	1	0	0	1	0	0	0	1	4/10	Sufficient
Rodacki et al. 2008 ⁺		1	0	0	0	0	0	0	1	1	0	1	3/10	Sufficient
Cristopolski et al. 2009		1	1	0	1	0	0	0	0	1	1	1	5/10	Sufficient
Christiansen 2008		1	1	1	1	0	0	0	1	0	1	1	6/10	Sufficient

* This item is not used to calculate the total PEDro Score

⁺ Controlled Clinical Trial (CCT)

3.4 Best Evidence Synthesis

Since there was no study found, which compares the two interventions, one best evidence synthesis was done based on the studies conducting balance training and one best evidence synthesis based on the studies carrying out a stretching program.

Balance Training

Gait velocity

The two studies conducting balance training are both high quality RCTs. They both focus on “gait velocity” as a factor in improving the gait pattern of elderly. Halvarsson et al. (2011) did not find evidence that balance training significantly increases “gait velocity” whereas Trombetti et al. (2011) found a significant improvement in “gait velocity”.

This results in conflicting/insufficient evidence that balance training is increasing “gait velocity”.

Stride Length

The same applies for “stride length” increase after balance training. The study by Halvarsson et al. (2011) shows no significant difference after the intervention, but in contrary the study conducted by Trombetti et al. (2011) shows a significant increase in “stride length”.

This results in conflicting/insufficient evidence for balance training improving “stride length”.

Cadence

When analyzing the two studies concerning the measurement of “cadence”, one study (Halvarsson et al., 2011) has found significant results and the other study (Trombetti et al., 2011) has found no significant differences when comparing intervention and control group at the follow-up assessment.

There is thus conflicting/insufficient evidence that balance training can improve the gait parameter “cadence”.

Stretching Program

Gait velocity

Four of the five studies conducting a stretching training are high quality RCTs (Watt et al., 2011a; Watt et al., 2011b; Cristopolski et al., 2009; Christiansen, 2008) and one study is a high quality CCT (Rodacki et al., 2009). The studies conducted by Watt et al. (2011b), Rodacki et al. (2009), Cristopolski et al. (2009) and Christiansen (2008) reported statistically significant differences between the intervention and control groups in treatment effect. One study, carried out by Watt et al. (2011a) reported no significant differences for “gait velocity”.

This results in strong evidence that stretching increases “gait velocity”.

Stride length

Three studies (Watt et al., 2011b; Rodacki et al., 2009; Christiansen, 2008) reported a significant improvement in “stride length” after the intervention and two studies (Watt et al., 2011a; Christiansen, 2008) reported a non-significant difference in this parameter.

As for “gait velocity” the best evidence synthesis for “stride length” also results in strong evidence that a stretching program is effective.

Cadence

Since not all stretching studies measured “cadence” only three studies were applicable for the best evidence synthesis (Watt et al., 2011a; Watt et al., 2011b; Rodacki et al., 2009). One high quality RCT conducted by Watt et al. (2011b) found a significant improvement in “cadence”, whereas the other high quality RCT by Watt et al. (2011a) and the high quality CCT (Rodacki et al., 2009) did not find significant results.

Analyzing these three studies results in the evidence for a significant change in “cadence” after stretching being conflicting/insufficient.

4. Discussion

The aim of this study was to investigate whether balance training or a stretching program can improve the gait of the elderly to a higher extent.

This review could not confirm the hypothesis that balance training is improving the gait pattern of elderly people more than a stretching program. No study was found, which compares balance training with a stretching intervention, so no statement on this hypothesis can be made.

Seven studies were included in this systematic review. Six of these were randomized controlled trials (RCT) (Halvarsson et al., 2011; Trombetti et al., 2011; Watt et al., 2011a; Watt et al., 2011b; Cristopolski et al., 2009; Christiansen, 2008) and one study was a controlled clinical trial (CCT) (Rodacki et al., 2009). According to the PEDro scale and its implication in this review, all included trials are of high methodological quality. The main findings are:

- 1) There is conflicting/insufficient evidence on the effect of balance training on the parameters “gait velocity”, “stride length” and “cadence” of the human gait.
- 2) There is strong evidence for the effect of stretching on the parameters “gait velocity” and “stride length” of elderly and conflicting evidence for its effect on “cadence”. Resulting in sufficient evidence that stretching can improve the gait of the elderly.

