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SOFT-COLLAR USE IN REHABILITATION OF WHIPLASH-ASSOCIATED DISORDERS - A SYSTEMATIC REVIEW AND META-ANALYSIS

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1.0 INTRODUCTION

Neck pain following motor vehicle crash is common and often leads to a diagnosis of Whiplash Associated Disorders (WAD) (Cassidy et al., 2000; Joslin et al., 2004; Pink et al., 2016) based on the Quebec Task Force (QTF) recommendations (Spitzer et al., 1995). While a large portion of those with WAD recover within a few months, approximately 50% develop ongoing symptoms (Carroll et al., 2008; Pobereskin, 2005; Rebbeck et al., 2006). While tissue-damage could explain initial symptoms, psychosocial factors, incl. hyperarousal, may contribute to persistent symptoms (Curatolo et al., 2011; Ritchie et al., 2015) impacting not only the individual (Ritchie et al., 2017) but also imposing an economic burden on society (Galasko et al., 2002; Lamb et al., 2013; Pink et al., 2016).

As such, identifying optimal and cost-effective treatment strategies for WAD is a priority among both researchers, health care professionals and funders (Galasko et al., 2002; Pink et al., 2016). However, despite advances in our knowledge of WAD, the number of injured people who develop persistent symptoms is not declining (Carroll et al., 2008; Jull, 2016b; Rasmussen et al., 2020). Interestingly, studies investigating the effect of a comprehensive guideline based treatment approach compared to a single session of advice (Lamb et al., 2013) or usual care (Jull et al., 2013) have shown no between-group differences. These results underpin the need for identifying effective treatment strategies and thereby potentially reducing the number of injured people reporting persistent WAD symptoms (Jull, 2016b; Jull et al., 2013; Michaleff et al., 2014).

For years a passive approach consisting of immobilization combined with soft-collar use before starting a gradual mobilization approach was standard care for acute WAD (Mealy et al., 1986). However, this passive rehabilitation strategy has been replaced by a more active strategy consisting of exercises and/or advice to stay active, which have shown more favourable outcomes on pain and disability (McKinney et al., 1989; Schnabel et al., 2004; Vassiliou et al., 2006). As such, clinical guidelines not only favour an active or act-as-usual approach but also recommend against soft-collar use when treating acute WAD (Cameron et al., 2014; Gross et al., 2013; Teasell et al., 2010). However, it has been suggested that while an active approach shows favourable outcome compared to immobilization, short term soft-collar use in the very early stages may not have any detrimental effect on the overall outcome (Muzin et al., 2008). Considering that using soft-collars may be effective in reducing pain (Naylor & Mulley, 1991) and that there seems to be no long-term

detrimental effects (Gennis et al., 1996; Muzin et al., 2008), it may be time to re-evaluate if there is a place for soft-collar use in a contemporary treatment strategy for WAD rehabilitation. While the results of a recent systematic review (Ricciardi et al., 2019) did not support the use of a soft-collar, there were several methodological concerns particularly related to the included studies that question the findings and limit their clinical implications (XXXX et al.). Therefore, the aim of this review was to investigate the effectiveness of using a soft-collar on self-reported pain and disability when treating patients with acute WAD.

2.0 METHODS

This systematic review was registered in the PROSPERO registry (XXXX) and adheres to the PRISMA-guidelines for health care intervention studies (Liberati et al., 2009).

2.1 Search strategy

Electronic databases (AMED, CINAHL Complete, Cochrane Library, Embase, Medline, PEDro, PsycINFO, PubMed, SPORTDiscus) were searched until the 28/01-2020 using broad search terms such as neck pain, whiplash, WAD, collar, cervical orthosis etc. either alone or combined with AND/OR (see search strategy for PubMed in supplementary file 1). The search strategy was adjusted according to the specifications of the individual database being searched. In order to identify all relevant literature, no restriction for publication year or WAD severity (grade I-IV) was used. When a review or a guideline involving soft-collar use in WAD was identified, a chain-search was conducted in order identify relevant randomized, controlled trials (RCT) which were then included in the review process.

2.2 Eligibility criteria & study selection

RCTs published in English, Danish, Swedish or Norwegian which assessed the effectiveness of a soft-collar, alone, or in addition to non-surgical treatments (best care/wait-and-see, exercise or other non-surgical interventions) compared to non-surgical treatments without soft-collar use for acute or subacute (<12-weeks) WAD were included in this systematic review. Studies that included participants with WAD symptoms for >12-weeks and studies using a semi-rigid or rigid collar were excluded.

Study selection was conducted independently by two of the authors (X and X) in three steps, 1) Title screening, 2) Abstract screening and 3) Full-text screening. The full-text was retrieved if a study was found eligible by at least one of the two authors. If the two authors were not able to evaluate study eligibility from title or abstract, the full-text was retrieved to ensure that all eligible studies were included. In case of disagreement on inclusion, a third author (X or X) made the final judgement regarding including or excluding a study.

2.3 Outcome measures

Only self-reported neck pain (VAS/NRS scales were preferred over other scales) and disability at the end of treatment (primary endpoint) and at 1-year follow-up (secondary endpoint) were of interest for this review. If no data were reported for the primary endpoint, the closest data-point was used and if no 1-year follow-up was reported, the longest possible follow-up was used. If disability was not directly reported, data on cervical range of motion (CROM) was accepted as a proxy as evidence suggest these outcomes are related in neck pain populations (Howell et al., 2012; Thorp & Willson, 2019) although not directly reflecting disability according the ICF-classification (World Health Organization, 2002).

