Fontys Paramedic University of Applied Sciences
Physiotherapy English Stream

The effect of interventions in reducing sedentary time in adults with a non-communicable disease
– A systematic review

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Preface

The following report is going to investigate the effect of interventions focusing on aiming to reduce
sedentary behavior in patients with a non-communicable disease, through the comparison of different literature studies the objective is to discover the most effective manner of therapy.

I favored this subject because sedentary behavior is becoming all the more popular, and yet many of us nowadays are unaware of the consequences of this type of demeanor. Prior to reading the project proposal I wasn’t aware of the exact meaning of sedentary behavior. Along with sedentary behavior, I wasn’t quite certain what non-communicable disease defined also. As I progressed with my literature study and deepened my knowledge into both topics, my curiosity increased tremendously. This subject is crucially important because it affects many people around the globe. Currently, our world is developing and we seem to become all the more dependent on our chair, therefore I believe this topic is really valuable and awareness of the aftermaths should be spread so that it is largely understood.

Furthermore, in my clinical affiliations I have met plenty of patients with chronic illnesses whom I believe could certainly benefit from increased physical activity levels. Therefore, it is very interesting to read about interventions which aim to reduce sedentariness. As a future physiotherapist it would be useful to implement this information into clinical practice. Hopefully, in the future health care professionals can use effective techniques to reducing sitting time, resulting in a better health care.

Looking back, I can say that have learned and developed very much through writing this research report. I have not experienced writing a literature study in this magnitude before. Along the way, I came across with several obstacles. Commencing with finding a legitimate research question, finding the right literature and then properly interpreting them in order to correctly transform them into this research report. Thankfully, due to clear feedback, explanation and support given by my tutor, Roderick Wondergem the outcome of this report was realized. I would like to show my appreciation for his help and support. Additionally, I would like to thank my friends Melanie Hendriks , Roy Pieper, and Alexandra Fisher, for help and support that they provided during the process of this research project.

*Julia Agmon,*

*May 2016, Maastricht.*
Abstract

Problem definition. Chronic diseases are accountable for the leading cause of mortality on the globe. Non-communicable disease (NCD) – a type of chronic illness – causes burden on multiple levels, ranging from personal to economical strain, resulting in immense number deaths annually. Dominant causes of NCD are physical inactivity as well as the execution of sedentary behavior (SB). Patients with chronic illnesses often live a sedentary lifestyle. Given the impact of this demeanor, research for effective interventions is of considerable public significance. Objective. This study aimed to unfold the effectiveness of interventions focusing to reduce sedentary behavior in patients with a non-communicable disease. Method. This literature study searched for randomized controlled trials and controlled clinical trials on scientific database PubMed. Studies were only included when subjects had a certain type of NCD, aimed to reduce SB, written in English and Dutch, if they were published between 2006 and 2016. Medical Subject Headings (MeSH-terms) and keywords, including synonyms were used for inquiry. The Physiotherapy Evidence Database Scale (PEDro-scale) was used to assess the methodological quality. The results were valued by the use of a best evidence synthesis (BES). The BES was applied three times, once for each type of NCD of the involved articles. Results. This systematic review included six randomized controlled trials. Sedentary behavior was objectively measured in every study. The studies included the following NCDs: DM type II, Chronic Obstructive Pulmonary Disease (COPD), stroke patients. In all studies but one, the amount of time sitting was measured as a primary outcome. Altogether, 324 participants were included. The interventions applied to different kinds of NCDs were evaluated. Best-evidence synthesis results provided most effectiveness concerning interventions applied to Diabetes Mellitus type II (DM type II) patients. No or insufficient evidence of the effectiveness was found for the interventions that were implemented in literature investigating reduction in SB time in COPD and stroke. Conclusion. Interventions applied into studies investigating SB in DM type II patients are most effective. The interventions include counseling together with an objective motivational tool, pedometer. In the future, multiple randomized controlled trials with larger populations are needed. Additionally, studies of high quality are needed to provide high quality evidence on the most effective intervention to reduce SB in patients with a NCD, preferably including a greater variety in types of NCDs, aiming to sustain long term positive effects on reduced sedentary behavior.

Keywords: Non-communicable disease (NCD) · Sedentary behavior (SB) · systematic review
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</table>
Introduction

A hominid condition that shows persistent aftermaths that come with time is also known as a chronic condition or disease. Commonly the phrase *chronic* administers to the duration of the disease persisting more than three months. Of all deaths, 60% is the repercussion of chronic disease. Numerous examples of chronic illnesses are: heart disease, stroke, cancer, chronic respiratory diseases, diabetes, and viral diseases like hepatitis C and HIV/AIDS. All these are accountable for the leading cause of mortality on earth. The number of people dying due to a chronic disease in 2005 was 35 million, half of this population was below the age of 70 years.¹

Mentioned above are examples of chronic illnesses. There is a certain type of chronic illness which isn’t transmitted from one individual to another. This type is also known as a non-communicable disease (NCD). The duration of a NCD is prolonged and ordinarily it advances calmly. The four major types of NCDs are cardiovascular illnesses (heart attacks and stroke), cancers, chronic respiratory diseases such as asthma and COPD, diabetes. Approximately 38 million people die annually due to a NCD. If the main types of NCDs would be ranked in order with the highest fatality rate, the initial number is cardiovascular disease, accounting 17.5 million deaths, pursued by cancer accounting 8.2 million deaths, respiratory conditions accounting for 4 million deaths, and diabetes accounting for 1.5 million deaths.²

Beyond the manifold consequences of chronic illnesses and NCDs on a personal level, it causes a burden on multiple planes. The World Economic Forum considers chronic illnesses to be a major risk to the global economy.³ Chronic illnesses foster humongous economical overburden, causing tremendous amounts of health care expenses. 312.6 billion dollars is what it costs America as a result of cardiovascular disease and stroke costs in 2009. Another example is, for stroke alone there is an approximation of 2-4% of total health care costs consumed in the United States of America.⁴