Bridenbaugh et al. (2011) discovered that “improved gait regularity and automaticity is increasing gait safety and reducing the fall risk”. The average parameters of the human gait are a stride length of 158 cm for men and 132 cm for women; cadence is 117 steps per minute on average, and this results in a mean gait velocity of 1,54 m/s for men and 1,31 m/s for women (Murray et al., 1964; Murray et al., 1970). One can interpret improved gait regularity and thus a reduced fall risk as a change of gait parameters back to these standard values. Furthermore, gait velocity is a “sensitive indicator of health in the elderly” (Guralnik, Ferrucci, Pieper, Leveille, Markides, & Ostir, 2000) and with a slow gait speed (< 100 cm/s) the risk of falling is also higher (Verghese et al., 2009).

Even though the research question cannot be answered ultimately, several conclusions can be drawn.

Since no study was found which compares balance training and stretching, no conclusion can be made on which training is more effective in improving the gait pattern of older people and thus reduce the risk of falling. The only conclusions, which can be made, are on one hand the effects of balance training on the gait pattern and on the other hand the effect of stretching exercises on the gait pattern. In this study it was also assumed that an improved gait pattern is leading to improved gait regularity and thus to a reduced risk of falling.

The two high quality RCTs conducting balance training had directly opposite outcomes in the three gait parameters. Resulting in conflicting evidence for the improvement of the gait pattern and thus for decreasing the risk of falling in this study.

It is essential to consider that the two studies did not carry out the same training program. One study included a progressive and individually adjusted balance training (Halvarsson et al., 2011) and the other study carried out balance training based on music (Trombetti et al., 2011).

Another difference of the two trials is the percentage of participants that had already experienced a fall before. In the study by Halvarsson et al. (2011) (90%) it was higher percentage compared to Trombetti et al. (2011) (55%). However, the mean age and the higher amount of female than male subjects were similar in both trials. It is also important to consider that only two studies carried out this kind of balance training. Another study by Kyoung, Seung, & Chang (2012) combined balance training with cognitive tasks and was therefore not eligible for this review. Certainly, it does show significant differences in all three parameters, “gait velocity”, “stride length” and “cadence”.

Additionally, there is also a disparity in duration of the interventions. Halvarsson et al. (2011) executed the balance training for 12 weeks whereas Trombetti et al. (2011) conducted balance training for 6 months. The fact that the 6 month continuing training lead to significant outcomes for “gait velocity” and “stride length” in contrary to the 12 weeks lasting training, might suggest that a longer durable balance training can be more beneficial in reducing the risk of falling.

To evaluate the long-term effects Halvarsson, Franzén, Olsson, Oddsson, and Ståhle (2013) conducted several follow-up assessments based on the balance study by Halvarsson et al. (2011). They evaluated the subjects again 6 months and 1 year after the end of the intervention. The conclusion is that positive training effects began to diminish 6 months after the end of the intervention, suggesting that at this point another balance intervention might be important to maintain the positive effects of the training.

An opposite outcome is seen for stretching training. One can conclude that there is sufficient evidence that a stretching program can improve the gait pattern of elderly people and hence reduce the risk of falling. Nevertheless, there are some important issues to acknowledge when interpreting these results. First of all, there were more studies identified for stretching than for balance training, five on the contrary to two. One of these studies did not have a direct control group to their intervention, but used a “group with equivalent physical characteristics” as control group (Rodacki et al., 2008). This group underwent the same gait assessment as the intervention group. Therefore this study was treated as a controlled clinical trial in this review and was included in the methodological quality assessment and best evidence synthesis, hence, the results have to be interpreted with caution. Four studies were high quality RCTs (Watt et al., 2011a; Watt et al., 2011b; Cristopolski et al., 2009; Christiansen, 2008) and one study was a high quality CCT (Rodacki et al., 2009). The PEDro score was used in order to have a similar assessment of RCTs and CCTs. For comparability reasons the PEDro scale was not adapted to the CCT included in this research.

Secondly, there is strong evidence for two out of three parameters, namely “gait velocity” and “stride length”, that stretching can significantly improve the gait pattern. For the parameter “cadence” only conflicting evidence is found. This is partly because only three out of five studies measured cadence (Watt et al., 2011a; Watt et al., 2011b; Rodacki et al., 2009). The three studies that did include “cadence” in their measurements had opposite results. One RCT showed statistically significant

changes (Watt et al., 2011b) and the other two, one RCT and one CCT (Watt et al., 2011a; Rodacki et al., 2009) did not. This results in the evidence for stretching on “cadence” being conflicting.