2.4 Data extraction

Purpose of the study, number of participants allocated to intervention or control group, type of intervention, outcome measures (pain and disability), baseline and follow-up measurements and results were extracted (Table 1). Data were extracted independently by the same two authors who evaluated study eligibility independently and in case of disagreement a third author made the final judgement. To illuminate potential overlap between the RCTs used in different reviews/guidelines, the number of times a study was cited in a review or the number of reviews a specific RCT was related to was also noted (see supplementary file 2).

2.5 Risk of bias & quality assessment

This review assessed all included RCTs using the 11-item PEDro-scale which have previously shown to be sufficiently reliable and valid for assessing methodological quality of RCTs (de Morton, 2009; Maher et al., 2003). All but the first item, which should be answered 'yes' or 'no', can be given

one point and thereby giving a maximum score of 10. A higher score equals better quality (<4=Poor; 4-5=Fair; 6-8=Good; 9-10=Excellent) (Teasell et al., 2010). Furthermore, it was evaluated whether groups were treated similarly, besides the allocated interventions, or if the results could be biased by elements not accounted for in the protocol such as a difference in the number of sessions with a health care provider. Such differences are known as clinical heterogeneity (Fletcher, 2007; Higgins & Green, 2011) and are normally used to illustrate intervention differences between RCTs but in this review it is used to describe potential differences between groups in individual studies.

Two authors (X and X) assessed all included RCT's using the PEDro-scale. All assessments were conducted independently before comparing results. In case of disagreement, a third author made the final judgement.

2.6 Data synthesis and statistical methods

Estimations of self-reported neck pain and disability (or CROM) from individual RCTs at the primary endpoint were summed using a random effects model meta-analysis and expressed as standardized mean difference (SMD), adjusted to Hedges g with 95% confidence intervals. The SMD was estimated as the difference in mean at the primary endpoint between groups receiving a soft-collar or not divided by the pooled standard deviation (SD). If only standard error was available, this was used to estimate the SD (Higgins & Green, 2011). If SD was only reported for baseline data, this was used as an estimation of the SD at the primary endpoint. As proposed by Cohen, a SMD of 0.2, 0.5 and 0.8 was interpreted as small, moderate and large effect size, respectively (Cohen, 1988). Heterogeneity was estimated as between-study variance (τ^2) and calculated as I^2 statistics expressing the proportion of variation (inconsistency) in the combined estimates due to variance between studies. An I^2 of 0% indicate no inconsistency between the results of the included RCTs while 100% indicated maximum inconsistency. An alpha below 0.05 (two-tailed) was considered significant. For significant findings a Weighted Mean Difference (WMD) was calculated. Analysis was conducted using Stata 16.1 (StataCorp, College Station, TX, USA).

The overall certainty of evidence across studies for the outcomes was assessed by two authors (X and X) using Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach with disagreements being rectified by a 3rd author. Using this approach the confidence in an effect estimate across RCTs starts as high but is then downgraded up to three levels

based on risk of bias (Selection bias, performance bias, detection bias, reporting bias and other bias), inconsistency (heterogeneity of results indicated by overlapping CI and I^2 values etc.), indirectness (differences between study -populations, -interventions or -outcomes), imprecision (if the upper or lower CI boundary would cause different interpretation or the estimates comes from small sample studies) or *publication bias* (indication of only some trials being published) following the GRADE-guideline recommendations (Guyatt et al., 2011a; Guyatt et al., 2011b).

2.7 Change to the PROSPERO protocol

AMED, PsycINFO and SPORTDiscus databases were also searched while language was restricted to English, Danish, Swedish or Norwegian to ensure correct interpretation of potential studies.

Studies where soft-collars were used in both the intervention and the control condition were excluded in order to be able to answer our research question regarding the effectiveness of soft-collar use on pain and disability.

The primary outcome was specified to neck pain instead of pain in general as this is the most relevant area of pain in WAD.

A meta-analysis was conducted for pain intensity and ROM for the primary endpoint only as large variation in the secondary endpoint made it impossible to make any meaningful comparison of studies.

GRADE-assessment of the certainty of evidence was conducted for all outcomes and studies included in the meta-analyses.

3.0 RESULTS

The final search gave 3.251 hits. After removing duplicates, 1.987 studies were considered eligible for title and abstract screening, which yielded 159 studies for full-text screening. Following full-text screening a total of 42 studies (38 reviews and 4 RCTs reported in 6 articles) were included in this review (fig.1). A chain-search through the literature included in the 38 reviews identified the same four RCTs (reported in 6 articles) that were found during the systematic search (see supplementary file 2). One RCT was reported in three papers (Rosenfeld et al., 2000; Rosenfeld et al., 2003; Rosenfeld et al., 2006). Of these articles, only Rosenfeld et al. (2003) was included as it was were

most specific to the outcome measures at the primary- and secondary endpoint for the current review. In total four articles representing four RCTs were included.

3.1 Study characteristics

Study characteristic can be seen in table 1 for all included RCTs. The four included RCTs were published between 1986 and 2003 with two being published prior to 2000. The number of participants with WAD included in the four RCTs varied greatly between studies with the smallest study including 61 participants while the largest included 201, giving a total of 462 WAD participants (Table 1). However, only 409 participants with WAD were considered in this review, as Rosenfeld et al. (2003) delayed treatment onset for two of four WAD groups. Therefore, data from these groups were not included in order to ensure comparability to the other included studies. All RCTs recruited participants with WAD in the acute or subacute phase. Two RCTs included participants within 24-96 hours after injury (Bonk et al., 2000; Rosenfeld et al., 2003). Two RCTs do not clarify the time-factor on inclusion but participants were recruited from emergency departments and were therefore assumed to be in the acute phase (Borchgrevink et al., 1998; Mealy et al., 1986).

