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| **CRITICALLY APPRAISED TOPIC** |

**FOCUSED CLINICAL QUESTION**

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| What is the impact of manual therapy **(i)** on working aged adults (ages 20-65) with ***neck pain* (p)** as compared to therapeutic exercise **(c)**, measured by pain and function **(o)** within 6 weeks? |

**AUTHOR**

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**CLINICAL SCENARIO**

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| The patient is a 51-year-old male corporate office employee who spends 8+ hours a day sitting at his desk on the computer. He is not physically active and experiences intermittent neck pain that he attributes to prolonged sitting at work. The patient expresses that his workload takes a toll on his available time and energy to do other activities. He is not overly keen about physical exercise and freely admits that he won’t take the time to perform home exercises. For individuals like this patient who have a strong affinity to passive treatments, who are limited for time, stressed with work responsibilities, and are noncompliant with exercise, I would like to know if manual therapy is as effective or more effective as traditional therapeutic exercise for the treatment of neck pain. |

**SUMMARY OF SEARCH**

[Best evidence appraised and key findings]

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| Eight studies met the inclusion and exclusion criteria including 3 systematic reviews and 5 single blind RCT’s.   * Combined treatment of manual therapy (MT) and therapeutic patient education (TPE) is similarly effective as combined treatment of manual therapy (MT), therapeutic patient education (TPE) and therapeutic exercise (TEX) for reducing pain, disability, and fear avoidance.1 * Manual therapy alone may have benefits in reducing disability but does not appear to be effective in reducing pain-related fear of movement or reinjury and is not as effective as therapeutic patient education and therapeutic exercise in reducing disability.1 * There is no existing evidence that directly contrasts manual therapy and exercise therapy without confounding variables. |

**CLINICAL BOTTOM LINE**

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| A multimodal approach that includes manual therapy (MT) 1,2 therapeutic patient education (TPE)1 and therapeutic exercise (TEX) 1,2 is the most beneficial treatment strategy for adult patients aged 18-65 with chronic neck pain. If time is a constricting variable in the patient or clinician’s practice, or if compliance with home exercise is a concern, the evidence supports a combined treatment of MT and TPE. The evidence does not support or refute the use of manual therapy as a stand-alone treatment. 1,2 |

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| ***This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor*** |

*The above information should fit onto the first page of your CAT*

**SEARCH STRATEGY**

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| **Terms used to guide the search strategy** | | | |
| **P**atient/Client Group | **I**ntervention (or Assessment) | **C**omparison | **O**utcome(s) |
| “Neck Pain”  “Cervical Pain”  “Cervical Spine Pain”  “Upper back pain”  “cervicalgia” | Manual therapy  Massage  Manual lymph\* drainage  MLD  Mobilization  Soft tissue mobilization  Functional mobilization  Scar mobilization  Myofascial release  MFR  Strain counterstrain  SCS  Positional Release Technique  PRT  Craniosacral therapy  Active Release Technique  ART  Graston  Manipulation  Joint mobilization  Joint manipulation  Joint thrust  High Velocity Low Amplitude  HVLA  Muscle energy techniques  MET  Mulligan  Manual Traction  Passive range of motion  PROM | Therapeutic exercise  Exercise  McKenzie  MDT  Mechanical Diagnosis and therapy  Exercise\*  training  aerobic  endurance  strength  hypertrophy  power  range of motion  conditioning  agility  body mechanics  coordination exercises  developmental  movement pattern  neuromotor development  neuromuscular education  neuromuscular re\*  perceptual training  rehabilitation | Pain  Patient-reported function  Function |