Being aware of the financial aspects and prevalence of chronic illnesses, risk factors of NCDs will be described. All countries and all age categories are fragile to risk factors that commit to NCDs. Several examples of such risk factors are: unsound diets, exposure to tobacco smoke, and physical inactivity. The World Health Organization (WHO) states that physical inactivity is a considerable independent and modifiable risk factor for NCDs.⁵

One dominant cause of NCDs mentioned above is physical inactivity. Physical inactivity is the ⁴th leading risk factor for global mortality which leads to about 3.2 mortalities, physical inactivity attributes to 6-10% of deaths caused by NCDs.⁶⁻⁷ Physical activity (PA) is described as each bodily movement formed by skeletal muscles that require energy expenditure. There is plenty of literature available about PA. However, it is not always clearly defined what the different types of PA imply. PA can be classified as a low, moderate, or high level, defined by the Global Physical Activity Questionnaire (GPAQ) analysis framework.⁵ GPAQ is developed by the WHO for PA surveillance and is supported by literature as a valid, reliable and adaptable tool, see table 1 in appendix i.⁵
In a study by Hildebrandt V.H et al., physical inactivity is defined as spending less than 30 minutes in moderate PA level at any day of the week during winters and summers. Routine moderate intensity of physical activity such as walking, has significant advantages for our health. People who are engaged in routine physical activity condense incidence of chronic illness and premature death.

Compared with physical inactivity, there is another common independent risk factor for having a NCD. This is the execution of sedentary (sitting) behavior (SB). SB applies to activities that don’t increase energy expenditure fundamentally above the resting level and cover all activities like sitting, lying down, sleeping, watching television, and other styles of screen-based entertainment. Practically, SB consists of activities which involve energy expenditure at the level of 1.0 – 1.5 metabolic equivalent units (METs). The MET concept is explained as a practical and simple procedure to express energy cost of PAs as a multiple of the resting metabolic rate. One MET is the energy cost of resting quietly. Commonly clustered with SB is light physical activity, but it is in fact a discriminatory activity construct, involves energy expenditure at the level of 1.6 – 2.9 METs. Recent evidence indicates that SB is unfavorably associated with health outcomes, including NCDs such as type 2 diabetes and all-cause mortality.

Human beings were created to engage in movement, and yet in the present-day world, from all activities together we execute SB. According to the WHO, 60 – 85% of the population leads a sedentary lifestyle. Currently sedentary lifestyle consequents in being one of the more deliberate public health complications. This chair depending behavior contributes to the continually increasing epidemic of chronic illnesses witnessed within modern ambiances stated by a study by Henson et al.

To scale down the impact of NCDs on a primary and secondary prevention level, it is key to handle it with a holistic approach that connects individual, social and economical determinants of health. To name an example to clarify the relevance of secondary prevention: once a patient suffers a cardiovascular illness like stroke there is an accumulated risk on suffering a recurrent stroke. On average in 50% of the people having any kind of previous vascular event, secondary stroke occurs. Forbye, the rate of fatality enhances even more than in a patient that has a stroke for the first time. Subsiding the amount SB is an example of such a prevention tactic, reduction in SB is linked with health benefits.

Raised awareness of the benefits of reduction in SB, should stimulate health care professionals to use an improved approach for secondary prevention for patients with a NCD. This will support a decrease in the worsening of the patient’s current condition. Additionally, it will diminish the risk of having other chronic illnesses. Physical therapy performs a crucial role when it comes to prevention and rehabilitation of the four main NCDs. Physical therapists are well aware of the humonous importance of PA for these patients. Physiotherapists play an essential part in promoting health, preventing disease along with improving and maintaining PA, movement potential and functional independence. Evidence should demonstrate the effectiveness of physiotherapy interventions. Mentioning the information indicates the importance of physiotherapists influencing behavior of these chronic ill patients.

Valuable health care is compulsory with the intention to prevent worsening of consequences of NCD on the patient and to decrease risk factors for other chronic illnesses. Having collected the information mentioned above, it emphasizes the importance of interventions which are needed to support secondary
prevention of NCDs. However, there is a lack of understanding what the effect is of interventions which focus on reducing sedentary behavior in patients with a NCD. Thus this study will mainly focus on patients with NCDs and their sedentary behavior. Having clear understanding about the effect of interventions focusing on sedentary behavior in NCD patients, will enable health care professionals to have clearer (and more evidence based) guidelines leading to a worthier health care in the future. This systematic review aims to answer the following question: What is the effect of interventions focusing on reducing sedentary time (ST) in patients with a non-communicable disease?
Method

Inclusion and exclusion criteria.
Studies needed to meet the following in- and exclusion criteria. Included will be randomized controlled trials (RCTs) and Controlled Clinical trials (CCTs) that investigated NCD patients and interventions aimed to reduce ST. Merely studies of adult populations with a chronic illness in the age range 18 and older were included. Purely studies in English or Dutch were obtained. Solely studies were included that were published in the period of 2006 until 2016, in order to acquire the most recent evidence. Studies that involve SB in healthy populations were excluded. Furthermore, literature including subjects below the age of 18 have been ruled out.

Search strategy.
The literature search for this systematic review was executed between February 2016 and April 2016. The digital scientific database that was used in order to obtain the available literature was PubMed. The search terms were compiled according to the research question. Search terms that were involved in the search strategy: sedentary and chronic illness. In order to obtain the maximum amount of articles related to the key words, synonyms were used. Therefore, the synonyms of the key words were also recorded in the search syntax. Besides the primary key words, Medical Subject Headings (MeSH-terms) were used. Keywords were used in several orders combined with the words AND and OR. There was searched for full text, when it was unavailable further retrieving was executed through bieb.nu in order to obtain the article’s full text. A full search syntax can be found in the appendix II.

Selection procedure.
The selection procedure was implemented by one reviewer. The selection was divided in three distinctive forms while taking in- and exclusion criteria into consideration. Foremost, the titles of all obtained articles were analyzed based on the topic. Articles that made headway to the following screening phase, were assessed on their abstract. Decisively, the acquired studies based upon abstract were screened through reviewing full text articles. Ultimately, screening of the attained articles regarding relevant publications was performed to assess whether or not they could be included furthermore.