The included RCTs used a variety of different types of interventions in combination with or compared to soft-collar use (Table 1), although Bonk et al. (2000) did not define the specific type of collar used in their study. In general the studies investigated an active approach consisting of mobilization and/or exercise with or without soft-collar use (Bonk et al., 2000; Mealy et al., 1986; Rosenfeld et al., 2003) or act-as-usual compared to Immobilization using a soft-collar (Borchgrevink et al., 1998).

Adverse events were only reported by one study (Bonk et al., 2000) with one participant in the active group being excluded due to developing neurological symptoms after inclusion.

3.2 Risk of bias assessment

The PEDro-score for all studies (table 2) ranged from 5-8 out of 10 points with a mean score of 6.25 (SD 1.09), i.e. the studies were of fair-good quality. The main concern for all studies based on the PEDro-scale was blinding, as it was deemed not possible to blind participants (item-5) or the health care professional (item-6) to treatment allocation.

Clinical heterogeneity was a problem in three of four RCTs (table 2), i.e. for the majority of studies, the groups were not similarly treated in other aspects than the investigated intervention. In the three studies (Bonk et al., 2000; Mealy et al., 1986; Rosenfeld et al., 2003) one group receiving an active approach participated in multiple treatment sessions compared to a group using a soft collar with or without verbal/written information.

3.3 Effect on pain

All studies reported pain measures in some form such as 0-10/0-100 Visual Analogue Scale (VAS) or by using a Likert scale to estimate intensity or duration of pain. A detailed description of pain outcomes for all studies can be seen in table 1.

In general, the studies investigating an active approach or act-as-usual found significantly less self-reported pain intensity when compared to treatment with a soft-collar (Borchgrevink et al., 1998; Mealy et al., 1986; Rosenfeld et al., 2003). However, Bonk et al. (2000) used a study-design where the two WAD groups were compared to baseline-data from healthy controls and found that an active approach was not significantly different from the controls at 6- or 12-weeks, while the soft-collar group was significantly worse compared to the controls at 6-weeks.

Only two studies could be included in meta-analysis (Mealy et al., 1986; Rosenfeld et al., 2003). Bonk et al. (2000) did not report any specific pain scores and Borchgrevink et al. (1998) investigated an act-as-usual approach. The analysis of the two studies (Mealy et al., 1986; Rosenfeld et al., 2003) using data from 1- and 6-months respectively, revealed a SMD of -0.80 (-1.20, -0.41), $I^2=0.0\%$ (fig.2), in favour of the active approach corresponding to 2.18cm (1.16, 3.20) on a VAS scale.

The GRADE-assessment rated the overall certainty of the evidence as low for self-reported pain with evidence being downgraded two levels due to risk of bias and imprecision (table 3).

3.4 Effect on disability or neck range of motion

None of the included studies reported disability data. However, all studies reported data on CROM either for individual directions or as a total score. A detailed description of CROM outcomes for all studies can be seen in table 1.

Mealy et al. (1986) found significant increased total CROM for the group receiving an active approach compared to using a soft-collar while Bonk et al. (2000) only reported this as a non-significant trend in contrast to Rosenfeld et al. (2003) who reported no between group difference at any time point. This latter result is similar to those of Borchgrevink et al. (1998) who did not find any group difference when comparing act-as-usual to immobilization using a soft-collar.

For the meta-analysis of total CROM only studies reporting data from an active approach and soft-collar use were included as Borchgrevink et al. (1998) investigated an act-as-usual approach. Bonk et al. (2000) was excluded from analysis as CROM was not reported in consistent units. CROM Total (fig.3) was reported by two studies (Mealy et al., 1986; Rosenfeld et al., 2003) and based on data from 1- and 6-months respectively, no significant effect was seen (SMD of 0.16 (-0.21, 0.54), $I^2=0.0\%$). For the specific CROM directions rotation was chosen for the analysis as it theoretically represent elements of all movement directions due coupled nature of active cervical intervertebral movements (Oatis, 2009). CROM Rotation (fig.4) was reported by two studies (Bonk et al., 2000; Rosenfeld et al., 2003) and using data from 6-weeks and 6-months respectively, no significant effect was seen (SMD of 0.54 (-0.19, 1.27), $I^2=76.36\%$).

The GRADE-assessment rated the overall certainty of the evidence as very low for both CROM Total and Rotation with evidence being downgraded three levels due to risk of bias, inconsistency (CROM Rotation), indirectness, and imprecision (table 3).

4.0 DISCUSSION

This systematic review examined 4 RCTs comprising 409 individuals with acute WAD to investigate the effects of soft-collar use on pain and disability outcomes. Meta-analysis (2 RCTs) indicated that an active or act-as-usual approach resulted in significantly less pain at short-term follow-up compared to rest and immobilization with a soft-collar. No studies reported disability outcomes. Meta-analysis of CROM outcomes (2 RCTs) found no significant difference between soft-collar use and active treatment approaches. Whilst all studies were of fair-good quality, the overall certainty of evidence was low to very low with several common methodological flaws and the interpretation of findings was hampered by the presence of clinical heterogeneity.

In general, our findings favour an active or act-as-usual approach over standard treatment or immobilization using a soft-collar. Despite the limited number of RCTs on the topic and low to very low certainty of evidence, the studies included in the current review are the same that have been used to recommend against soft-collar use in reviews and guidelines (Cameron et al., 2014; Gross et al., 2013; Teasell et al., 2010; Wong et al., 2015). The argument used for such recommendation is that soft-collar use is ineffective or has a detrimental effect on recovery with regards to pain and disability in those with acute WAD (Cameron et al., 2014; Gross et al., 2013). This is to some extent supported by the current results where the meta-analysis revealed a significant group difference for pain but not CROM favouring an active approach over soft-collar. The group difference regarding pain was 2.18 cm on a VAS scale, which is considered a clinically important difference (MacDowall et al., 2018) and thereby meaningful for a patient (Jaeschke et al., 1989). However, as the results also highlighted several methodological concerns it is important to consider these when interpreting the findings of this review.

