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Review article

The clinical reasoning process in randomized clinical trials with patients with non-specific neck pain is incomplete: A systematic review

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ABSTRACT

Objective: Primarily to evaluate the completeness of the description of the clinical reasoning process in RCTs with patients with non-specific neck pain with an argued or diagnosed cause i.e. an impairment or activity limitation. Secondly, to determine the association between the completeness of the clinical reasoning process and the degree of risk of bias.
Data sources: Pubmed, Cinahl and PEDro were systematically searched from inception to July 2016.
Study selection: RCTs (n = 122) with patients with non-specific neck pain receiving physiotherapy treatment published in English were included.
Data extraction: Data extraction included study characteristics and important features of the clinical reasoning process based on the Hypothesis-Oriented Algorithm for Clinicians II (HOAC II)].
Data synthesis: Thirty-seven studies (30%) had a complete clinical reasoning process of which 8 (6%) had a 'diagnosed cause' and 29 (24%) had an 'argued cause'. The Spearmans rho association between the extent of the clinical reasoning process and the risk of bias was −0.2.
Conclusions: In the majority of studies (70%) the described clinical reasoning process was incomplete. A very small proportion (6%) had a 'diagnosed cause'. Therefore, a better methodological quality does not necessarily imply a better described clinical reasoning process.

1. Introduction

Non-specific neck pain is a major concern in the adult Western world population. A recent review reports a 12-month prevalence ranging from 30% to 50%, with activity limitations ranging from 2 to 11%. About 10% of these patients will develop a chronic pain disorder (Hogg-Johnson et al., 2008). Additionally, neck pain poses an important socio-economic burden on society because pain, stiffness or loss of mobility associated with neck pain often results in utilization of diagnostic assessments and treatments (Korthals-de Bos et al., 2003). For effective treatment of non-specific neck pain, physiotherapists should be able to rely, within their clinical reasoning process, on the evidence from scientific research. However, scientific research evidence is poorly integrated in physiotherapy (Greenhalgh et al., 2014; Heneghan et al., 2017). One possibility is that RCTs do not reflect "real world" of physiotherapy clinical practice (Balague et al., 2012; Tsakitzidis et al., 2013).

High quality randomized controlled trials (RCTs) are generally considered to provide the best evidence for interventions as they tend to be highly internally valid. Internal validity refers to how "well" the research was performed (Eldridge et al., 2008). High internal validity of the included studies is of paramount importance as this determines the level of confidence for making recommendations for treatment methods. However, in addition to high internal validity, studies must also be of sufficient external validity in order to be able to generalise the results to the population as seen in clinical practice (Katrak et al., 2004). External validity refers to the "real world" applicability of the research findings or generally the clinical relevance (Eldridge et al., 2008). Several authors have stressed the importance of assessing the clinical relevance of RCTs, in addition to the internal validity (Herbert and Bo, 2005; van Tulder et al., 2003). A prerequisite for external validity is a recognisable clinical reasoning process which can be verified and understood by clinicians.

An instrument that supports the description of the clinical reasoning

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process is the Hypothesis-Oriented Algorithm for Clinicians II (HOAC II) (Rothstein et al., 2003). The HOAC II provides a systematic algorithm, consisting of key components, for the clinical reasoning process of physiotherapists. Within this clinical reasoning process, hypothetico-deductive strategies (Edwards et al., 2004) and/or pattern recognition are used (Norman, 2005; Rushton and Lindsay, 2010). In the clinical practice of a physiotherapist a diagnostic strategy is used, which includes history taking and clarification of the patients complaints, i.e. the patient-experienced problems. Next, the physiotherapist needs to generate one or more (alternative) hypotheses as to the cause or causes of the complaint. The HOAC defines the term "cause(s)" as the possible reason(s) for the neck pain or disability; i.e. impairments, limitations in activities or restrictions in participation. These hypotheses guide the physical examination, which serves to refute or to confirm these hypotheses. The final clinical hypothesis guides the choice for an intervention to eliminate or reduce the cause of the problem. Finally outcome measures should be used to test the clinical hypothesis. Unlike the HOAC II, we consider these outcome measures as twofold: 1) at the level of the patient, i.e. they measure the patients complaint (problem related outcome) and 2) at the level of the physiotherapist. i.e. they measure the effect of the intervention (intervention related outcome). In this way, there is a distinction between the immediate effect of the intervention, reflecting the working mechanism of the intervention and, the experienced effect of the patient (Lee et al., 2017).

A complete clinical reasoning process starts therefore with the physiotherapeutic diagnostic process. Diagnosis in physiotherapy is the result of a clinical reasoning process which results in the identification of existing or potential impairments, limitations in activities and restrictions in participation and of factors affecting functioning positively or negatively (Guccione, 1991; World Confederation for Physical Therapy, 2017).

The physiotherapist has to determine which impairments, limitations in activities and restrictions in participation are a potential cause or causes of the experienced problem of the patient. The dictionary definition of diagnosis is "the identification of the nature of an illness or other problem by examination of the symptoms" (Oxford University Press, 2017). Therefore, part of the diagnostic process is performing one or more applicable test(s) for identifying a possible cause of the patient experienced problem. In our paper we consider this to be a 'diagnosed cause'. In RCTs these tests should be used to make sure that every participant actually has the assumed cause and can be included in the study. When the diagnostic process only consists of propositions, of what could be a cause, without testing, we consider this an 'argued cause'. In RCTs this argumentation is often found in the introduction section. Hence, the main difference between a study with a 'diagnosed cause' and an 'argued cause' is that in the "argued cause" studies it is possible that the study sample did not have an impairment or activity limitation at all, despite a complaint of pain. In research it is of great importance to know if the population under research actually did have the impairment or activity limitation the intervention intents to influence. Without the presence of an impairment or activity limitation, there is no need to intervene. This is why, unlike the HOAC, we distinguish between a physiotherapeutic 'diagnosed cause' and 'argued cause'.