Furthermore the study that conducted a stretching training and resulted in non-significant results for “gait velocity” (Watt et al., 2011a) is different comparing the participants with the study by Watt et al. (2011b). The two studies used the exact same intervention procedure, but with a different population. However, both have opposite outcomes. The study conducted on healthy elderly (Watt et al., 2011a) got no significant improvements in the gait pattern and the study that used frail elderly subjects (Watt et al., 2011b) did get significant results on the exact same parameters. This suggests that the baseline characteristics of the participants are causative for the difference in this outcome and not the intervention.

There is one factor present in all included studies, whether they used balance or stretching exercises. All studies had a higher amount of female participants. This might be due to a bigger representation of the female sex in the elderly population in general compared with the male sex (United Nations, 2001).

A pilot study by Rochat, Martin, Pilot-Ziegler, Najafi, Aminian, & Büla (2008) found that a low-intensity gait and balance program, which lasts 10 weeks results in small but significant gains in gait performance. Relating to this research, the reason balance training did not show significant improvements might be that no gait training was implemented. However, although Rochat et al. (2008) show that balance training can improve the gait pattern of elderly significantly, this stands in opposite to the present research.

Another systematic review with meta-analysis, conducted by Sherrington, Whitney, Lord, Herbert, Cumming, & Close (2008) compared RCTs that conducted exercise programs, including balance programs for elderly and focused on fall rates as outcome measurement. The authors reasoned from the meta-analysis that there is strong evidence that exercise programs can reduce the fall rate in older people. In all studies that were included an overall reduction of 17% in fall rates was seen. The researchers concluded furthermore, that it „confirms the importance of balance training in falls prevention“.

The included studies confirmed that both, balance training and stretching, are safe interventions for elderly. In all studies only one fall resulting in injury happened during the intervention (Christiansen, 2008). All other subjects did not experience a fall, fractures or any other injury during the training.

However, one has to keep in mind that four studies (Halvarsson et al., 2011; Trombetti et al., 2011; Rodacki et al., 2009; Cristopolski et al., 2009) always had supervision of the subjects when conducting the intervention. Three studies (Watt et al., 2011a; Watt et al., 2011b; Christiansen, 2008) supervised their subjects as well, but only at the first session at the laboratory and weekly or twice a week at the subject's homes, to assure that the participants carried out the stretches correctly.

Strengths of this review are for one that the focus lies on gait parameters and not on functional gait tests. This enables a different interpretation and view on risk of falling in the elderly. Another strong

point is the strict definition of inclusion and exclusion criteria in this review. This assures that only suitable trials are included in the analysis, which reduces the risk of bias.

In addition one has to acknowledge the particular focus on distinct gait parameters, which can be influenced by specific training. This is important when transferring the results of this review into physiotherapy practice.

This review also has some limitations that have to be kept in mind.

First the research question could not be answered, because there was no study identified that directly compared balance training with stretching exercises in elderly people. Thus the treatment methods can only be interpreted separately from each other and no direct conclusion is possible.

Secondly, one study that was not a true CCT was included in the results and best evidence synthesis. Therefore one has to keep that in mind and interpret the results with caution.

Thirdly, usually two or three independent researchers carry out a systematic review. This is done to get a more reliable result compared to only one researcher doing the review, as was the case in this study. This is important for the inclusion and exclusion of studies, for the data-extraction and the assessment of methodological quality of the included studies.

Fourthly, only studies that exclusively conducted balance and/or stretching training were included. This left out many trials that combined several training programs or carried out a multifactorial training.

Fifthly, there is the possibility that not all applicable studies were obtained. This is possibly due to misleading titles or different keywords than the included ones and their synonyms. Another reason can be that a relevant article was not included in the searched databases or that an article was not available in full text and thus could not be found with the used search strategy.

Several recommendations for future research can be made. To get an answer on the research question and thus be able to draw a conclusion a randomized controlled trial, which compares balance training with stretching exercises is necessary.

Secondly, more studies discussing the effects of balance training on the gait pattern are needed to clarify the momentarily conflicting and insufficient evidence.