For the majority of studies, treatments focusing on rest and immobilization using a soft-collar were used as a control group for an active or act-as-usual treatment. The PEDro-assessment revealed lack of blinding as a concern for the included RCTs (Table 2) which would be the case for most RCTs investigating an active or exercise approach, where blinding of clinicians and patients is difficult. Lack of blinding of both clinicians and patient participants could cause any beneficial intervention effect to be exaggerated (Savovic et al., 2012) as well as a potential nocebo effect in the group receiving the control intervention (Feys et al., 2014; Whitehead, 2004). This could result in greater improvements in patients receiving an active approach than those given a standard treatment including soft-collar use.

Another important fact to consider when interpreting results of such studies, is that if the aim is to measure the effect of using a soft-collar, all other aspects of the study should be comparable (Kamper, 2018; Kendall, 2003). This was not the case in three of four studies (table 1 & 2). In three studies, the active group received several treatment sessions for up to 6-weeks while the soft-collar group received fewer sessions (Bonk et al., 2000; Mealy et al., 1986; Rosenfeld et al., 2003). This may create an attention bias as one group spent considerably more time with the researcher or clinician compared to the other group (Kamper, 2018). Increased time with a health care professional may improve the therapeutic alliance, which is known to play an important role in both

adherence to and outcome of treatment (Hall et al., 2010; O'Keeffe et al., 2016). The majority of studies used a variety of different modalities in either one or all groups making interpretation of the effect of just one of these difficult, in this case the effect of soft-collar use on pain and disability. Furthermore, one study (Rosenfeld et al., 2003), used written information on rest and activity advice for the soft-collar group. Such a difference in the intervention between groups may have skewed the results, as there is some indication that using written information regarding neck pain as a stand-alone intervention may actually have a detrimental effect on pain, disability and medication-use (Derebery et al., 2009).

While the current findings favour an active approach with regards to pain, an RCT by Kongsted et al. (2007) found no difference in pain and disability between an initial passive approach using a semi-rigid collar while maintaining normal activity levels for the first weeks after WAD injury and prior to commencing an active approach compared to an active- or act-as-usual approach. Likewise, another study comparing soft-collar use for 2- or 10-days following a whiplash injury found no difference on pain, disability or CROM at either 2- or 6-months follow-up (Dehner et al., 2006). Similarly, a non-randomized trial by Gennis et al. (1996) found no difference in pain between those either wearing a soft-collar or not for 2-weeks, when the groups were compared at 6- and 12-weeks. Although these studies did not fulfil the inclusion criteria of this review due to the use soft-collars in both groups, non-randomization or using a semi-rigid collar, they indicate that an initial short-term soft-collar use may not be harmful (Dehner et al., 2006; Gennis et al., 1996; Kongsted et al., 2007). Keeping this in mind, it is thought-provoking to ask the question as to why injuries to the neck are treated differently to extremity injuries (Jull, 2016a). Advice of initial rest and a supportive bandage is consistent with the current guidelines for ankle sprains (Vuurberg et al., 2018). For some –patients with WAD, a soft-collar used intermittently for a short period in the acute stage, in combination with an active approach could potentially be more effective in relieving pain than the active approach alone. Based on the current review this cannot be excluded and future studies on soft-collar use in WAD-populations which are appropriately controlled in order to minimize clinical heterogeneity are needed. Although outside the scope of the current work, future studies should consider the potential impact of soft-collar use in a bio-psycho-social framework to illuminate any effects on outcomes.

4.1 Strengths and limitations

A strength of this review was that it not only assessed the quality and certainty of the literature using the PEDro-scale and GRADE-assessment but it also accounted for potential clinical heterogeneity, which has the potential to affect the overall interpretation of studies compared to assessment based on PEDro and GRADE alone. A major weakness of the current review is the limited RCTs available, the large variation in long term follow-up as well as the absence of studies reporting disability data.

5.0 CONCLUSION

The four included RCTs favoured an active/act-as-usual approach over soft-collar use with regards to pain intensity. While the PEDro-assessment showed fair-good quality of the RCTs, the certainty of evidence was low to very low according to the GRADE-assessment and there were some methodological concerns, including the fact that some studies did not account for clinical heterogeneity. As such, the current evidence should be interpreted with caution. Therefore, there is a need for future studies investigating soft-collar use in contemporary practice with an appropriate study design accounting for attentional effects in order to make future recommendations on soft-collar use in WAD rehabilitation.

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FIGURES

Figure 1: Flow diagram showing the process of identifying eligible studies.

Figure 2: Forest plot of pain at primary endpoint between groups receiving a soft-collar or not as part of the intervention.

Figure 3: Forest plot of total cervical range of motion (CROM Total) at primary endpoint between groups receiving a soft-collar or not as part of the intervention.

Figure 4: Forest plot of cervical range of motion in rotation (CROM Rotation) at primary endpoint between groups receiving a soft-collar or not as part of the intervention.