Quality assessment.
The included studies were graded on methodological quality, by means of the ‘Physiotherapy Evidence Database Scale’ (PEDro-scale). The PEDro-scale is a valid, reliable and international apparatus used to evaluate the methodological quality of RCTs which is significant in physical therapy. The scale consists of 11 criteria wherein a RCT can be gauged. All 11 criteria of the scale were examined by a scoring system ranging from 0 – 10 in outcome. The number closer to a 10 indicated a very good score meaning a high quality, the lower the number the lesser the quality of the RCT. The outcome of the total score, indicated a certain quality of the study, the higher the number the higher the quality, and vice versa. The PEDro-scale will be found in appendix I.²⁰

Data extraction.
A data-extraction table was used to provide all relevant information of the diverse studies that were derived.
The table included diverse aspects and a few examples are: the kind of study (study design), year of publication, span of ST, study population, author, measurement tools.

**Data analysis.**

Due to the diversity of the outcome measurements and the types of interventions, it was impossible to apply statistical pooling on the outcomes of the included RCTs. For this literature review, a best-evidence synthesis (BES)\textsuperscript{19} has been executed. Because this literature study consisted out of three main types of NCDs, the BES has been employed for a total of three times. Through the three synthesizes, the aim was to analyze and collate the outcomes of the interventions of the various included literature, in order to determine extent of evidence of the diverse interventions. This BES-list is based upon the five phases according to Tulder et al.\textsuperscript{21-22} The BES tool evaluated the evidence from “strong” to “no” or “insufficient” evidence (table 2).

**Table 2. Best-Evidence Synthesis List (BES-list) by ‘van Peppen et al.’ \textsuperscript{19}**

| Strong evidence | Provided by statistically significant findings in outcome measures in  
<table>
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<tbody>
<tr>
<td></td>
<td>• at least two high-quality RCTs, with PEDro scores of at least 4 points\textsuperscript{a}</td>
</tr>
</tbody>
</table>

| Moderate evidence | Provided by statistically significant findings in outcome measures in  
|---|---|
| | • at least one high-quality RCT  
| | • at least one low-quality RCT (≤ 3 points on PEDro) or one high-quality CCT\textsuperscript{b} |

| Limited evidence | Provided by statistically significant findings in outcome measures in  
|---|---|
| | • at least one high-quality RCT or  
| | • at least two high-quality CCTs\textsuperscript{c} (in the absence of high-quality RCTs) |

| Indicative findings | Provided by statistically significant findings in outcome measures in at least  
|---|---|
| | • one high-quality CCT or low-quality RCTs\textsuperscript{c} (in the absence of high-quality RCTs), or  
| | • two studies of a non-experimental nature with sufficient quality (in absence of RCTs and CCTs)\textsuperscript{d} |

| No or insufficient evidence |  
|---|---|
| | • In the case that results of eligible studies do not meet the criteria for one of the above stated levels of evidence, or  
| | • in the case of conflicting (statistically significant positive and statistically significant negative) results among RCTs and CCTs, or  
| | • in the case of no eligible studies |

\textsuperscript{a}If the number of studies that show evidence is < 50% of the total number of studies found within the same category of methodological quality and study design (RCT, CCT or non-experimental studies), no evidence will be classified.
Results

Selection procedure
The commencing search in PubMed yielded 1077 articles. Firstly, the attained articles were screened based solely upon their title, thereby 801 studies have been excluded. The articles were exclusively omitted due to the in- and exclusion criteria. Subsequently, the remaining 276 articles have been screened based on their abstract, which decreased the number of remaining articles to 24. Additionally, of these 24 articles 16 articles were excluded due to their outcome. Two articles were eliminated because no full text was available. The aim of this literature study was to review studies that included subjects with a NCD and must have had the aim to decrease the amount of SB. Therefore, outright 18 articles were excluded during the final stage of the selection procedure. No studies were added via the snowball method. Thence, this finalizes the selection procedure with six articles that conformed the inclusion criteria. The selection procedure is orderly displayed in a flowchart (figure 1).

Figure 1. Flowchart selection procedure.
General study characteristics
The six included studies were published between February 2010 and February 2016. All studies included subjects that had a NCD. Three yielded articles studied subjects with COPD. Two out of the six comprised articles investigated SB in patients with T2DM and one of the admitted studies investigated the time spent sedentarily in stroke survivors. The studies were executed in the following countries: Australia, Belgium, Portugal, United States of America (USA), and Japan. All studies were written in English. The total amount of participants which of the included articles is a total of 324. Of these 324 subjects, 253 subjects are included in the analysed study population.

The total amount of interventions that took place for the IG and CG was 17, which consisted out of seven distinct interventions. Interventions were composed of counseling (n=5), studies operated with a pedometer as a motivational tool (n=4). Furthermore, interventions inhaled pulmonary rehabilitation (PR) (n=2), placebo message counseling (n=1), health education (n=1), chair exercises (n=1), and usual care (n=4). Five out of the six studies had a combination of the interventions implemented, whereas one study mainly focused on the counselling aspect. Even though there is overlap between the included articles, yet comparisons are present. Counseling which was applied to five studies, differed in duration ranging from 7 to 24 weeks. Also the manner in which counseling was applied varied. De Greef et al. applied five cognitive behavioral group sessions (± 90 min./session) combined with a pedometer. The second included study of de Greef et al. applied counseling through one session face-to-face and the remaining counseling sessions through telephone (7 calls in total, ±20 min./call), the intervention was combined with a pedometer. Cruz et al. implemented PA-focused behavioral intervention based on Social Cognitive Theory (session of 20-30 min./each) for three months during PR and three months after PR completion along with a pedometer. English et al. implemented four counseling sessions with the message to sit less and move more. The first session was face-to-face; the remaining sessions were delivered by phone. Larson et al. investigated into a self-efficacy enhancing intervention, consisting out of 16 sessions (15 min. each) combined with upper body resistance training (UBR). Kawagoshi et al. had an intervention group (IG) which received PR and a pedometer. For control groups (CGs) in the included studies, in all but two, usual care was implemented. English et al. included an attention-matched CG, composed out of four sessions with a placebo message: increasing calcium for bone health, for this group data of a food frequency questionnaire was collected. Larson et al. included two different CGs, both received one educational session combined with either UBR or gentle chair exercises. These data are provided in the descriptive data table 4.