Thirdly, it might be useful to conduct studies with a longer lasting intervention period. This can perhaps change the results in balance training since the shorter trial did not get significant outcomes.

Clinical Relevance

The fact that stretching the lower extremity can result in an improved gait pattern and reduced risk of falling can be used in daily practice physiotherapy. Elderly people can be guided in stretching training, if they have a higher risk of falling. It is an inexpensive method and people can be instructed either individually or in a group course. It does not take much time (about 4 - 9 min a day) and can lead to a significant reduction of their fall risk.

5. Conclusion

Due to the absence of a suitable article, the question, whether balance training or stretching is improving gait and thus decreasing the fall risk in elderly people to a higher extent, cannot be answered. Nevertheless, this review gives two other important conclusions.

1) There is conflicting/insufficient evidence on the effect of balance training on the parameters “gait velocity”, “stride length” and “cadence” of the human gait. Therefore, there is not sufficient evidence that balance training can reduce the risk of falling in the elderly through changes in gait.

2) There is strong evidence for the effect of stretching on the parameters “gait velocity” and “stride length” of the human gait and conflicting evidence for its effect on “cadence”. Therefore, there is sufficient evidence that stretching training can have a positive effect on the risk of falling in the elderly. However, no direct evidence was found in this systematic review.

6. References

- Barak, Y., Wagenaar, R. C., & Holt, K. C. (2006). Gait characteristics of elderly people with a history of falls: a dynamic approach. *Physical Therapy* , 1501-1510.
- Bridenbaugh, S. A., & Kressig, R. W. (2011). Laboratory review: the role of gait analysis in seniors' mobility and fall prevention. *Gerontology* , 256-264.
- Christiansen, C. L. (2008). The Effects of Hip and Ankle Stretching on Gait Function of Older People. *Archives of Physical Medicine and Rehabilitation* , 1421-1428.
- Cristopolski, F., Barela, J. A., Leite, N., Fowler, N. E., & Rodacki, A. L. (2009). Stretching exercise program improves gait in the elderly. *Gerontology* , 614-20.
- de Morton, N. A. (2009). The PEDro scale is a valid measure of the methodological quality of clinical trials: a demographic study. *Australian Journal of Physiotherapy* , 129-133.
- Feland, J. B., Myrer, J. W., Schulthies, S. S., Fellingham, G. W., & Measom, G. W. (2001). The effect of duration of stretching of the hamstring muscle group for increasing range of motion in people aged 65 years or older. *Physical Therapy* , 1110-1117.
- Guralnik, J. M., Ferrucci, L., Pieper, C. F., Leveille, S. G., Markides, K. S., & Ostir, G. V. (2000). Lower extremity function and subsequent disability: consistency across studies, predictive models, and value of gait speed alone compared with the short physical performance battery. *The journals of gerontology. Series A, Biological sciences and medical sciences.* , M221-M231.
- Halvarsson, A., Franzén, E., Olsson, E., Oddsson, L., & Ståhle, A. (2013). Long-term effects of new progressive group balance training for elderly people with increased risk of falling – a randomized controlled trial. *Clinical Rehabilitation* , 450-458.
- Halvarsson, A., Olsson, E., Farén, E., Pettersson, A., & Ståhle, A. (2011). Effects of new, individually adjusted, progressive balance group training for elderly people with fear of falling and tend to fall: a randomized controlled trial. *Clinical rehabilitation* , 1021-1031.
- Jacobson, B. H., Thompson, B., Wallace, T., Brown, L., & Rial, C. (2011). Independent static balance training contributes to increased stability and functional capacity in community-dwelling elderly people: a randomized controlled trial. *Clinical rehabilitation* , 549-556.
- Kimura, T., Kobayashi, H., Nakayama, E., & Hanaoka, M. (2007). Effects of aging on gait patterns in the healthy elderly. *Anthropological Science* , 67-72.
- Knudson, D. (2006). The Biomechanics of Stretching. *Journal of Exercise Science & Physiotherapy* , 3-12.
- Kyoung, J. L., Seung, S. S., & Chang, H. S. (2012). The Effect of Biofeedback-based Balance Training while Performing Cognitive Tasks on Temporal and Spatial Parameters and Gait Stability of the Elderly. *Journal of Physical Therapy Science* , 645-649.
- Maher, C. G., Sherrington, C., Herbert, R. D., Moseley, A. M., & Elkins, M. (2003). Reliability of the PEDro Scale for Rating Quality of Randomized Controlled Trials. *Physical Therapy* , 713-721.
- Melzer, I., & Oddsson, L. L. (2013). Improving balance control and self-reported lower extremity function in community-dwelling older adults: a randomized control trial. *Clinical rehabilitation* , 195-206.