Table 1 - Study characteristics for all included RCT's.

| Standard or active treatment with or without soft-collar use | | | | | | |
|---|--|--|---|--|---|--|
| Author | Purpose of study | Population and interventions | Outcome | Pain intensity at primary and secondary endpoint | CROM at primary and secondary endpoint | Conclusion |
| Mealy K et al. (1986), <i>Early mobilization of acute whiplash injuries</i> | To investigate the response to "...standard treatment compared with that of another group given alternative treatment of daily neck exercises and mobilisation..." | Acute WAD (N=61; Grade IV excluded). All received analgesics (non-specified) when needed. Group 1) Active treatment (n=31): Ice, heat, neck mobilization and cervical exercise. Treatment period is unclear. Group 2) Standard treatment (n=30): Soft-collar use and advised on two week rest before gradual mobilization. | Pain (0-10 linear analogue scale, unspecified location) and CROM (Total) at baseline at 1 (primary endpoint) & 2 months (secondary endpoint). No dropouts reported. | Pain intensity (Mean & SEM): Baseline: • Group 1: 5.71 (0.44) • Group 2: 6.44 (0.41) Primary endpoint: • Group 1: 2.85 (0.57)* • Group 2: 5.08 (0.48) Secondary endpoint: • Group 1: 1.69 (0.43)* • Group 2: 3.94 (0.58) | CROM (Total; Mean & SEM): Baseline: • Group 1: 19.92° (1.74) • Group 2: 25.00° (2.17) Primary endpoint: • Group 1: 29.03° (2.12) • Group 2: 27.56° (2.09) Secondary endpoint: • Group 1: 34.11° (1.50) • Group 2: 29.57° (1.61)* | <i>"In conclusion, our results confirmed expectations that initial immobility after whiplash injuries gives rise to prolonged symptoms whereas a more rapid improvement can be achieved by early active management without any consequent increase in discomfort."</i> |
| Bonk AD et al. (2000), <i>Prospective, randomized, controlled study of activity versus collar and the natural history for whiplash injury</i> | To evaluate "...the possible natural outcome of acute whiplash with two approaches to treatment: activity versus collar use versus matched control subjects." | Acute (within 72hr) WAD (N=103; grade III-IV excluded). Anti-inflammatory/analgesics were allowed. Group 1) Active therapy (n=53): 7 sessions over 3 weeks consisting of cold treatment, passive and active mobilization, strength/isometric neck and exercises and postural advice. Group 2) Collar therapy (n=50): 3 weeks of daytime soft-collar use. | Neck pain intensity (unspecified scale) and CROM (Rotation) at baseline, 6- (primary endpoint) and 12-weeks (secondary endpoint). Group 1) 53 were allocated but only 47 were assessed at baseline, at 6 and 12weeks. Group 2) 50 was assessed at baseline and 47 at 6 and 12weeks. | Pain intensity: Only prevalence (%) of neck pain and no intensity values were reported. Baseline: • Group 1: 98% • Group 2: 96% Primary endpoint: • Group 1: 11% • Group 2: 62% Secondary endpoint: • Group 1: 2% • Group 2: 16% | CROM (Total; Mean & SD): Baseline: • Group 1: 126.5° (44.1) • Group 2: 119.6° (36.5) Primary endpoint: • Group 1: 176.9° (8.0) • Group 2: 165.1° (16.7) Secondary endpoint: • Group 1: 178.5° (4.6) • Group 2: 175.4° (8.1) | <i>"...The study confirms that active therapy, compared to use of a collar (or potentially the divergent effects of these two treatment approaches), results in a significant difference in rate of recovery..."</i> |

| | | | | | | |
|--|--|---|--|--|--|--|
| <p>Rosenfeld M et al. (2003), <i>Active intervention in patients with whiplash-associated disorders improves long-term prognosis</i></p> | <p>“...to evaluate the long-term efficacy of active compared with standard intervention for patients with WAD and to investigate the importance of early versus delayed initiation of intervention.”</p> | <p>Acute (within 96hr) WAD (N=97; Grade III-IV excluded). Only data for the groups starting treatment immediately after onset are included (n=44).</p> <p>Group 1) Active treatment (n=21): Active neck exercise and postural control. Intervention was stopped after 6 weeks or when symptoms resolved. If no improvement was obtained after 20 days a tailored neck exercise program was given.</p> <p>Group 2) Standard treatment (n=23): A leaflet containing information on rest and soft-collar use (first weeks), injury mechanisms, postural correction and activity advice incl. active shoulder, trunk and neck movements</p> | <p>Pain (VAS 0-100mm: combined score for neck, head & shoulder) and CROM (Total & Rotation) at baseline, 6 months (primary endpoint) and 3 years (secondary endpoint).</p> <p>Group 1) 21 was assessed at baseline and at 6 months. 18 was assessed at 3 years.</p> <p>Group 2) 23 was assessed at baseline and at 6 months. 21 was assessed at 3 years.</p> | <p>Pain intensity (Mean & SD): Baseline:</p> <ul style="list-style-type: none"> Group 1: 43mm (24.4) Group 2: 34mm (23.8) <p>Primary endpoint (change from baseline):</p> <ul style="list-style-type: none"> Group 1: -29.6mm (24)* Group 2: +0.74mm (30) <p>Secondary endpoint (change from baseline):</p> <ul style="list-style-type: none"> Group 1: -21mm (27.6)* Group 2: -1.8mm (29.7) | <p>CROM (Total; Mean & SD): Baseline:</p> <ul style="list-style-type: none"> Group 1: 270° (81) Group 2: 282° (50) <p>Primary endpoint (change):</p> <ul style="list-style-type: none"> Group 1: +51.9° (70) Group 2: +25.2° (62) <p>Secondary endpoint (change):</p> <ul style="list-style-type: none"> Group 1: +61.1° (61) Group 2: +16.2° (67) <p>CROM (Rotation; Mean & SD): Baseline:</p> <ul style="list-style-type: none"> Group 1: 114° (38) Group 2: 119° (21) <p>Primary endpoint (change):</p> <ul style="list-style-type: none"> Group 1: +23.6° (37) Group 2: +14.4° (37) <p>Secondary endpoint (change):</p> <ul style="list-style-type: none"> Group 1: +25.6° (34) Group 2: +11.8° (32) | <p>“The active intervention addresses both the organic and the functional aspects of WAD, reducing cervical pain and the need for sick leave and restoring impaired CROM. The main clinical implication is that patients with acute WAD 0, 1, or 2 should be instructed in self-mobilization as soon as possible.”</p> |
|--|--|---|--|--|--|--|