In all six included studies the amount of SB was measured in an objective manner. One study measured SB, also subjectively with a questionnaire (IPAQ). The aggregation of ST was measured in five admitted studies as a primary outcome, all of these five also had PA as a primary outcome. In one included article the amount of ST was a secondary outcome measurement. Commonly, all six articles used the unit: minutes per day (min./day) for the time spent sitting. English, et al. differentiated between total sitting time and sitting time in accumulated bouts ≥ 30 minutes. The manner in which sitting time was described varied slightly between articles, even so, concurrently in the articles itself. The outcome was either described as: sedentary time, sedentary behavior, sedentary activities, or sitting time. Besides the sitting time as a primary or secondary outcome, there were other outcome measurements. Nevertheless, these outcome measurements didn’t bring additional useful information which would be related to this study.
Quality assessment

In order to assess the methodological quality, this study used the PEDro-scale. The standard version was applied to all included RCTs. Based on the BES-list, a study is classified with a ‘high’ quality with a PEDro-score of four or higher. A study is qualified with ‘low’ when the PEDro-score is three or less. Based on the PEDro-scale results all included articles were considered of ‘high’ methodological quality. The scores of the PEDro-scale are displayed in the table below (table 3). In appendix I, full explanation of the PEDro-scale was given.

Table 3. Methodological quality assessment via PEDro-scale.

<table>
<thead>
<tr>
<th>Reference</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>PEDro-score</th>
<th>Qualification</th>
</tr>
</thead>
<tbody>
<tr>
<td>De Greef et al.</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>6</td>
<td>High</td>
</tr>
<tr>
<td>De Greef et al.</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>5</td>
<td>High</td>
</tr>
<tr>
<td>Cruz et al.</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>5</td>
<td>High</td>
</tr>
<tr>
<td>English et al.</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>7</td>
<td>High</td>
</tr>
<tr>
<td>Larson et al.</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>6</td>
<td>High</td>
</tr>
<tr>
<td>Kawagoshi et al.</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>4</td>
<td>High</td>
</tr>
</tbody>
</table>

Data extraction

De Greef et al. showed a significant decrease of ST after three months’ intervention for the IG, but for this group the amount of SB returned significantly to baseline levels in the long run. There were no changes found for the CG. Another study of de Greef et al. also showed a significant difference between IG and CG. Objectively and subjectively measured SB, showed a decrease in the IG and an increase in the CG. This study also showed lasting positive effects on SB, at least half a year post-intervention in contrast to the CG. The study of Kawagoshi et al. presented the intervention to be effective in improving PA but didn’t show significant difference from baseline to follow up regarding sitting time. Larson et al. didn’t present any significant changes in ST after four months, or after completion of the intervention, most likely because the SE-intervention group didn’t emphasize on reducing ST. English et al. showed for the IG and CG a decrease in both daily sitting time and sitting time in prolonged bouts (≥ 30 minutes). However, the outcomes of declined sitting time were not superiorly for the intervention participants. Cruz et al. displayed a significant decrease in sedentary activity in the IG compared to the CG after three months, however results were not maintained after follow up.

Three out of the six studies showed significant reductions in SB for the IGs. In the study of de Greef et al. SB showed an interaction effect between post-intervention and follow-up (T1-T2) but on the long term increased again to baseline levels. Solely, de Greef et al. showed lasting positive effects regarding SB for the IG. Two included articles presented no significant differences concerning SB whatsoever. One study presented a cutback in ST for both the IG and CG, however the outcomes for the IG were not superiorly. The results of the measurements in conjunction with other relevant data of the included studies are schematically represented (table 4).
Table 3. Overview of descriptive relevant data including outcomes of the six included studies.