**Final search strategy (history):** Final Search was **#29** which elicited **93 results**.

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| **29** | **#22 AND #14 AND #28 AND #10 NOT #8 NOT SHOULDER AND ((meta-analysis[Filter] OR randomizedcontrolledtrial[Filter] OR systematicreview[Filter]) AND (2000:2020[pdat])) AND ((randomizedcontrolledtrial[Filter] OR systematicreview[Filter]) AND (2010:2020[pdat]))** |
| **28** | **exercise OR aerobic OR endurance OR strength OR conditioning OR neuromuscular education** |
| **27** | **#22 AND #14 AND #16 AND #10 NOT #8 NOT SHOULDER AND ((meta-analysis[Filter] OR randomizedcontrolledtrial[Filter] OR systematicreview[Filter]) AND (2000:2020[pdat]))** |
| **25** | **#22 AND #14 AND #16 AND #10 NOT #8 NOT SHOULDER AND ((meta-analysis[Filter] OR randomizedcontrolledtrial[Filter] OR systematicreview[Filter]) AND (2000:2020[pdat]))** |
| **26** | **#22 AND #14 AND #16 AND #10 NOT #8 NOT SHOULDER AND ((meta-analysis[Filter] OR randomizedcontrolledtrial[Filter] OR systematicreview[Filter]) AND (2000:2020[pdat]))** |
| **24** | **#22 AND #14 AND #16 AND #10 NOT #8 NOT SHOULDER AND ((meta-analysis[Filter] OR randomizedcontrolledtrial[Filter] OR systematicreview[Filter]) AND (2000:2020[pdat]))** |
| **23** | **cervical pain[MeSH Terms]** |
| **22** | **neck pain[MeSH Terms]** |
| **21** | **#1 AND #14 AND #16 AND #10 NOT #8 NOT SHOULDER** |
| **20** | **#1 AND #14 AND #16 AND #10 NOT #8 NOT SHOULDER** |
| **19** | **#1 AND #14 AND #16 AND #10 NOT #8 NOT SHOULDER** |
| **18** | **#1 AND #14 AND #16 AND #10 NOT #8 NOT SHOULDER** |
| **17** | **#1 AND #14 AND #16 AND #10 NOT #8 NOT SHOULDER** |
| **16** | **exercise OR aerobic OR endurance OR strength OR hypertrophy OR power OR conditioning OR agility OR coordination OR movement pattern OR neuromuscular education OR rehabilitation** |
| **15** | **#1 AND #14 AND #3 AND #10 NOT #8 NOT SHOULDER** |
| **14** | **manual therapy OR massage OR mobilization OR manipulation OR muscle energy techniques** |
| **13** | **manual therapy OR massage OR mobilization OR myofascial release OR manipulation OR muscle energy techniques** |
| **12** | **manual therapy OR massage OR manual lymph\* drainage OR MLD OR mobilization OR soft tissue mobilization OR functional mobilization OR myofascial release OR MFR OR graston OR manipulation OR joint mobilization OR joint manipulation OR high velocity low amplitude OR HVLA OR muscle energy techniques OR MET OR manual traction** |
| **11** | **#1 AND #2 AND #3 AND #10 NOT #8 NOT SHOULDER** |
| **10** | **pain OR function** |
| **9** | **#1 AND #2 AND #3 AND #4 NOT #8 NOT SHOULDER** |
| **8** | **(Low Back) OR (Lumbar)** |
| **7** | **#1 AND #2 AND #3 AND #4 NOT SHOULDER** |
| **5** | **#1 AND #2 AND #3 AND #4** |
| **4** | **pain OR function OR patient-reported function OR outcome OR improve\*** |
| **3** | **therapeutic exercise OR exercise OR mcKenzie OR MDT OR mechanical diagnosis and therapy OR exercise\* OR training OR aerobic OR endurance OR strength OR hypertrophy OR power OR range of motion OR conditioning OR agility OR body mechanics OR coordination OR developmental OR movement pattern OR neuromotor development OR neuromuscular education OR neuromuscular re\* OR perceptual training OR rehabilitation** |
| **2** | **manual therapy OR massage OR manual lymph\* drainage OR MLD OR mobilization OR soft tissue mobilization OR functional mobilization OR scar mobilization OR myofascial release OR MFR OR strain counterstrain OR SCS OR positional release technique OR PRT OR craniosacral therapy OR active Release technique OR ART OR graston OR manipulation OR joint mobilization OR joint manipulation OR joint thrust OR high velocity low amplitude OR HVLA OR muscle energy techniques OR MET OR mulligan OR manual traction OR passive range of motion OR PROM** |
| **1** | **Cervical OR Cervical Spine OR Neck OR Cervicalgia OR upper back** |

*In the table below, show how many results you got from your search from each database you searched.*

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| **Databases and Sites Searched** | **Number of results** | **Limits applied, revised number of results (if applicable)** |
| **PubMed**  **PEDro (Searched “ manual therapy and exercise and neck pain”.)**  **Cochrane (Searched “manual therapy and exercise and neck pain”.)** | **16,687**  **105**  **341** | **Narrowed to 93 articles. See pubmed search hx for details**  **Narrowed to 49 by adding 2010 limit. A lot of overlap with pubmed.**  **Narrowed to 113 by adding 2010 limit and specific to Cochrane reviews.** |

## INCLUSION and EXCLUSION CRITERIA

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| **Inclusion Criteria** |
| * Patient population with neck pain and upper back/trapezius pain * Evaluated and treated by physical therapists, physiotherapist, or physiatrist * Standardized patient-reported measures used to assess pain and function * Randomized controlled trials * Systematic reviews * Meta-analysis |
| **Exclusion Criteria** |
| * Non - English * Poster presentations * Quasi-experimental studies * Narrative review articles * Case reports * Migraines * Known disc pathology, fracture, recent trauma or surgery |

**RESULTS OF SEARCH**

**Summary of articles retrieved that met inclusion and exclusion criteria**

*For each article being considered for inclusion in the CAT, score for methodological quality on an appropriate scale, categorize the level of evidence, indicate whether the relevance of the study PICO to your PICO is high/mod/low, and note the study design (e.g., RCT, systematic review, case study).*