Therefore the key components of the physiotherapeutic clinical reasoning process based on the HOACII and extended with our distinction between problem versus goal-related outcome and diagnosed versus argued cause are:

- a patient experienced problem (the complaint)
- a cause (either diagnosed or argued)
- a goal aimed at the diagnosed impairment, activity limitation or restriction in participation.
- a matched intervention to the goal
- an outcome measure related to the diagnosed cause (intervention related outcome)
- an outcome measure related to the patient's experienced problem (problem related outcome)

The assessment of the clinical relevance is increasingly important as evidenced by the updated method guideline for systematic reviews in the Cochrane back and neck group (Furlan et al., 2015). Now they recommend to specifically describe the type, intensity, dosage, frequency and duration of treatment. However, there is still little attention to the clinical reasoning process. Consequently, it remains unclear if risk of bias of a study is associated with the extent to which this study used (and described) a clinical reasoning process.

Therefore, the research questions are:

- Are the key components of the clinical reasoning process described within the methodology of RCTs on patients with non-specific neck pain?
- How many studies with a complete clinical reasoning process have a diagnosed cause?
- What is the association between the extent of a complete clinical reasoning process and the risk of bias?

2. Methods

This systematic review is reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Moher et al., 2009).

2.1. Data sources and searches

A comprehensive literature search was performed in MEDLINE, CINAHL and PEDro from inception to July 2016. The search was completed in collaboration with a medical information specialist (JM) (Rethlefsen et al., 2015). A sensitive search strategy was developed for MEDLINE with the acceptance of false positive findings (Appendix 1). To collect as many potentially eligible RCTs as possible, the search strategy combined two primary pathways. The first combined neck pain with physiotherapy and the second concerned the combination neck pain with the subheadings "rehabilitation", "therapy" and "prevention and control" because these subheadings included most likely also physiotherapy. The first and second pathways were combined with the Boolean term "OR". Subsequently, the outcome was limited for RCTs with the "Cochrane Highly Sensitive Search Strategy" for identifying randomized trials". In CINAHL the same strategy was used as in MEDLINE with an adapted Cochrane search strategy. In PEDro the Abstract and Title box was filled with "neck", the problem box with "pain" and the method box with "clinical trial".

The selection process and data extraction were performed by two independent researchers. The titles and abstracts were judged by these researchers based on the in- and exclusion criteria. Full text was reviewed for hits that could not be excluded based on title/abstract. After independently selecting the studies, they discussed differences until consensus was reached. If no consensus was reached, a third researcher (HW) was consulted and consensus was reached based on discussion between them.

2.2. Study selection

A study was included if it met the following criteria: full-text original article, published in English, adult patients (> 18 years old) with non-specific neck pain, mono disciplinary physiotherapy intervention and randomized controlled trial (RCT). RCTs with mixed population were included if the clinical reasoning process was described specifically for patients with non-specific neck pain instead of a mixed population. Non-specific neck pain was defined as pain (with or without radiation) located in the cervical spine and/or occiput region and/or cervico thoracic junction and muscles originating from the cervical

region acting on the head and shoulders, without underlying pathology, such as: trauma (fractures), infection, inflammatory disorders, neurologic pathology or systemic disease (Hogg-Johnson et al., 2008).

A study was excluded if: if the study was performed in patients with headache with or without non-specific neck pain, temporomandibular joint dysfunctions or trigger points in the trapezius region or trapezius myalgia. Also studies in patients with whiplash related neck pain were excluded.

2.3. Data extraction and quality assessment

Risk of bias was assessed using the PEDro scale (de Morton, 2009). The Intra-class Correlation Coefficient for consensus ratings is 0.68 (95% confidence interval 0.57–0.76) executed by experienced assessors; therefore ratings from the physiotherapy evidence database (www.pedro.org.au) were used (Maher et al., 2003). We considered a cut-off score of ≥6 as high quality (Veerbeek et al., 2011). When no score was available in the PEDro database, two authors independently assessed the risk of bias.

Two a-priori data extraction forms were developed for this review. One form to score patient and study characteristics of the RCTs (Appendix 2) and the other to score the HOAC II based clinical reasoning process rating scale (Table 1). To determine the completeness of the clinical reasoning process a 6-item scale was developed based on the HOAC II (Table 1). Two independent raters scored the RCTs on this scale. Differences were discussed until consensus was reached.

2.4. Data synthesis and analysis

We rated a clinical reasoning process complete if 1. an experienced problem was described, 2. a cause was 'diagnosed' or 'argued', 3. the main goal of the intervention was related to the 'cause', 4. the intervention matched the main goal, 5. the intervention related outcome measure matched the main goal of the physiotherapist and 6. the problem related outcome measure matched the patient-experienced problem (Table 1). The rating scale is described in Table 1. For each score on the HOAC II based clinical reasoning process rating scale, there was a prerequisite: there had to be a "+" score on the preceding item. Without a clearly defined cause, it is not possible to define a clear goal and for that reason it is not possible to match the intervention with intervention related outcome measures. Therefore, all 6 items should be scored with at least "+" or "?" before we scored the clinical reasoning process as complete.

Spearmans rho was calculated, to determine the association between PEDro scores and the number of positive items on the HOAC II based clinical reasoning process rating scale, using the software package of IBM SPSS Statistics 22.0 (SPSS Inc., Chicago, Il).