<table>
<thead>
<tr>
<th>First author, publication date, location (country)</th>
<th>De Greef et al. 2010, Belgium</th>
<th>De Greef et al. 2012, Belgium</th>
<th>Cruz et al. 2016, Portugal</th>
<th>English et al. 2016, Australia</th>
<th>Larson et al. 2014, USA</th>
<th>Kawagoshi et al. 2015, Japan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study design</td>
<td>Pilot RCT</td>
<td>RCT</td>
<td>RCT</td>
<td>Pilot RCT</td>
<td>RCT</td>
<td>Prospective RCT</td>
</tr>
<tr>
<td>Population (n, gender [%]): age (M±SD)</td>
<td>Total n= 41, 29.3%♀; [61,3]</td>
<td>IG: n= 60, 31%♀; [62±8]</td>
<td>CG: n= 32, 15.6%♀; [66,9±12.7]</td>
<td>Total n= 32, IG: n= 32, 37.2%♀; [66,4±8,4]</td>
<td>Total n= 85, IG: n= 35, 16.5%♀; [73±8]</td>
<td>Total n= 39, IG: (PR+P): n= 19, (PR only): n= 20, (7.4%♀)</td>
</tr>
<tr>
<td>Randomized:</td>
<td>n= 41</td>
<td>Analyzed: n= 41</td>
<td>n= 41</td>
<td>Analyzed: n= 41</td>
<td>n= 32</td>
<td>Analyzed: n= 32</td>
</tr>
<tr>
<td></td>
<td>n= 20, 35%♀</td>
<td>n= 21, 28.6%♀</td>
<td></td>
<td></td>
<td>n= 19, 37.2%♀</td>
<td></td>
</tr>
<tr>
<td>NCD of study population</td>
<td>DM type II patients</td>
<td>DM type II patients</td>
<td>COPD patients</td>
<td>Stroke survivors</td>
<td>COPD patients</td>
<td>COPD patients</td>
</tr>
<tr>
<td>Significant difference population characteristics</td>
<td>Only difference at baseline: health status in CG. (P=0.02)</td>
<td>Not significant differences in baseline characteristics were not sig. different between completers and dropouts (0.143 &lt; p &lt; 0.817)</td>
<td>Baseline characteristics were not significant different</td>
<td>Not mentioned in this study.</td>
<td>Not mentioned in this study.</td>
<td>There were no significant differences in baseline characteristics between the PR and PR + P groups.</td>
</tr>
<tr>
<td>Measurement tools: moment(s) of measurement</td>
<td>• Pedometer</td>
<td>• Pedometer (+ diary)</td>
<td>• Accelerometer (ActivPAL3 + Actigraph GT3+)</td>
<td>• Accelerometer (accelerometer)</td>
<td>• Actigraph (accelerometer)</td>
<td>• IG and CG: Accelerometer</td>
</tr>
<tr>
<td></td>
<td>• Accelerometer (IPAQ)</td>
<td>• Activity monitor for IG</td>
<td>• Food frequency questionnaire: for CG.</td>
<td>• Daily activity log.</td>
<td>• Self-report: Functional Performance Inventory (FPI)</td>
<td>• IG: Pedometer</td>
</tr>
<tr>
<td></td>
<td>[Baseline (T0), after 12 weeks (T1), follow-up after 1 year (T2)]</td>
<td>[Baseline (T0), 3 months (T1), 6 months (T2), and after behavioral intervention].</td>
<td>[Baseline (T0) and post-intervention after 7 weeks (T1)].</td>
<td></td>
<td>[Baseline (T0), after 4 months (T1), after 12 months follow-up (T2)]</td>
<td></td>
</tr>
<tr>
<td>Intervention(s) for the IG</td>
<td>• Cognitive behavioral program (counseling)</td>
<td>• 1 Face–face session</td>
<td>• IG: (SE-UBR):</td>
<td>• IG(PR+P):</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Pedometer (+ diary)</td>
<td>• Pedometer</td>
<td>• Self-efficacy enhancing (counseling).</td>
<td>• Pulmonary rehabilitation</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 7 support phone calls (counseling)</td>
<td>• PR</td>
<td>• UBR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sedentary time</td>
<td>PO: SB as well as PA.</td>
<td>PO: SB as well as PA.</td>
<td>PO: SA as well as daily PA.</td>
<td>PO: ST prolonged ≥ 30 min.</td>
<td>PO: SB together with PA.</td>
<td>PO: ST together with PA.</td>
</tr>
<tr>
<td>PO or SO</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Duration of intervention(s) for the IG | * 12 wks. counseling  
• 1 booster session (after 1/2 year)  
• Follow-up at week 52.  
* 6 months (24 weeks)  
• Intermediate term 1 year later.  
* PR: 3 months.  
• 3 months continued PA-focused behavioral intervention.  
* 12 wks. usual care  
• 1 group education session  
• Post-intervention at week 13  
• Follow-up at week 52.  
| Duration of intervention(s) for the CG | * 12 wks. usual care  
• 1 group education session  
• Post-intervention at week 13  
• Follow-up at week 52.  
| Difference min. ST/SB/SA within-group p-value. For the IG | SB was ↓22 (min./d) after 3 months.  
T0: 1183±90  
T1: 1111±118  
T2: 1187±99  
• Subjective:  
T0: 1140±90  
T1: 1117±87  
T2: 1128±88  
↓12 (min./d) SB from T0→T2  
• Objective:  
T0: 463±122  
T1: 453±146  
T2: 433±125  
Time spent in SA:  
T0: 536.4±86.6 min./d.  
T1: 525.5±83.7 min./d.  
T2: 525.5±83.7 min./d.  
• Total ST (min./d):  
T0: 1218±107  
T1: 1134±102  
T2: 1166±107  
↑48 (min./d) SB from T0→T2  
• Prolonged ST (min./d):  
T0: 46±10.0 (-67.5 to -4.8)  
T1: 56±18.3 (-121.7 to 33.3)  
T2: 54±12.9 (-121.7 to 33.3)  
P-value: 0.24  
| Difference min. ST/SB/SA within-group p-value. For the CG | SB was ↓26 (min./d) after 3 months.  
T0: 1206±94  
T1: 1180±104  
T2: 1187±111  
• Subjective:  
T0: 1118±109  
T1: 1134±102  
T2: 1166±107  
↑48 (min./d) SB from T0→T2  
• Objective:  
T0: 505±174  
T1: 539±187  
T2: 546±196  
Time spent in SA:  
T0: 625.9±93.3 min./d.  
T1: 604±86.6 min./d.  
T2: 604±86.6 min./d.  
• Total ST (min./d):  
T0: 1218±107  
T1: 1134±102  
T2: 1166±107  
↑48 (min./d) SB from T0→T2  
• Prolonged ST (min./d):  
T0: 44±24.2 (-121.7 to 33.3)  
T1: 59±21.5 (-121.7 to 33.3)  
T2: 54±12.9 (-121.7 to 33.3)  
P-value: 0.24  
| Between-group p-value | T0→T1  
P < 0.05  
• Subjective:  
P-value: N/A  
• General SA (min./day):  
P = 0.031  
At 3 months:  
P = 0.018  
At 6 months:  
P = 0.781  
• Total sitting time (min./d):  
P = 0.693  
• P = 0.0552  
(time X group-interaction)  
• P = 0.198  
T1→T2  
P < 0.001  
• Objective:  
P < 0.001  
• Prolonged sitting time (min./d):  
P = 0.821  
• P = 0.090  
(group X time-interaction)  

Legend: n, sample size; M, mean; SD, standard deviation; ♀, female; RAN, randomized group; AN, analyzed group; PO, primary outcome; SO, secondary outcome; IG, intervention group; CG, control group; ST, sitting/sedentary time; SB, sedentary behavior; SA, sedentary activity; PA, physical activity; ↓, decreased; ↑, increased; CI, confidence interval; SE-UBR self-efficacy with upper-body resistance training; ED-UBR: health education with upper-body resistance training; ED-Chair: health education with chair exercises; IPAP: international physical activity questionnaire; USA, United States of America.
Data analysis
Based upon the results of the methodological quality evaluation and the BES-list of ‘van Peppen et al.’ the BES is three times executed. The results of the BES are diagrammatically displayed into table 5.