- Miguez, J., Guimaraes, N., Tarso de, P., & Farinatti, V. (2005). Descriptive analysis of variables theoretically associated to the risk of falls in elder women. *Revista brasileira de medicina do esporte* , 299-305.
- Murray, M. P., Drought, A. B., & Kory, R. C. (1964). Walking patterns of normal men. *Journal of Bone & Joint Surgery* , 335-360.
- Murray, M. P., Kory, R. C., & Sepic, S. B. (1970). Walking patterns of normal women. *Archives of Physical Medicine and Rehabilitation* , 637-650.
- Rochat, S., Martin, E., Pilot-Ziegler, C., Najafi, B., Aminian, K., & Büla, C. J. (2008). Falls self-efficacy and gait performance after gait and balance training in older people. *Journal of the American Geriatrics Society* , 1154-1156.
- Rodacki, A. L., Souza, R. M., Ugrinowitsch, C., Cristopolski, F., & Fowler, N. E. (2009). Transient effects of stretching exercises on gait parameters of elderly women. *Manual therapy* , 167-172.
- PEDro Scale. (1999, June 21). *Physiotherapy Evidence Database*. Retrieved January 07, 2014, from Physiotherapy Evidence Database: <http://www.pedro.org.au/english/downloads/pedro-scale/>
- Sherrington, C., Whitney, J. C., Lord, S. R., Herbert, R. D., Cumming, R. G., & Close, J. C. (2008). Effective Exercise for the Prevention of Falls: A Systematic Review and Meta-Analysis. *Journal of the American Geriatrics Society* , 2234-2243.
- Spiriduso, W. W., Francis, K., & MacRae, P. (2005). *Physical Dimensions of Ageing 2nd Edition*. Champaign, Illinois, United States of America: Human Kinetics Pub Inc.
- Steultjens, E. M., Dekker, J., Bouter, L. M., van Schaardenburg, D., van Kuyk, M.-A. H., & van den Ende, C. H. (2003). Occupational Therapy for Rheumatoid Arthritis: A Systematic Review. *Arthritis & Rheumatism* , 672-685.
- Sturnieks, D. L., St George, R., & Lord, S. R. (2008). Balance disorders in the elderly. *Neurophysiologie clinique = Clinical neurophysiology* , 467-478.
- Sutherland, D. H., Olshen, R. A., Biden, E. N., & Wyatt, M. P. (1988). *The development of mature walking*. Philadelphia: J.B. Lippincott.
- Tinetti, M. E., & Kumar, C. (2010). The patient who falls: "It's always a trade-off". *Journal of the American Medical Association* , 258-266.
- Trombetti, A., Hars, M., Herrmann, F. R., Kressig, R. W., Ferari, S., & Rizzoli, R. (2011). Effect of Music-Based Multitask Training on Gait, Balance, and Fall Risk in Elderly People. *Archives of Internal Medicine* , 525-533.
- United Nations, (2001). *World Population Ageing: 1950-2050*. New York: United Nations Publications.
- van Peppen, R., Kwakkel, G., Wood-Dauphine, S., Hendriks, H., van der Wees, P., & Dekker, J. (2004). The impact of physical therapy on functional outcomes after stroke: what's the evidence? *Clinical Rehabilitation* , 833-862.
- Verghese, J., Holtzer, R., Lipton, R. B., & Wang, C. (2009). Quantitative gait markers and incident fall risk in older adults. *The journals of gerontology. Series A, Biological sciences and medical sciences* , 896-901.

Watt, J. R., Jackson, K., Franz, J. R., Dicharry, J., Evans, J., & Kerrigan, D. C. (2011a). Effect of a Supervised Hip Flexor Stretching Program on Gait in Elderly Individuals. *Physical Medicine and Rehabilitation* , 324-329.

Watt, J. R., Jackson, K., Franz, J. R., Dicharry, J., Evans, J., & Kerrigan, D. C. (2011b). Effect of a supervised hip flexor stretching program on gait in frail elderly patients. *PM & R : the journal of injury, function, and rehabilitation* , 330-335.