3. Results

The literature search retrieved 2799 studies. After removing the duplicates, 2331 remained for further screening. Fig. 1 describes the screening process. One hundred and twenty-two studies were included (Akhter et al., 2014; Ali et al., 2014; Andrade Ortega et al., 2014; Aquino et al., 2009; Bakar et al., 2014; Beer et al., 2012; Beinert and Taube, 2013; Beltran-Alacreu et al., 2015; Bid et al., 2014; Borisut et al., 2013; Borman et al., 2008; Brage et al., 2015; Briem et al., 2007; Casanova-Mendez et al., 2014; Celenay et al., 2016a,b; Chiu et al., 2004; Chiu et al., 2005; Chiu et al., 2011; Cleland et al., 2005; Cleland et al., 2007, 2010; Cook et al., 2015; Cunha et al., 2008; David et al., 1998; Dawood et al., 2013; de Camargo et al., 2011; Deepa et al., 2014; Dunning et al., 2012; Dusunceli et al., 2009; Dziedzic et al., 2005; Escortell-Mayor et al., 2011; Evans et al., 2012; Falla et al., 2006; Falla et al., 2007; Falla et al., 2008; Falla et al., 2013; Gallego Izquierdo et al., 2016; Ganesh et al., 2014; Giombini et al., 2013; Gonzalez-Iglesias et al., 2009a; Gonzalez-Iglesias, Fernandez-de-las-Penas, Cleland, & Gutierrez-Vega Mdel, 2009b; Griffiths et al., 2009; Griswold, Learman, O'Halloran and Cleland, 2015; Haas et al., 2003; Hakkinen et al., 2007; Hakkinen et al., 2008; Helewa et al., 2007; Hoving et al., 2002; Hudson and Ryan, 2010; Humphreys and Irgens, 2002; Izquierdo Perez et al., 2014; Javanshir et al., 2015; Jordan et al., 1998; Jull et al., 2007, 2009; Kanlayanaphotporn et al., 2009; Kanlayanaphotporn et al., 2010; Karlsson et al., 2014; Khan et al., 2014; Kim et al., 2015; Kim and Kwag, 2016; Kjellman and Oberg, 2002; Klaber Moffett et al., 2005; Ko et al., 2010; Krauss et al., 2008; Kumar et al., 2011; Lansinger et al., 2007; Lansinger et al., 2013; Lau et al., 2011; Leaver et al., 2010; Lee et al., 2013; Lee and Kim, 2016; Lee et al., 2016; Lluch et al., 2014a,b; Lopez-Lopez et al., 2015; Maayah and Al-Jarrah, 2010; Madson et al., 2010; Mansilla-Ferragut et al., 2009; Martel et al., 2011; Martinez-Segura et al., 2006, 2012; Masaracchio et al., 2013; McLean et al., 2013; Monticone et al., 2012; O'Leary, Falla, Hodges, Jull and Vicenzino, 2007; O'Leary et al., 2007, 2012; Paoloni et al., 2013; Pillastrini et al., 2016; Pires et al., 2015; Pool et al., 2010; Puentedura et al., 2011; Puntumetakul et al., 2015; Rendant et al., 2011; Revel et al., 1994; Rolving et al., 2014; Rudolfsson et al., 2014; Saavedra-Hernandez et al., 2013, 2012; Saayman et al., 2011; Salom-Moreno et al., 2014; Sarig Bahat, Takasaki, Chen, Bet-Or and Treleaven, 2015; Schomacher, 2009; Sherman et al., 2014; Sillevis et al., 2010; Snodgrass et al., 2014; Sterling et al., 2001; Taimela et al., 2000; Thompson et al., 2016; Vernon et al., 1990; Viljanen et al., 2003; von Trott et al., 2009;

Table 1
HOAC II based clinical reasoning process rating scale.

	Items	Score
1	Is a patient-experienced problem described?	+ A patient-experienced problem, for example pain or activity limitation must be described as an inclusion criterion. - A patient-experienced problem is not described as an inclusion criterion.
2	Is the cause of the problem diagnosed or argued?	++ A cause is 'diagnosed' if a test is used to determine the cause of the patient-experienced problem and that this test is described as an inclusion criterion. + A cause is 'argued' if the argumentation is described in the introduction section but no further objectification took place as an inclusion criterion ? A cause is unclear if the argumentation described in the introduction is multi interpretable. - A cause is not described.
3	Is the main goal of the intervention(s) related to the cause (as described in 2)?	+ The main goal of the intervention should be to eliminate the 'argued' or 'diagnosed' cause. - The main goal is not to eliminate the argued or diagnosed goal.
4	Does the intervention(s) match the main goal (as described in 3)?	+ The intervention should be aimed at achieving the main goal. - The intervention is not focused on the main goal.
5	Does the intervention related outcome measure match the direct goal (as described in 3)?	+ The intervention related outcome measure should measure the change of the cause. - There is no outcome measure that measure the change of the cause
6	Does the problem related outcome measure match the patient-experienced problem (as described in 1)?	+ The problem related outcome measure should measure the change of the experienced problem by the patient. - There is no outcome measure that measure the chance in the patient-experienced problem.