Act-as-usual compared to soft-collar

| | | | | | | |
|--|---|--|--|--|---|---|
| <p>Borchgrevink GE et al. (1998), <i>Acute treatment of whiplash neck sprain injuries: a randomized trial of treatment during the first 14 days after a car accident</i></p> | <p>“...to compare the clinical outcome of two groups of patients; each group received a different intervention during the first 14 day after neck sprain injuries occurred: instruction to carry on as usual or immobilization with a soft collar and sick leave”</p> | <p>Acute WAD (N=201; Grade III-IV excluded). All were prescribed neck home-exercises and anti-inflammatory/analgesics.</p> <p>Group 1) Act-as-usual (n=82 of initial 96): Act-as-usual without any sick leave or soft-collar use.</p> <p>Group 2) Immobilization (n=96 of initial 105): 2 weeks of sick leave and soft-collar use.</p> | <p>Pain (VAS 0-100mm) was assessed at 6-weeks (primary endpoint) and 6 months (secondary endpoint)</p> <p>CROM (rotation) was assessed at baseline, 2-weeks (primary endpoint) and 6 months (secondary endpoint).</p> <p>Group 1) 96 was assessed at baseline and 82 at 6 months.</p> <p>Group 2) 105 was assessed at baseline and 96 at 6 months.</p> | <p>Pain intensity (VAS; Mean & SEM): Baseline:</p> <ul style="list-style-type: none"> Group 1: 33.0mm (2.5) Group 2: 38.1mm (2.6) <p>Primary endpoint:</p> <ul style="list-style-type: none"> Group 1: 32.9mm (3.9) Group 2: 29.7mm (2.7) <p>Secondary endpoint:</p> <ul style="list-style-type: none"> Group 1: 26.6mm (2.6)* Group 2: 31.1mm (3.2) | <p>CROM (Rotation; Mean & SD): Baseline:</p> <ul style="list-style-type: none"> Group 1: Not reported Group 2: Not reported <p>Primary endpoint:</p> <ul style="list-style-type: none"> Group 1: 140.1° (35.4) Group 2: 140.3° (35.4) <p>Secondary endpoint:</p> <ul style="list-style-type: none"> Group 1: 153.1° (31.0) Group 2: 153.9° (34.9) | <p>“In conclusion, the authors of this study found that patients who were instructed to continue engaging in their normal activities (act as usual) after neck sprain injury had a better outcome than patients who took sick leave from work and who were immobilized with soft neck collars during the first 14 days after the accident”.</p> |
|--|---|--|--|--|---|---|

Table 1: Study characteristics for all included RCT's. Data is presented for neck pain intensity and CROM (Total & Rotation) at primary- and secondary endpoint or at the closest available data points to these. *indicates a significant between group difference reported in the individual RCT.

Table 2 - Risk of bias assessment

| Standard or active treatment with or without soft-collar use | | | | |
|--|-------------|------------------|--|---|
| Author | PEDro-Score | PEDro-assessment | Methodological concerns | Risk of Clinical heterogeneity |
| Mealy K et al. (1986), <i>Early mobilization of acute whiplash injuries</i> | 6 | Good | Inadequate description of eligibility criteria (Not included in the score) No blinding of participants. No blinding of therapists. No adequate follow-up No intention to treat analysis. | Yes: one group received daily manual therapy and exercises while the other group were advised to rest for two weeks before beginning gradual mobilization |
| Bonk AD et al. (2000), <i>Prospective, randomized, controlled study of activity versus collar and the natural history for whiplash injury, in Germany</i> | 5 | Fair | No concealed allocation. No blinding of participants. No blinding of therapists. No blinding of assessors. No Intention-to-treat analysis | Yes: One group received 2-3 treatment session per week consisting of passive and active mobilization, as well as neck exercises etc. while the other group used a soft-collar for three weeks. |
| Rosenfeld M et al. (2003), <i>Active intervention in patients with whiplash-associated disorders improves long-term prognosis</i> | 8 | Good | No blinding of participants. No blinding of therapists. | Yes: Half of the participants was treated by a health care professional for up to 6 weeks while the other half received written information on mechanisms of injury, activity advice and postural correction. |
| Act-as-usual compared to soft-collar | | | | |
| Borchgrevink GE et al. (1998), <i>Acute treatment of whiplash neck sprain injuries: a randomized trial of treatment during the first 14 days after a car accident</i> | 6 | Good | No concealed allocation. No blinding of participants. No blinding of therapists. No intention to treat analysis. | No: One group was advised to use a soft-collar for two weeks while the other group was instructed to act-as-usual |

Table 2: Risk of bias assessment for the included RCTs.