The first BES included studies with a DM type II subject group. Both RCTs have statistical significant results regarding a decreased amount of ST in minutes per day for the IG compared to the CG. Both RCTs presented a high methodological quality. Therefore, the BES-list indicated ‘strong’ evidence for the effect of interventions which were applied to decrease SB in DM type 2 patients compared to “usual care” in the control groups.

The second BES included studies with COPD patients as a subject population. Cruz et al. solely showed statistical significant results on the short term for the COPD related RCTs, additionally this study had a high methodological quality. Larson et al. and Kawagoshi et al. didn’t provide statistically significant results for decreased sedentary time in the IG in contrast to the CG. Thus, the BES-list revealed “no” or “insufficient” evidence, for the effectiveness of the interventions that are applied to subjects with COPD.

The third BES for the study that included stroke survivors. English et al. had a high methodological quality but didn’t represent any statistically significant results between the IG and CG, aiming to reduce ST in stroke patients in the long term. This study did show significant short term results in decreased extent in total ST and ST in prolonged bouts (≥ 30 minutes) for IG and CG, but the IG short term results weren’t superior counter to the CG. Thus, the BES-list points out that there is “no” or “insufficient” evidence for effectiveness of the interventions aiming to decrease SB for stroke survivors.
Table 5. Outcomes best-evidence synthesis

<table>
<thead>
<tr>
<th>BES-nr.</th>
<th>First author, publication date, location (country)</th>
<th>Type of NCD of study population</th>
<th>Between group p-value</th>
<th>Pedro-score</th>
<th>Quality of study according to BES-list</th>
<th>Measure of evidence according to BES-list</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>• De Greef et al.23 2010, Belgium</td>
<td>DM type II</td>
<td>• P &lt; 0.001&lt;sup&gt;123&lt;/sup&gt;</td>
<td>*6&lt;sup&gt;23&lt;/sup&gt;</td>
<td>High (All included a PEDro-score &gt; 4)</td>
<td>Strong evidence</td>
</tr>
<tr>
<td></td>
<td>• De Greef et al.24 2012, Belgium</td>
<td></td>
<td>• P &lt; 0.001&lt;sup&gt;24&lt;/sup&gt;</td>
<td>*5&lt;sup&gt;24&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>• Cruz et al.25 2016, Portugal</td>
<td>COPD</td>
<td>• P= 0.018&lt;sup&gt;25&lt;/sup&gt;</td>
<td>*5&lt;sup&gt;25&lt;/sup&gt;</td>
<td>High (All included a PEDro-score &gt; 4)</td>
<td>No or insufficient evidence</td>
</tr>
<tr>
<td></td>
<td>• Larson et al.27 2014, USA</td>
<td></td>
<td>• P= 0.0552&lt;sup&gt;27&lt;/sup&gt;</td>
<td>*6&lt;sup&gt;27&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Kawagoshi et al.28 2015, Japan</td>
<td></td>
<td>• P= 0.198&lt;sup&gt;28&lt;/sup&gt;</td>
<td>*4&lt;sup&gt;28&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>• English et al.26 2016, Australia</td>
<td>Stroke</td>
<td>• P= 0.693&lt;sup&gt;26&lt;/sup&gt;</td>
<td>*7&lt;sup&gt;26&lt;/sup&gt;</td>
<td>High (included a PEDro-score &gt; 4)</td>
<td>No or insufficient evidence</td>
</tr>
</tbody>
</table>

Legend: BES-nr, number of the executed Best Evidence Synthesis; NCD, non-communicable disease; BES-list, Best Evidence Synthesis list; P, P-value; Green coloration, statistical significant between group P-value; Red coloration, evidence exists for the interventions; Blue coloration, no or insufficient evidence exists for the interventions.
Discussion

In this systematic review, the effect of interventions which aimed to reduce ST in patients with a NCD has been investigated. By doing so, it aimed to answer the following research question; what is the effect of interventions focusing on reducing ST in patients with a NCD? According to the results it appeared that the interventions which aim to reduce ST in patients with DM type II, seemed to be most effective, in contrast to the CG. These study interventions were composed of counseling sessions combined with a pedometer. There is no or insufficient evidence to prove the effectiveness of interventions – compared to the CG – aiming to reduce ST in patients with the following NCDs: stroke and COPD. Ultimately, results revealed that people with a NCD sat less and showed short terms reductions in SB.

The studies that did not provide statistical significant reductions in ST included Larson et al.\textsuperscript{27} and Kawagoshi et al.\textsuperscript{28} The IG of Larson et al.\textsuperscript{27} consisted of UBR and counseling to enhance self-efficacy. The intervention did not emphasize the importance of reducing ST and this may contribute to no significant reductions regarding ST.\textsuperscript{27} In the study of Kawagoshi et al.\textsuperscript{26} the IG received PR and a pedometer. Both studies mainly focused on increasing PA, rather than specifically decreasing SB, this may contribute to no significant presented reductions in SB for these two studies.\textsuperscript{27-28}

Based on the included articles in this review it seems to matter what intervention was provided to a population with a certain type of NCD, due to the fact that there is strong evidence of the effectiveness. The interventions applied to the DM type II study was proven to be most effective according to the BES. The study of English et al.\textsuperscript{26} had no significant outcomes between IG and CG in decreasing ST on the long term. However, this could have been contributed due to the attention-matched CG. The intervention investigated into the total ST and ST in pro-longed bouts (> 30 minutes), both resulted reductions.\textsuperscript{26} The intervention consisted of counseling sessions with a main message to “sit less and move more” and encouragement to regularly break up sitting time with short bursts of light-intensity activity, seems to be effective in reducing ST rather than an approach to generally advice to increase PA. So despite the fact that long-term effects weren’t sustained, these results are valuable because it’s demonstrated that it is possible for stroke survivors to sit less each day and this population group often has insurmountable barriers to exercise regularly.