World Health Organization, (2007). *WHO Global Report on Falls Prevention in Older Age WHO Global Report on Falls Prevention in Older Age*. Geneva: World Health Organization.

7. List of tables

Table 1 Keywords and Synonyms	8
Table 2 Baseline Characteristics of Participants in Studies conducting a Balance Program	13
Table 3 Baseline Characteristics of Participants in Studies conducting a Stretching Program	13
Table 4 Details about Intervention and Follow-up in Balance Studies.....	14
Table 5 Details about Intervention and Follow-up in Stretching Studies	15
Table 6 Outcome Measures of Balance Studies	16
Table 7 Outcome Measures of Stretching Studies	16
Table 8 Methodological Quality according to the PEDro Scale in Balance Studies	16
Table 9 Methodological Quality according to the PEDro Scale in Stretching Studies	16

8. List of figures

Figure 1 Flow Chart of the Selection Procedure	12
--	----

9. Appendices

Appendix I: Search Strings

Pubmed
(Physiotherapy OR physical therapy OR treatment) AND (aged [MeSH]) AND (postural balance [MeSH]) AND (Training program OR Exercise OR training OR exercise program) AND (Gait improvement OR Gait [MeSH] OR walking OR better gait OR gait training OR gait parameters OR gait pattern) AND (accidental falls [MeSH] OR Risk of falling OR falling)
(Muscle Stretching Exercises [MeSH] AND (Gait [MeSH]) AND (aged [MeSH])
Medline
(Physiotherapy OR physical therapy OR treatment) AND MH aged AND (training program OR exercise OR training OR exercise program) AND (gait improvement OR MH "Gait" OR walking OR better gait OR gait training OR gait parameters OR gait pattern) AND MH accidental falls AND (risk of falling OR falling)
(MH "Muscle stretching exercises") AND (MH "gait") AND (MH "aged")
PEDro
(Physiotherapy OR physical therapy OR treatment) AND (Aged OR Elderly) AND (training program OR Exercise OR training OR Exercise program) AND (gait improvement OR gait OR walking OR better gait OR gait training OR gait parameters OR gait pattern) AND (falls OR risk of falling or falling)
Stretching AND gait AND elderly

Appendix II: PEDro Scale**PEDro scale**

1. eligibility criteria were specified	no ☐ yes ☐ where:
2. subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	no ☐ yes ☐ where:
3. allocation was concealed	no ☐ yes ☐ where:
4. the groups were similar at baseline regarding the most important prognostic indicators	no ☐ yes ☐ where:
5. there was blinding of all subjects	no ☐ yes ☐ where:
6. there was blinding of all therapists who administered the therapy	no ☐ yes ☐ where:
7. there was blinding of all assessors who measured at least one key outcome	no ☐ yes ☐ where:
8. measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	no ☐ yes ☐ where:
9. all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by "intention to treat"	no ☐ yes ☐ where:
10. the results of between-group statistical comparisons are reported for at least one key outcome	no ☐ yes ☐ where:
11. the study provides both point measures and measures of variability for at least one key outcome	no ☐ yes ☐ where:

The PEDro scale is based on the Delphi list developed by Verhagen and colleagues at the Department of Epidemiology, University of Maastricht (Verhagen AP *et al* (1998). *The Delphi list: a criteria list for quality assessment of randomised clinical trials for conducting systematic reviews developed by Delphi consensus. Journal of Clinical Epidemiology*, 51(12):1235-41). The list is based on "expert consensus" not, for the most part, on empirical data. Two additional items not on the Delphi list (PEDro scale items 8 and 10) have been included in the PEDro scale. As more empirical data comes to hand it may become possible to "weight" scale items so that the PEDro score reflects the importance of individual scale items.

The purpose of the PEDro scale is to help the users of the PEDro database rapidly identify which of the known or suspected randomised clinical trials (ie RCTs or CCTs) archived on the PEDro database are likely to be internally valid (criteria 2-9), and could have sufficient statistical information to make their results interpretable (criteria 10-11). An additional criterion (criterion 1) that relates to the external validity (or "generalisability" or "applicability" of the trial) has been retained so that the Delphi list is complete, but this criterion will not be used to calculate the PEDro score reported on the PEDro web site.