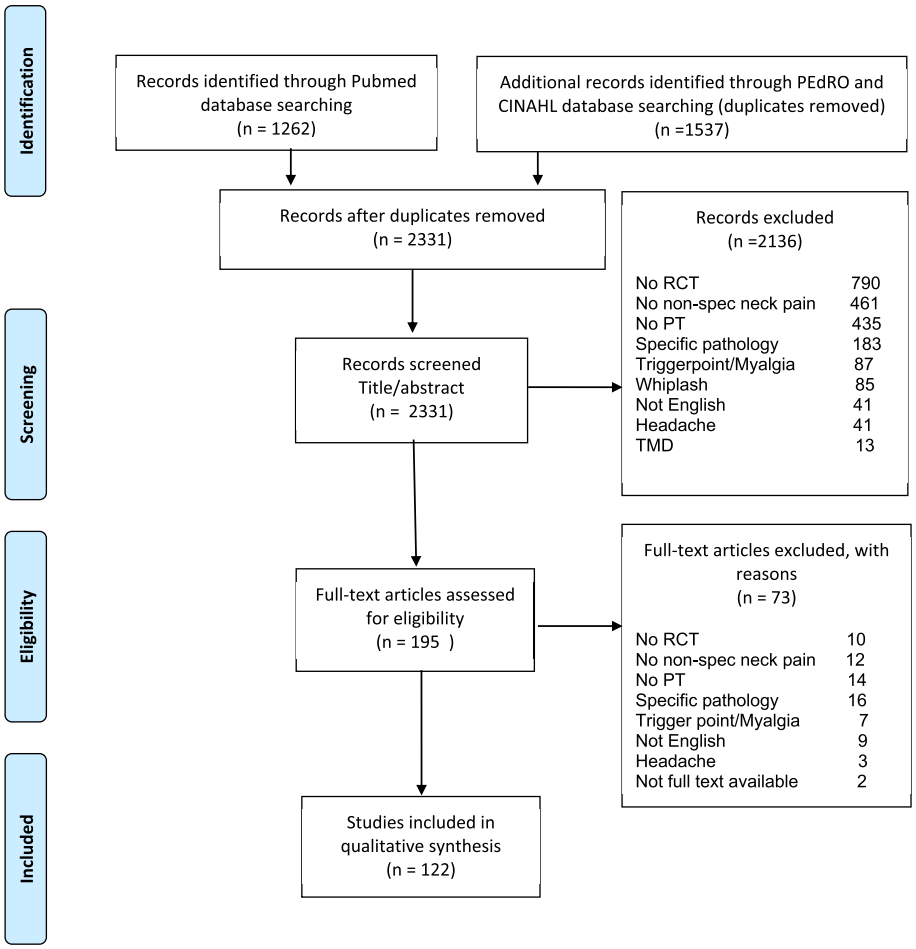

Fig. 1. Flowchart of articles reviewed.

Vonk et al., 2009; Walker et al., 2008; Yang et al., 2015; Ylinen et al., 2003, 2005; Ylinen, Hakkinen, Nykanen, Kautiainen and Takala, 2007; Ylinen et al., 2007; Zaproudina et al., 2007).

Appendix 2 gives an overview of the participant and study characteristics. Sample sizes varied from 9 (Hudson and Ryan, 2010) to 393 (Viljanen et al., 2003) participants. Recruitment took place in various ways, for example by newspaper advertisement or recruitment from different kind of clinics. There were more female than male participants in the study populations. Twenty-three (19%) studies included only females pursuing a homogeneous study population (Bakar et al., 2014; Borisut et al., 2013; Brage et al., 2015; Cunha et al., 2008; Falla et al., 2006; Falla et al., 2007; Falla et al., 2008; Falla et al., 2013; Hakkinen et al., 2008; Jull et al., 2007, 2009; Karlsson et al., 2014; Ko et al., 2010; Mansilla-Ferragut et al., 2009; O'Leary et al., 2007a,b; Pires et al., 2015; Rudolfsson et al., 2014; Viljanen et al., 2003; Ylinen et al., 2003, 2005, Ylinen et al., 2007a,b). Ninety-eight (80%) studies included participants with chronic neck pain (Akhter et al., 2014; Andrade Ortega et al., 2014; Aquino et al., 2009; Bakar et al., 2014; Beer et al., 2012; Beinert and Taube, 2013; Beltran-Alacreu et al., 2015; Borisut et al., 2013; Borman et al., 2008; Brage et al., 2015; Casanova-Mendez et al., 2014; Celenay et al., 2016a,b; Chiu et al., 2004, 2005, 2011; Cook et al., 2015; Cunha et al., 2008; David et al., 1998; Dawood et al., 2013; Dunning et al., 2012; Dusunceli et al., 2009; Dziedzic et al., 2005; Escortell-Mayor et al., 2011; Evans et al., 2012; Falla et al., 2006; Falla et al., 2007; Falla et al., 2008; Falla et al., 2013; Gallego Izquierdo et al., 2016; Ganesh et al., 2014; Giombini et al., 2013; Griffiths et al., 2009; Haas et al., 2003; Hakkinen et al., 2007, 2008; Helewa et al., 2007; Hoving et al., 2002; Hudson and Ryan, 2010; Izquierdo Perez et al., 2014; Javanshir et al., 2015; Jull et al., 2007, 2009; Kanlayanaphotporn et al., 2009, 2010; Karlsson et al., 2014; Khan et al., 2014; Kim et al., 2015; Kim and Kwag, 2016; Kjellman and Oberg, 2002; Krauss et al., 2008; Lansinger et al., 2007, 2013; Lau et al., 2011; Lee and Kim, 2016; Lluch et al., 2014a,b; Lopez-Lopez et al., 2015; Maayah and Al-Jarrah, 2010; Madson et al., 2010; Mansilla-Ferragut et al., 2009; Martel et al., 2011; Martinez-Segura et al., 2006, 2012; Masaracchio et al., 2013; Monticone et al., 2012; O'Leary et al., 2007a,b; O'Leary et al., 2012; Paoloni et al., 2013; Pillastrini et al., 2016; Pires et al., 2015; Puntumetakul et al., 2015; Rendant et al., 2011; Revel et al., 1994; Rudolfsson et al., 2014; Saavedra-Hernandez et al., 2013; 2012; Saayman et al., 2011; Salom-Moreno et al., 2014; Sarig Bahat et al., 2015; Schomacher, 2009; Sherman et al., 2014; Sillevis et al., 2010; Snodgrass et al., 2014; Sterling et al., 2001; Taimela et al., 2000; Thompson et al., 2016; Viljanen et al., 2003; von Trott et al., 2009; Vonk et al., 2009; Walker et al., 2008; Yang et al., 2015; Ylinen et al., 2003, 2005, Ylinen et al., 2007a,b; Zaproudina et al., 2007).