In this review four articles didn’t present long term effects, nor follow-up sessions by phone.\textsuperscript{23,26-28} Cruz et al.\textsuperscript{25} didn’t provide long term positive effects regarding SB, yet presented follow-up by phone like de Greef et al.\textsuperscript{24} Difference in outcome on long term between the two studies with telephone follow-up may be contributed by the different environment in which the subjects were present.\textsuperscript{24-25} The patients in Cruz et al.\textsuperscript{26} firstly received counseling sessions in person during PR which later changed to their usual environment – home –, as opposed to the subjects of de Greef\textsuperscript{24} whom only received the first session in person and seven remaining calls in the same environment. Additionally, the phone call sessions for 20 minutes per session for de Greef\textsuperscript{24} but the duration for follow up calls of Cruz et al\textsuperscript{25} is not mentioned, so it’s questionable whether the intensity and duration of the phone call had an influence on the results on the long term. A RCT pilot investigating into an intervention aiming to reduce and break-up overweight/obese adults’ overall ST showed significant reductions in ST, yet this was measured over a short time span.\textsuperscript{30} This intervention included phone support and behavioral self-monitoring, similar to interventions of the included studies also showed short and long term positive effects in a reduction in SB. The manner of interventions seems to be effective in reducing SB.
Results in significant reduction in ST was noticed in short terms for three studies\textsuperscript{23-25}. The reason why only short term positive results are significantly provided for these studies could be explained by the intervention overlap; consisting out of counseling combined with a pedometer. The duration between both studies differed, (12 weeks\textsuperscript{23} as opposed to 24 weeks\textsuperscript{24}). Furthermore, the sample size in de Greef et al.\textsuperscript{24} was greater. Counseling varied between groups: de Greef\textsuperscript{23} consisted of 5 group sessions while in the study of de Greef\textsuperscript{24}, there were 7 individual counseling sessions. There is a division in attention when comparing counseling in group forms as opposed to individual counseling. The Greef et al.\textsuperscript{23} had one booster session half a year post-intervention in contrast to seven follow-up calls over a time span of 24 weeks. These are all factors which could possibly influence long term outcomes in decreased SB. This outcome is in harmony with previous literature. Dunn et al. indicate long-term effects of interventions on reducing sedentary behavior.\textsuperscript{29}

The BES-list indicated strong evidence for the included articles with DM type II patients which is in harmony with the results.\textsuperscript{23-24} On the other hand, for studies that included COPD patients the BES-list revealed “no” or “insufficient” evidence, likewise in harmony with results, showing no significant results on reduction of ST.\textsuperscript{25,27-28} However, for Cruz et al.\textsuperscript{25} short term significant results were found. The BES-list which was executed for stroke survivors indicated “no” or “insufficient” evidence, however it should be taken into consideration that this study did show significant results on short terms for the IG and CG. The IG did significantly improve; a small CG could contribute to the fact that there was a difference with the CG.\textsuperscript{26}

**Strong and weak points of the included literature**

In all the included articles objective measurement tools were used, all studies included an accelerometer.\textsuperscript{23-28} In all except one included article, measurement on long and short term were evaluated.\textsuperscript{23,24,26-28} Cruz et al.\textsuperscript{25} was the single article that didn’t study the long term data. Besides that, in all included studies are in most continents of the world so it’s rather global (USA, Belgium, Portugal, Australia, Japan) which provides worldwide information on interventions that were used to decrease this SB, which is representative because SB is worldwide administered.

Besides the strengths of the included articles, there are several weak points for the current study. These include for example the smaller subject population. De Greef et al.\textsuperscript{23} and English et al.\textsuperscript{26} mentioned a weak factors regarding to the measurement tools. The accelerometer and the pedometer are weak aspects of their studies because of their inability to provide information relative to non-ambulatory activity.\textsuperscript{23} English et al.\textsuperscript{26} said that the Actigraph tends to underestimate step counts in people with slow walking speeds.\textsuperscript{26} Another aspect notable is that more than half of the study population is male. This could raise the question how the interventions would have been effected if a greater female or rather, a more balanced male: female ratio was present in the included studies. Additionally, for included articles with COPD patients only one assessor evaluated it which creates an enormous bias.\textsuperscript{25}

The study population of all the included articles has an age of at least 60 years and older. Therefore, the outcomes don’t say as much about the effect of the interventions for patients with an NCD whom are younger than 60 years old. In several included studies there were dropout rates, especially in Larson et al.\textsuperscript{27} – which increases the extent of bias –, from the 85 subjects that were randomized 34 subjects were analyzed.\textsuperscript{23,26-28} In the study by de Greef\textsuperscript{24} and by Cruz\textsuperscript{25}, there were no drop outs. The study by de Greef et
al.\textsuperscript{23} (2010) looks very similar to the other study of de Greef et al.\textsuperscript{24} (2012), but it seems as if the article from 2012 is a follow-up study of the study which was performed into 2010. The study of 2010 could have been a pilot study.

**Strong and weak points of the current study**

This literature study included solely RCTs. All included RCTs are not older than 6 years, which provides very recent data. Weak points of this literature study are the following: only 6 articles are included. This literature study was reviewed by only one assessor which indicates an enormous bias. The amount of NCDs was not equally balanced, there were three studies investigating COPD\textsuperscript{25,27-28} and two investigating DM type II\textsuperscript{23,24} and one study investigated into stroke.\textsuperscript{23} A better diversity qua number of NCDs, would provide a more representative result regarding that globally the different kinds of NCDs are wider spread as well.