Table 3 – Grade assessments

Non-surgical treatments compared to Soft collar, alone, or in addition to non-surgical treatments for Whiplash Associated Disorders (WAD)

Patient or population: Whiplash Associated Disorders (WAD)

Setting: ED & Outpatient clinics

Intervention: Non-surgical treatments

Comparison: Soft collar, alone, or in addition to non-surgical treatments

| Outcomes | Risk with Soft collar, alone, or in addition to non-surgical treatments | Non-surgical treatments vs. soft collar, alone, or in addition to non-surgical treatments Effect size (SMD or MD) with 95% CI | Relative effect (95% CI) | № of participants (studies) | Certainty of the evidence (GRADE) | Comments |
|---|---|--|--------------------------|-----------------------------|-------------------------------------|--|
| Pain at primary endpoint (Pain) | - | SMD 0.8 SD lower (1.2 lower to 0.41 lower) | - | 105 (2 RCTs) | ⊕⊕○○ LOW ^{a,b} | Non-surgical treatments may result in a large reduction in pain at primary endpoint. For explanations, see below table. |
| Disability at primary endpoint - not reported | - | - | - | - | - | Not reported |
| CROM (Total) at primary endpoint (CROM Total) assessed with: Degrees | - | SMD 0.16 SD higher (0.21 lower to 0.54 higher) | - | 105 (2 RCTs) | ⊕○○○ VERY LOW ^{a,c,d} | Non-surgical treatments may have little to no effect on CROM Total at primary endpoint but the evidence is very uncertain. For explanations, see below table. |
| CROM (Rotation) at primary endpoint (CROM Rotation) | - | SMD 0.54 SD higher (0.19 lower to 1.27 higher) | - | 141 (2 RCTs) | ⊕○○○ VERY LOW ^{a,c,d,e} | Non-surgical treatments may have little to no effect on CROM Rotation at primary endpoint but the evidence is very uncertain. For explanations, see below table. |

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; SMD: Standardised mean difference

Primary endpoint: Short term

CROM: Cervical Range of Motion

GRADE Working Group grades of evidence

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. Downgraded one level for risk of bias (lack of blinding and clinical heterogeneity), i.e. studies are at moderate risk of bias according to Guyatt et al., 2011b.

b. Downgraded one level for imprecision (the upper and lower CI boundary cause different interpretation with regards to clinical relevance)

c. Downgraded one level for indirectness (CROM was used as a proxy for disability)

d. Downgraded one level for imprecision (the upper and lower CI boundary causes different interpretation as CI crosses no effect line)

e. Downgraded one level for inconsistency (heterogeneity of results indicated by little overlap of CI, I² values and statistical test for heterogeneity)