All RCTs reported pain as the most experienced problem by the participants (Akhter et al., 2014; Ali et al., 2014; Andrade Ortega et al., 2014; Aquino et al., 2009; Bakar et al., 2014; Beer et al., 2012; Beinert and Taube, 2013; Beltran-Alacreu et al., 2015; Bid et al., 2014; Borisut et al., 2013; Borman et al., 2008; Brage et al., 2015; Briem et al., 2007; Casanova-Mendez et al., 2014; Celenay et al., 2016a,b; Chiu et al., 2004, 2005, 2011; Cleland et al., 2005, 2007, 2010; Cook et al., 2015; Cunha et al., 2008; David et al., 1998; Dawood et al., 2013; de Camargo et al., 2011; Deepa et al., 2014; Dunning et al., 2012; Dusunceli et al., 2009; Dziedzic et al., 2005; Escortell-Mayor et al., 2011; Evans et al., 2012; Falla et al., 2006; Falla et al., 2007; Falla et al., 2008; Falla et al., 2013; Gallego Izquierdo et al., 2016; Ganesh et al., 2014; Giombini et al., 2013; Gonzalez-Iglesias et al., 2009a,b; Griffiths et al., 2009; Griswold et al., 2015; Haas et al., 2003; Hakkinen et al., 2007, 2008;

Helewa et al., 2007; Hoving et al., 2002; Hudson and Ryan, 2010; Humphreys and Irgens, 2002; Izquierdo Perez et al., 2014; Javanshir et al., 2015; Jordan et al., 1998; Jull et al., 2007, 2009; Kanlayanaphotporn et al., 2009, 2010; Karlsson et al., 2014; Khan et al., 2014; Kim et al., 2015; Kim and Kwag, 2016; Kjellman and Oberg, 2002; Klaber Moffett et al., 2005; Ko et al., 2010; Krauss et al., 2008; Kumar et al., 2011; Lansinger et al., 2007, 2013; Lau et al., 2011; Leaver et al., 2010; Lee et al., 2013; Lee and Kim, 2016; Lee et al., 2016; Lluch et al., 2014a,b; Lopez-Lopez et al., 2015; Maayah and Al-Jarrah, 2010; Madson et al., 2010; Mansilla-Ferragut et al., 2009; Martel et al., 2011; Martinez-Segura et al., 2006, 2012; Masaracchio et al., 2013; McLean et al., 2013; Monticone et al., 2012; O'Leary et al., 2007a,b; O'Leary et al., 2012; Paoloni et al., 2013; Pillastrini et al., 2016; Pires et al., 2015; Pool et al., 2010; Puentedura et al., 2011; Puntumetakul et al., 2015; Rendant et al., 2011; Revel et al., 1994; Rolving et al., 2014; Rudolfsson et al., 2014; Saavedra-Hernandez et al., 2013, 2012; Saayman et al., 2011; Salom-Moreno et al., 2014; Sarig Bahat et al., 2015; Schomacher, 2009; Sherman et al., 2014; Sillevis et al., 2010; Snodgrass et al., 2014; Sterling et al., 2001; Taimela et al., 2000; Thompson et al., 2016; Vernon et al., 1990; Viljanen et al., 2003; von Trott et al., 2009; Vonk et al., 2009; Walker et al., 2008; Yang et al., 2015; Ylinen et al., 2003, 2005, Ylinen et al., 2007a,b; Zaproudina et al., 2007).