**Relevance for clinical practice**

The outcomes of this literature for can be of clinical relevance, because there is clarity of the effectiveness of interventions especially applied for the study with diabetes mellitus type II.\textsuperscript{23,24} However, the reductions in SB for stroke patients clearly are valuable and interventions solely aiming to decrease SB have shown to be effective. The interventions composing of objective measurement tools, combined with counseling sessions and follow up support with telephone indicate according to the BES-list, to have strong evidence for their effectiveness. Additionally, the counseling therapy by phone is a cost-effective and feasible alternative, consequences in better adherence degrees in contrast to face-to-face interventions.\textsuperscript{28}

**Recommendations**

In the future, RCTs with high quality are needed which should investigate into larger sample sizes. Additionally, there should be a better balance concerning the ratio, female and male subjects. In order to have a proper methodological quality in the future, it is necessary to consistently apply blinding to participants and evaluators. It can be recommended to investigate primarily into the reduction of sedentary time in NCD patients with an approach that aims solely to reduce SB, rather then interventions with general lifestyle advice or general advice to increase physical activity. This approach seems to be proven more effective in reducing ST.\textsuperscript{26} In order to sustain long term effects, it can be recommended to use a follow-up method with telephone. This seems to be a cost-effective and feasible strategy to obtain long lasting results.\textsuperscript{26} Another recommendation for practice could include the use of WhatsApp as a reminder or motivational tool, it is questionable to which group of intervention it should be given to because not all generations are well capable of the usage of WhatsApp.
Conclusion

SB is a common aspect influencing the risk of having a NCD. Yet, sedentariness is universally administered in our nowadays society, especially prevailing in patients with a NCD. Therefore, this study investigated into studies focusing on aiming to reduce this chair depending demeanor. The research question of this systematic review states: what is the effect of interventions focusing on reducing sedentary time in patients with a non-communicable disease? The interventions which have been applied to diabetes mellitus type II patients, seem to have most evidence for their effectiveness, according to the performed best-evidence synthesis. The most effective interventions consist out of counseling sessions combined with objective measurement tools used to increase motivation. In the future, RCTs with a high methodological quality are needed to provide high quality evidence on the most effective intervention to reduce SB in patients with a NCD, preferably with large sample sizes and including a greater variety in types of NCDs. Furthermore, the studies should aim to sustain long term positive effects on reduced SB.
Bibliography


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8. Hildebrandt V.H, Chorus AMJ, Stubbe JH. Trendrapport Bewegen en gezondheid. 2013. TNO.


27. Larson J, Covey M, Kapella M, Alex C, McAuley E. Self-efficacy enhancing intervention increases light


Appendix I – Table: categories of physical activity

Table 1. Physical activity intensity by Global Physical Activity Questionnaire (GPAQ)\textsuperscript{16}

<table>
<thead>
<tr>
<th>Physical activity (PA) intensity</th>
<th>Reaching the criteria below:</th>
</tr>
</thead>
</table>
| High / vigorous PA              | • At least 3 days, at least 1500MET-min/week OR
|                                 | • 7 or more days any combination of walking, moderate- or vigorous-intensity activities        |
|                                 | accumulating at least 3000 MET-min/week.                                                    |
| Moderate PA                     | Doesn’t meet the high/vigorous category:                                                       |
|                                 | • 3 or more days of vigorous-intensity activity of at least 20 min/day OR                      |
|                                 | • 5 or more days of moderate-intensity activity and/or walking of at least 30 min/day OR      |
|                                 | • 5 or more days of any combination of walking, moderate- or vigorous-intensity activities     |
|                                 | accumulating at least 600 MET min/week.                                                      |
| Low PA                          | Doesn’t meet any of the above described criteria:                                              |
|                                 | • No activity is reported or some activity is reported but not enough to meet high and moderate|
|                                 | categories.                                                                                  |
### Appendix II – Search syntax & search terms

<table>
<thead>
<tr>
<th>Search terms</th>
<th>Items found</th>
</tr>
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<td>#2 “Chronic disease”</td>
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<td>589228</td>
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<td>#4 “Chronic ill patients”</td>
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<td>1751</td>
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<td>#8 “Non-transmissible disease”</td>
<td>77</td>
</tr>
<tr>
<td>#9 “NCD”</td>
<td>1531</td>
</tr>
<tr>
<td>#10 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9</td>
<td>1406532</td>
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<td>#11 Sedentary</td>
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<tr>
<td>#13 “Sedentary behavior”</td>
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<td>#14 “Occupational sedentary behaviour”</td>
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<td>#15 “Occupational sedentary behavior”</td>
<td>470</td>
</tr>
<tr>
<td>#16 “Sedentary time”</td>
<td>7392</td>
</tr>
<tr>
<td>#17 “Sedentary lifestyle”</td>
<td>7562</td>
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<td>#18 “Sitting time”</td>
<td>4615</td>
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<tr>
<td>#27 #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26</td>
<td>2327372</td>
</tr>
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</table>
Appendix III – PEDro-scale

**PEDro scale**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>eligibility criteria were specified</td>
</tr>
<tr>
<td>2.</td>
<td>subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)</td>
</tr>
<tr>
<td>3.</td>
<td>allocation was concealed</td>
</tr>
<tr>
<td>4.</td>
<td>the groups were similar at baseline regarding the most important prognostic indicators</td>
</tr>
<tr>
<td>5.</td>
<td>there was blinding of all subjects</td>
</tr>
<tr>
<td>6.</td>
<td>there was blinding of all therapists who administered the therapy</td>
</tr>
<tr>
<td>7.</td>
<td>there was blinding of all assessors who measured at least one key outcome</td>
</tr>
<tr>
<td>8.</td>
<td>measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups</td>
</tr>
<tr>
<td>9.</td>
<td>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”</td>
</tr>
<tr>
<td>10.</td>
<td>the results of between-group statistical comparisons are reported for at least one key outcome</td>
</tr>
<tr>
<td>11.</td>
<td>the study provides both point measures and measures of variability for at least one key outcome</td>
</tr>
</tbody>
</table>

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 **Points are only awarded when a criterion is clearly satisfied.** 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 **Concealed allocation** 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.

Criterion 5-7 **Blinding** 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 both the number of subjects initially allocated to groups and 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 **intention to treat** 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 **between-group** 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 x 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 **point measure** 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. **Measures of variability** 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.