Figure 1

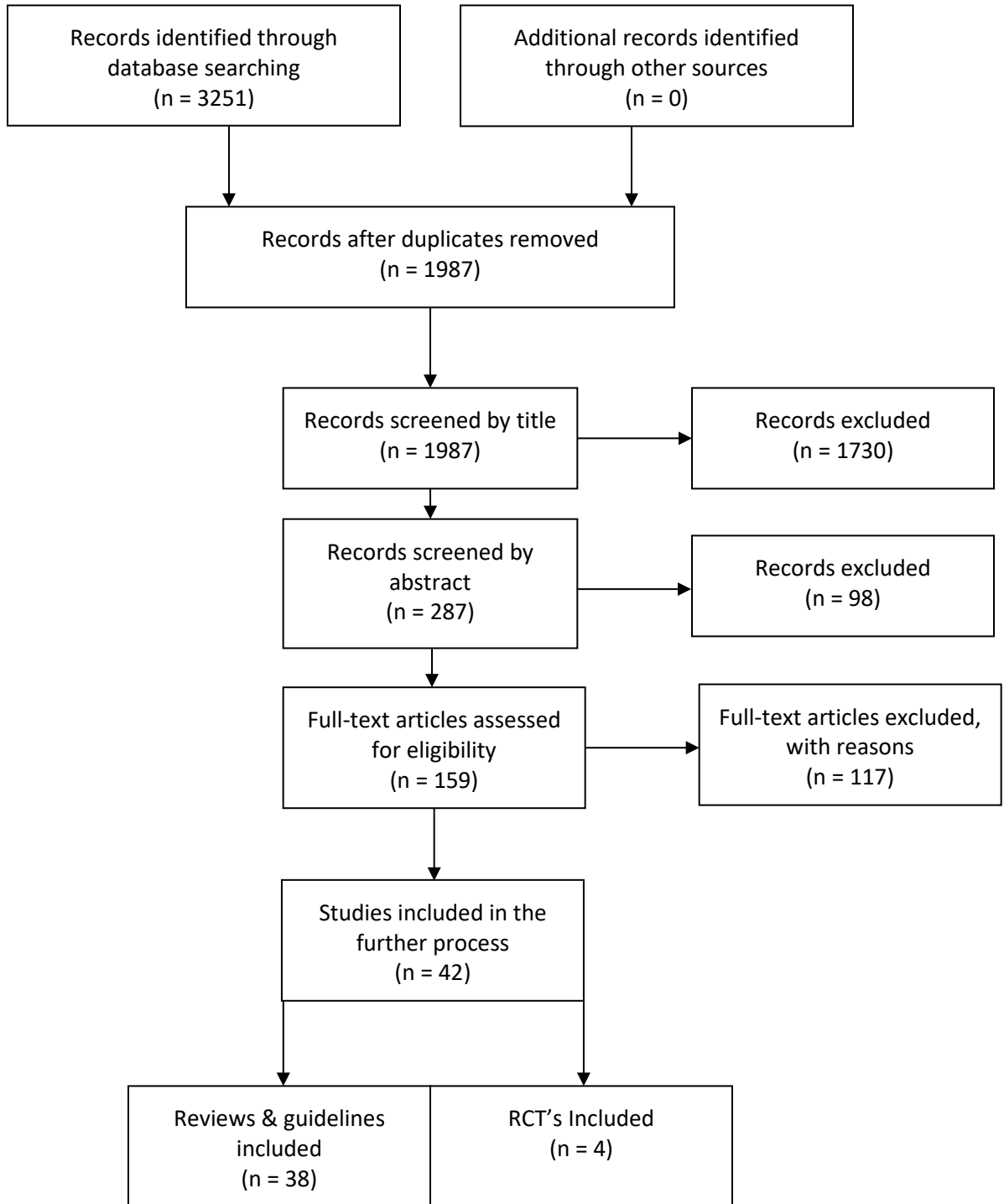


Figure 2 - Pain

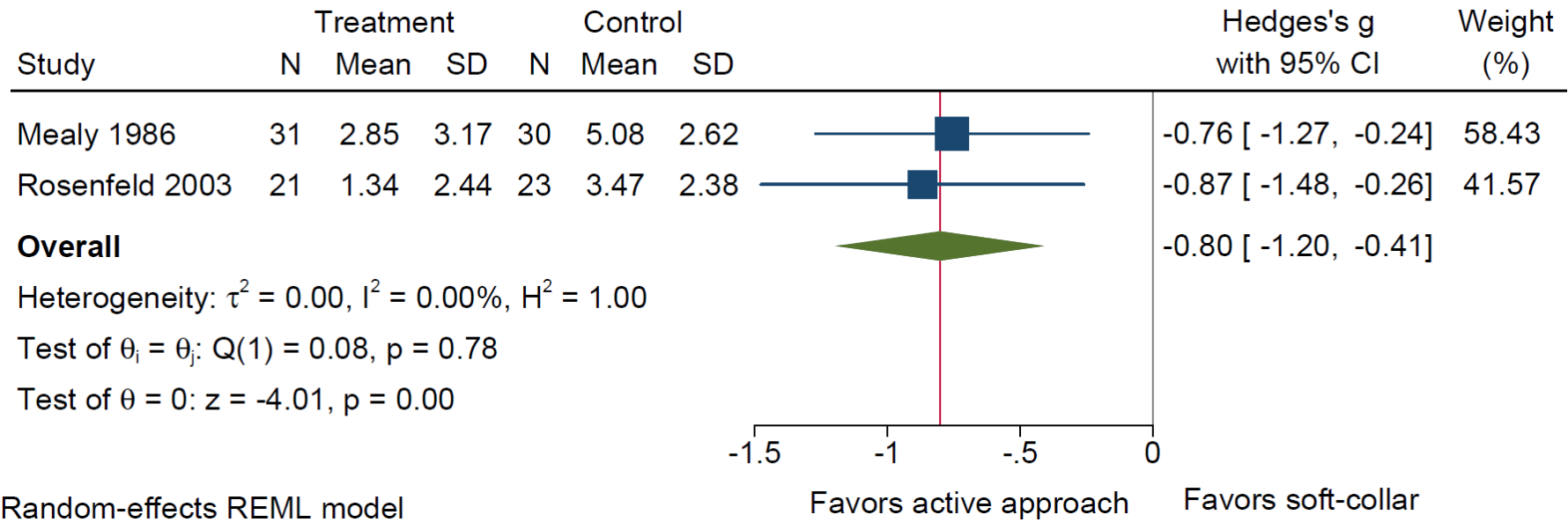


Figure 3 – CROM Total

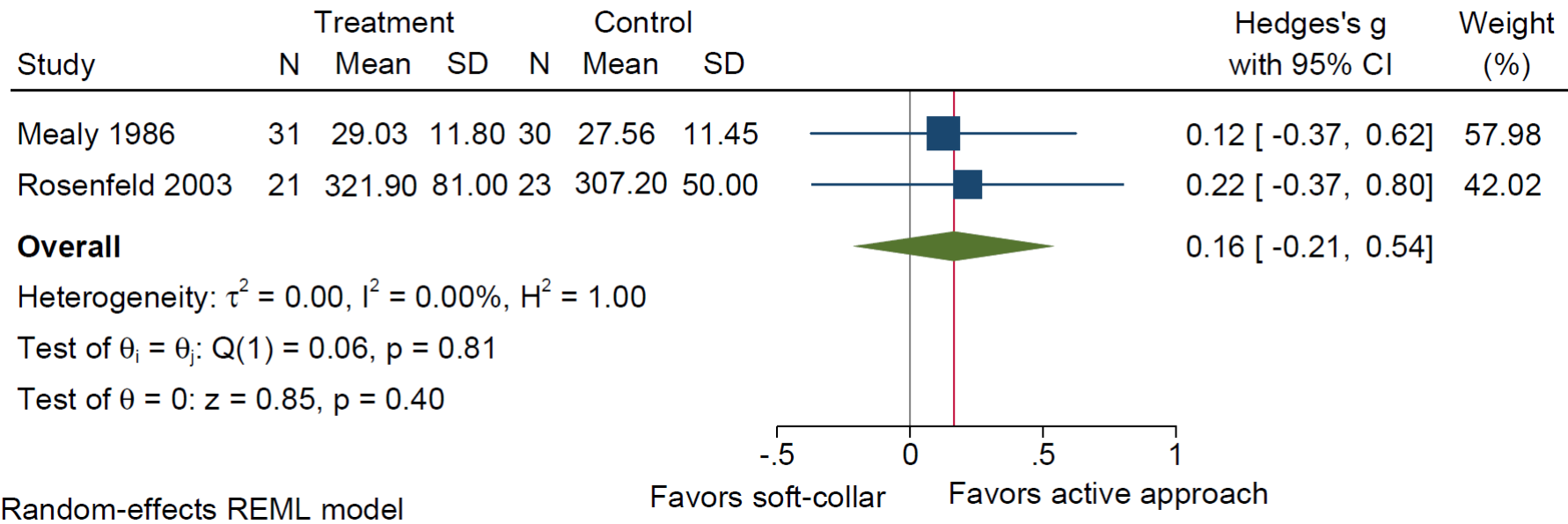


Figure 4 - CROM Rotation