The PEDro scale should not be used as a measure of the "validity" of a study's conclusions. In particular, we caution users of the PEDro scale that studies which show significant treatment effects and which score highly on the PEDro scale do not necessarily provide evidence that the treatment is clinically useful. Additional considerations include whether the treatment effect was big enough to be clinically worthwhile, whether the positive effects of the treatment outweigh its negative effects, and the cost-effectiveness of the treatment. The scale should not be used to compare the "quality" of trials performed in different areas of therapy, primarily because it is not possible to satisfy all scale items in some areas of physiotherapy practice.

Last amended June 21st, 1999

Notes on administration of the PEDro scale:

All criteria	<u>Points are only awarded when a criterion is clearly satisfied.</u> If on a literal reading of the trial report it is possible that a criterion was not satisfied, a point should not be awarded for that criterion.
Criterion 1	This criterion is satisfied if the report describes the source of subjects and a list of criteria used to determine who was eligible to participate in the study.
Criterion 2	A study is considered to have used random allocation if the report states that allocation was random. The precise method of randomisation need not be specified. Procedures such as coin-tossing and dice-rolling should be considered random. Quasi-randomisation allocation procedures such as allocation by hospital record number or birth date, or alternation, do not satisfy this criterion.
Criterion 3	<i>Concealed allocation</i> means that the person who determined if a subject was eligible for inclusion in the trial was unaware, when this decision was made, of which group the subject would be allocated to. A point is awarded for this criteria, even if it is not stated that allocation was concealed, when the report states that allocation was by sealed opaque envelopes or that allocation involved contacting the holder of the allocation schedule who was “off-site”.
Criterion 4	At a minimum, in studies of therapeutic interventions, the report must describe at least one measure of the severity of the condition being treated and at least one (different) key outcome measure at baseline. The rater must be satisfied that the groups’ outcomes would not be expected to differ, on the basis of baseline differences in prognostic variables alone, by a clinically significant amount. This criterion is satisfied even if only baseline data of study completers are presented.
Criteria 4, 7-11	<i>Key outcomes</i> are those outcomes which provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.
Criterion 5-7	<i>Blinding</i> means the person in question (subject, therapist or assessor) did not know which group the subject had been allocated to. In addition, subjects and therapists are only considered to be “blind” if it could be expected that they would have been unable to distinguish between the treatments applied to different groups. In trials in which key outcomes are self-reported (eg, visual analogue scale, pain diary), the assessor is considered to be blind if the subject was blind.
Criterion 8	This criterion is only satisfied if the report explicitly states <i>both</i> the number of subjects initially allocated to groups <i>and</i> the number of subjects from whom key outcome measures were obtained. In trials in which outcomes are measured at several points in time, a key outcome must have been measured in more than 85% of subjects at one of those points in time.
Criterion 9	An <i>intention to treat</i> analysis means that, where subjects did not receive treatment (or the control condition) as allocated, and where measures of outcomes were available, the analysis was performed as if subjects received the treatment (or control condition) they were allocated to. This criterion is satisfied, even if there is no mention of analysis by intention to treat, if the report explicitly states that all subjects received treatment or control conditions as allocated.
Criterion 10	A <i>between-group</i> statistical comparison involves statistical comparison of one group with another. Depending on the design of the study, this may involve comparison of two or more treatments, or comparison of treatment with a control condition. The analysis may be a simple comparison of outcomes measured after the treatment was administered, or a comparison of the change in one group with the change in another (when a factorial analysis of variance has been used to analyse the data, the latter is often reported as a group $\times$ time interaction). The comparison may be in the form hypothesis testing (which provides a “p” value, describing the probability that the groups differed only by chance) or in the form of an estimate (for example, the mean or median difference, or a difference in proportions, or number needed to treat, or a relative risk or hazard ratio) and its confidence interval.
Criterion 11	A <i>point measure</i> is a measure of the size of the treatment effect. The treatment effect may be described as a difference in group outcomes, or as the outcome in (each of) all groups. <i>Measures of variability</i> include standard deviations, standard errors, confidence intervals, interquartile ranges (or other quantile ranges), and ranges. Point measures and/or measures of variability may be provided graphically (for example, SDs may be given as error bars in a Figure) as long as it is clear what is being graphed (for example, as long as it is clear whether error bars represent SDs or SEs). Where outcomes are categorical, this criterion is considered to have been met if the number of subjects in each category is given for each group.