Of the 122 studies thirty-seven studies, (30%) scored a complete clinical reasoning process (Fig. 2). Fifty-six studies (46%) scored "-" on item 2 (cause) of the rating scale and therefore, the problem related outcome, matched intervention and intervention related outcome measures also scored negative (Akhter et al., 2014; Ali et al., 2014; Andrade Ortega et al., 2014; Beltran-Alacreu et al., 2015; Borman et al., 2008; Brage et al., 2015; Chiu et al., 2011; Cleland et al., 2007; Cook et al., 2015; Cunha et al., 2008; David et al., 1998; Dusunceli et al., 2009; Dziedzic et al., 2005; Escortell-Mayor et al., 2011; Evans et al., 2012; Gonzalez-Iglesias et al., 2009b; Griffiths et al., 2009; Griswold et al., 2015; Hakkinen et al., 2008; Helewa et al., 2007; Hoving et al., 2002; Hudson and Ryan, 2010; Izquierdo Perez et al., 2014; Jordan et al., 1998; Kanlayanaphotporn et al., 2009, 2010; Karlsson et al., 2014; Kumar et al., 2011; Lansinger et al., 2007, 2013; Lau et al., 2011; Leaver et al., 2010; Madson et al., 2010; Martel et al., 2011; Masaracchio et al., 2013; McLean et al., 2013; Monticone et al., 2012; Paoloni et al., 2013; Pool et al., 2010; Puntumetakul et al., 2015; Rendant et al., 2011; Saavedra-Hernandez et al., 2013, 2012; Schomacher, 2009; Sherman et al., 2014; Snodgrass et al., 2014; Taimela et al., 2000; Thompson et al., 2016; Viljanen et al., 2003; von Trott et al., 2009; Walker et al., 2008; Ylinen et al., 2003; Ylinen et al., 2007a,b; Zaproudina et al., 2007). Sixty-six RCTs (54%) described a cause of the experienced problem (Bakar et al., 2014; Beer et al., 2012; Beinert and Taube, 2013; Bid et al., 2014; Borisut et al., 2013; Briem et al., 2007; Casanova-Mendez et al., 2014; Celenay et al., 2016a,b; Chiu et al., 2004; Chiu et al., 2005; Cleland et al., 2005, 2007; Dawood et al., 2013; de Camargo et al., 2011; Deepa et al., 2014; Dunning et al., 2012; Falla et al., 2006; Falla et al., 2007; Falla et al., 2008; Falla et al., 2013; Gallego Izquierdo et al., 2016; Ganesh et al., 2014; Giombini et al., 2013; Gonzalez-Iglesias et al., 2009a; Griffiths et al., 2009; Haas et al., 2003; Hakkinen et al., 2008; Humphreys and Irgens, 2002; Javanshir et al., 2015; Jull et al., 2007, 2009; Khan et al., 2014; Kim et al., 2015; Kim and Kwag, 2016; Kjellman and Oberg, 2002; Klaber Moffett et al., 2005; Ko et al., 2010; Krauss et al., 2008; Lee et al., 2013; Lee and Kim, 2016; Lee et al., 2016; Lluch et al., 2014a, b; Maayah and Al-Jarrah, 2010; Mansilla-Ferragut et al., 2009; Martinez-Segura et al., 2012; O'Leary et al., 2007a,b; O'Leary et al., 2012; Pillastrini et al., 2016; Pires et al., 2015; Puentedura et al., 2011; Revel et al., 1994; Rolving et al., 2014; Rudolfsson et al., 2014; Saayman et al., 2011; Salom-Moreno et al., 2014; Sarig Bahat et al., 2015; Sillevis et al., 2010; Sterling et al., 2001; Vernon et al., 1990; Vonk et al., 2009; Yang et al., 2015; Ylinen et al., 2005). Forty-six studies (38%) had an 'argued' or 'unclear' cause (the argued cause pathway) (Bakar et al., 2014; Borisut et al., 2013; Briem et al., 2007; Casanova-Mendez et al., 2014; Celenay et al., 2016a,b; Chiu et al., 2004; Chiu et al., 2005; Cleland et al., 2005; de Camargo et al., 2011; Dunning et al., 2012; Falla et al., 2006; Falla et al., 2007; Falla et al., 2008; Falla et al., 2013; Gallego Izquierdo et al., 2016; Ganesh et al., 2014; Giombini et al., 2013; Gonzalez-Iglesias et al., 2009a; Griffiths et al., 2009; Haas et al., 2003; Hakkinen et al., 2007; Humphreys and Irgens, 2002; Javanshir et al., 2015; Khan et al., 2014; Kim et al., 2015; Klaber Moffett et al., 2005; Ko et al., 2010; Lee et al., 2016; Lluch et al., 2014b; Maayah and Al-Jarrah, 2010; Martinez-Segura et al., 2012; O'Leary et al., 2007a,b; O'Leary et al., 2012; Pires et al., 2015; Revel et al., 1994; Rolving et al., 2014; Rudolfsson et al., 2014; Salom-Moreno et al., 2014; Sarig Bahat et al., 2015; Sillevis et al., 2010; Sterling et al., 2001; Vernon et al., 1990; Vonk et al., 2009; Yang et al., 2015; Ylinen et al., 2003). Twenty studies (16%) scored a 'diagnosed' cause (the diagnosed cause pathway) (Beer et al., 2012; Beinert and Taube, 2013; Bid et al., 2014; Cleland et al., 2010; Dawood et al., 2013; Deepa et al., 2014; Jull et al., 2007, 2009; Kim and Kwag, 2016; Kjellman and Oberg, 2002; Krauss et al., 2008; Lee et al., 2013; Lee and Kim, 2016; Lluch et al., 2014a; Mansilla-Ferragut et al., 2009; Martinez-Segura et al., 2006; O'Leary et al., 2007a,b; Pillastrini et al., 2016; Puentedura et al., 2011; Saayman et al., 2011).

The researched population in these 20 (16%) studies with a "diagnosed cause" *actually* had the impairment or activity limitation that the intervention intended to improve. However 5 (4%) RCTs had no cause related goal and thereafter, 4 (3%) no intervention related outcome

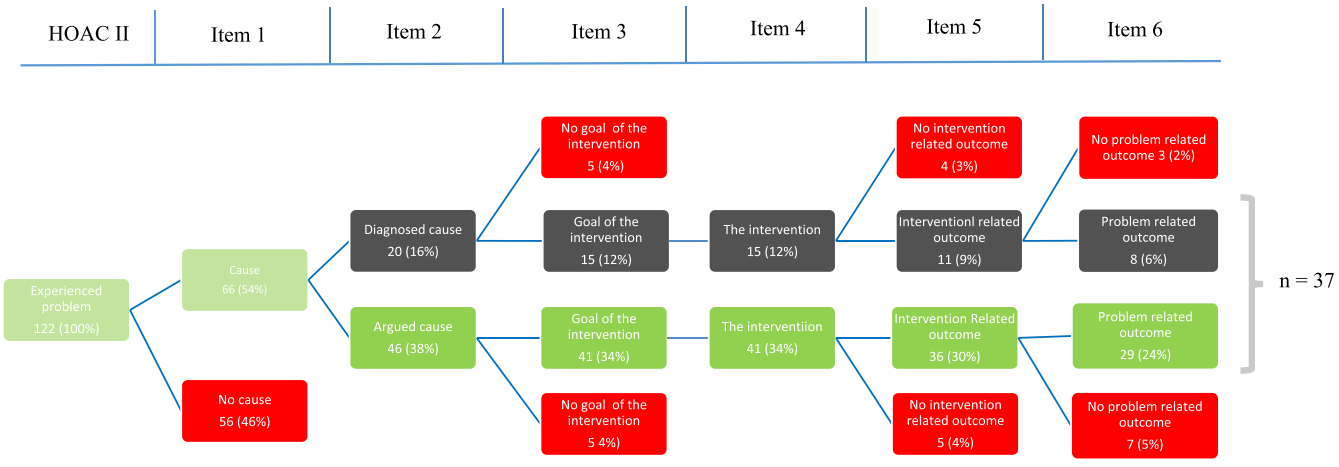

Fig. 2. HOAC II clinical reasoning process rating outcome.

measures. Therefore 11 (9%) of the included studies had a diagnosed cause with at least one intervention related outcome measure (Beer et al., 2012; Beinert and Taube, 2013; Cleland et al., 2010; Dawood et al., 2013; Jull et al., 2007; Jull et al., 2009; Kim and Kwag, 2016; Lee et al., 2013; Lee and Kim, 2016; Mansilla-Ferragut et al., 2009; O'Leary et al., 2007a,b). Of these 11 studies 8 (6%) presented also problem outcome measures and therefore completed the entire clinical reasoning process (Beer et al., 2012; Beinert and Taube, 2013; Cleland et al., 2010; Dawood et al., 2013; Jull et al., 2007, 2009; Kim and Kwag, 2016; Lee and Kim, 2016).

The detailed score of the components of the clinical reasoning process is described in Appendix 3.

The PEDro scores ranged from 2 to 10 with a median of seven. Because the majority, 87 (71%) of the studies, scored ≥ 6, the overall methodological quality was high. Of five studies no score was available in the PEDro database (Hakkinen et al., 2007, 2008; Kanlayanaphotporn et al., 2009; Kanlayanaphotporn et al., 2010; Saavedra-Hernandez et al., 2012). Therefore the first two authors assessed the Risk of Bias. Finally, there was a small negative correlation between PEDro scores and the number of positive items on the HOAC II based clinical reasoning process rating scale (spearmans rho −0.2).

4. Discussion

This review illustrates that the minority of studies (n = 37; 30%) describe the complete clinical reasoning process, and that only a very small proportion of these studies with a complete clinical reasoning process (n = 8; 6%) had a 'diagnosed cause'. In fact, the HOAC II key-component most frequently missing was the "cause" (either diagnosed or argued), with nearly half of the studies not describing any cause at all. It could be argued that these are the ultimate "trial and error" RCTs because even an argued cause, that is, an argued reason why the intervention could be effective, is missing. The HOAC II key-component most frequently described is the "intervention". This means that in all the included RCTs with a cause, the interventions were described in terms of a cause matching the predefined goals.

Only 11 (9%) of the included studies had a diagnosed cause with at least one intervention related outcome measure (Beer et al., 2012; Beinert and Taube, 2013; Cleland et al., 2010; Dawood et al., 2013; Jull et al., 2007; Jull et al., 2009; Kim and Kwag, 2016; Lee et al., 2013; Lee and Kim, 2016; Mansilla-Ferragut et al., 2009; O'Leary et al., 2007a,b). These studies make it possible to understand the clinical reasoning process used for the choice of the intervention and what the intervention aimed to achieve (the goal). In contrast to studies with a 'diagnosed' cause, in studies with "an argued cause" it remained unclear what the impairment, activity limitation or restriction in participation was. Thus, it is possible that in these studies the population did not have an impairment, activity limitation or restriction in participation at all. To illustrate; there were 5 studies aiming to improve neck Range of Motion (ROM), but the authors did not find any improvement in ROM (Hakkinen et al., 2007, 2008; Kanlayanaphotporn et al., 2009; Kanlayanaphotporn et al., 2010; Saavedra-Hernandez et al., 2012). However, their conclusion that the intervention had no effect on ROM can be questioned as ROM at baseline was equal to norm values (Swinkels and Swinkels-Meewisse, 2014). This could occur because a diagnosed ROM limitation was not used as an inclusion criterion. Although some participants could have a ROM limitation, the possibility remains limited to achieve a good result if norm values are measured at baseline. This example clearly emphasises the need to define and measure specific impairments, activity limitations or restriction in participation as inclusion criteria for participants.

Recently, Hoffmann et al. made recommendations to enhance the usability of systematic reviews (Hoffmann et al., 2014). Within the PICO (Patient/Intervention/Comparison/Outcome) format the intervention should be given as much consideration as the other components. They recommend the use of their Template for Intervention Description and Replication (TIDierR) checklist (Groeneweg et al., 2017). The TIDierR checklist and guide was published with the specific aim of improving the completeness of reporting and ultimately the replicability of interventions. The authors included an item into the TIDieR checklist to describe any rationale, theory, or goal of the elements essential to the intervention (Groeneweg et al., 2017). This is to gain insight into the working mechanism of the intervention. They also state that "the known or supposed mechanism of action of the active components of the intervention should be described because if the active components of the intervention were omitted, the intervention would be ineffective" as demonstrated in our 'ROM' example.

Added to this, there is now a consensus statement about reporting spinal manipulative therapy including the item "rationale of the therapy" (Kjellman et al., 1999). This also underpins the need for a diagnosed impairment or activity limitation with matching goal of the intervention and intervention related outcome to understand if an intervention is to be effective and further understand its working mechanism. This knowledge is of the utmost importance for the physiotherapist to make evidence based decisions during the clinical reasoning process and, this knowledge is lacking in 91% of the RCTs included in this review.

Finally we assessed if the risk of bias and clinical reasoning were correlated. There was a small negative correlation of −0.2 of the PEDro scores with extent of the clinical reasoning process. The negative score implies that lower risk of bias is associated with lower complete clinical reasoning. These finding indicates that a better methodological quality does not necessarily imply a better clinical reasoning process. As stated earlier, the updated method guideline for systematic reviews in the Cochrane back and neck group strongly advises the use of the TIDieR checklist for describing the intervention (Furlan et al., 2015). However, the clinical reasoning process is broader and was more optimally represented in the previous edition in the Cochrane back and neck group guideline (van Tulder et al., 2003). For the next version of the guideline we strongly advise to consider incorporating assessment of the clinical reasoning process, or otherwise to at least include a description of the diagnostic process, so it becomes possible to asses if the population under research had the impairment or activity limitation that the intervention intended to improve.

This systematic review (SR) has limitations. Firstly, we did not request additional information from authors. Authors may not have reported clinical reasoning while in fact it did take place. Therefore it is possible that a negative score was given despite the fact that clinical reasoning has taken place. However, the main omission in the scored clinical reasoning processes was the diagnostic process. Diagnostic inclusion criteria objectify the assumed cause of the experienced problem and were used in only 16% of the RCTs. In addition, it is unlikely that authors forget to mention inclusion criteria. Hence, it is not expected that an unfair negative score, due to unreported clinical reasoning, will often occur.

Secondly, It is possible that researchers have adopted a different framework or model that underpins the choice of the intervention. However many other models of clinical reasoning in physiotherapy all use a diagnostic process to substantiate the choice of intervention (Edwards et al., 2004; Elven et al., 2015; Jones and O'Shaughnessy, 2014; Jones, 1992). Furthermore, the WCPT policy statement: "Description of physical therapy" stated that: "physiotherapist are professionally required to undertake a comprehensive examination/assessment of the patient/client", thereby clearly illustrating that a diagnostic process is a conditional part of the physiotherapeutic process (World Confederation for Physical Therapy, 2017). Despite the importance of the diagnostic process, our review highlights that the absence of a diagnostic process is the main omission in the included studies.

Thirdly, we realise that there is no Gold Standard for clinical reasoning. We developed a scoring list by using the HOAC II steps. The HOAC II has two advantages. First, it is compatible with "the guide to

physiotherapist practice's (Rothstein et al., 2003). This ensures that the HOAC is in line with daily physiotherapy practice. Second, in the structure of the HOAC II the hypothetico-deductive reasoning model is incorporated. The advantage here is that this model has its roots in the empirical-analytical research paradigm matching the RCT methodology (Edwards et al., 2004). In summary, the HOAC II is consistent with the physiotherapy process and in line with the RCT methodology. In addition, although scoring the clinical reasoning process is subjective, by using the HOAC as a scoring tool we are confident that the scorings system is at least more transparent. Finally, we only judged whether the key components were present, not whether the components were valid. This could be subject to further study.

A strength of this study is the large number of included studies. As we anticipated finding a large body of RCTs as we used a sensitive search strategy, strict inclusion and exclusion criteria were applied and myalgia, whiplash and headache were excluded in order to include a homogeneous population with non-specific neck pain. Because of the sensitive search it is not expected that many studies have been missed, or that these missed studies (if any) will have a substantial impact on our main findings. Another strength was the use of the PEDro ratings. The reliability of PEDro scores is known for trained raters (Maher et al., 2003). Therefore, we adopted the scores from the PEDro organisation website, because trained raters performed their ratings. This way we made sure that the listed scores are of sufficient reliability.

To our knowledge, this is the first systematic review that provides an overview of the completeness of the clinical reasoning process of RCT's in patients with non-specific neck. In the non-specific neck pain literature we found only one review of Kjellmann et al. with similarities to this study (Kjellman et al., 1999). It concerned patients with neck pain but they also included specific pathology. In contrast to our study, they evaluate the inclusion criteria, intervention and outcome measures. They reported that no study used functional limitations as an inclusion criterion. In fact, none of their included RCTs had a diagnosed problem as an inclusion other than a specific pathology. They also found a great diversity in interventions and that mostly PROMS were used as outcome measures with the exception of ROM as a regularly used impairment outcome measure. Our study more or less confirms these findings. Despite a different research population, a study of Hoogeboom et al. also shows similarities with our study (Hoogeboom et al., 2012). In contrast to our study they scored part of the clinical reasoning process where they specifically targeted the validity of the intervention. The best comparable item was the match between the diagnosed cause and the intervention. They scored a match in 8% of the studies, which is quiet comparable with our score of 12%.

Future research should focus on all key elements discussed in this review. Diagnostic tests should be reported as inclusion criteria with their matching interventions. In addition, measurement properties of these tests should be reported. This is equally important for the reporting of appropriate outcome measures, which should include both intervention and patient related outcomes. For example; two studies with a complete clinical reasoning process about endurance training showed good results on intervention related outcome measures however, poor results on problem related outcome measures (Beer et al., 2012; Jull et al., 2009). The use of problem related outcome measures could have led, unjustly, to the conclusion that this intervention had no effect. This underpins the importance of using both types of outcomes measures.

The outcome of diagnostic tests should lead to relevant subgroups matching the chosen intervention. This fits within the current discussion about subgroups and classification systems and the need to develop targeted treatments for known impairments and activity limitations or developed classification systems for patients with non-specific neck pain (Childs et al., 2004; Clair et al., 2006; Liu et al., 2017; Wang et al., 2003). We hope that this review contributes to the subgroup discussion.

In summary a complete line of clinical reasoning appears to be of paramount importance for the examination of a specific intervention with its matching specific effect in order to understand working mechanisms of interventions. In general, this study was a first step to provide insight in the completeness of the clinical reasoning process within RCTs on non-specific neck pain.

In conclusion: In the majority of studies no complete clinical reasoning process was described, therefore lacking, to a large extent, the external validity. A very small proportion (9%) had an diagnosed cause with a matching intervention and intervention related outcome measures, thereby determining what needs to be treated and if the goal of the intervention was reached. Finally, the small negative correlation between the extent of the clinical reasoning process and the risk of bias, indicates that a better methodological quality does not necessarily imply a better clinical reasoning process.

Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.msksp.2018.01.011.

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