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| --- | --- | --- | --- | --- |
| **Author (Year)** | **Risk of bias (quality score)\*** | **Level of Evidence\*\*** | **Relevance** | **Study design** |
| **Fredin (2017)**2 | **AMSTAR – 8/11** | **Level 1** | **High** | **Systematic Review** |
| **Hidalgo (2017)**3 | **AMSTAR – 6/11** | **Level 1** | **High** | **Systematic Review** |
| **Beltran-Alacreu (2015)**1 | **PEDro – 9/11** | **Level 1** | **High** | **Single-Blind RCT** |
| **Skillgate (2020)**4 | **PEDro – 9/11** | **Level 1** | **Moderate** | **Single-Blind RCT** |
| **Miller (2010)**5 | **AMSTAR – 6/11** | **Level 3 (includes level 3 study)** | **High** | **Systematic Review** |
| **Ganesh (2015)**6 | **PEDro – 8/11** | **Level 1** | **High** | **Single-Blind RCT** |
| **Dunning (2016)**7 | **PEDro – 9/11** | **Level 1** | **Moderate** | **Single-Blind RCT** |
| **Domingues (2019)**8 | **PEDro – 9/11** | **Level 1** | **High** | **Single-Blind RCT** |

\*Indicate tool name and score

\*\*Use Portney & Watkins Table 16.1 (2009); if downgraded, indicate reason why

**BEST EVIDENCE**

The following 2 studies were identified as the ‘best’ evidence and selected for critical appraisal. Rationale for selecting these studies were:

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| * **Fredin 2017** – I chose this SR because it was clearly the strongest quality SR of the three and I wanted to include one SR and one RCT for my CAT. In addition, this article was well organized, and clearly explained the characteristics of the included studies, as well as the list and reasons for the studies they excluded. * **Beltran-Alacreu 2015** – For the RCT, after considering relevance and risk of bias I was between Domingues and Beltran-Alacreu. Between the two, it was actually an easy selection because the Domingues article was designed such that there was manual therapy + exercise, versus a “usual care” group. The UC group received some manual therapy interventions and I felt the overlap of the intervention with the control was not appropriate for drawing sound conclusions. Further, my PICO is trying to discern the difference between manual therapy and exercise, not to combine them. Another thing to mention, although not part of my PICO, I like how the Beltran-Alacreu article includes an intervention group where therapeutic patient education (TPE) is part of the comparison. This article was one of the excluded RCT’s in the Fredin SR due to this inclusion of TPE and it being too comprehensive to be considered “general education”.   1. I believe it’s good that my RCT is not also part of the SR (due to redundancy). And 2. As part of my CAT, I can make a comment on how patient education in combination with these interventions may impact patient outcomes. |

**SUMMARY OF BEST EVIDENCE**

**(1) Description and appraisal of (Manual therapy, exercise therapy, or combined treatment in the management of adult neck pain – A systematic review and meta analysis) by (Fredin et al., 2017)**

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| **Aim/Objective of the Study/Systematic Review:** |
| The aim of the study by Fredin et al. was to review the current body of literature in order to assess whether or not a combined approach to rehabilitation utilizing both manual therapy (MT) and exercise therapy (ET) was more effective than either therapy alone in relieving pain and improving function in adult patients with grade I and II neck pain. |
| **Study Design**  [e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]  Note: For systematic review, use headings ‘search strategy’, ‘selection criteria’, ‘methods’ etc. For qualitative studies, identify data collection/analyses methods. |
| This study by Fredin et al. is a systematic review and meta-analysis.  **Search Strategy:** Systematic search for publications was conducted within the databases of MEDLINE, EMBASE, AMED, CENTRAL, and PEDro. The databases were searched from the earliest available data up until June of 2017. Their search strategy utilized the following groups of terms; trial terms (random\*, trial, group), symptom terms (neck, cervical, pain, ache), and treatment terms (manual therapy, massage, traction, mobilization, manipul\*, active, exerci\*, training). Titles that included the words cancer, carcinoma, femur, femoral, and fracture were excluded. The PEDro database was searched by combining exerci\* with stretching, massage, manipulation, or massage; pain; head or neck; musculoskeletal; and clinical trial.  **Selection Criteria:** There were two review authors that performed separate searches of the literature, included studies and assessed them based upon the inclusion/exclusion criteria. The inclusion criteria was as follows: Must be a Randomized Controlled Trial (RCT); Patient was older than 18 years of age; the patient had to have grade I or II neck pain; the trial must compare MTs and one or more ETs to the same MTs or ETs alone; reported outcomes must include pain intensity and/or disability on numerical scales. The exclusion criteria included: patients with known pathology or radicular signs; mixed population studies; populations that had a specific subgroup of neck pain (e.g headaches); studies that included additional therapies (e.g. electrotherapy) and studies where participants received treatment prior to baseline measures.  **Data Extraction:** Data was extracted by the first author and reviewed by the second author. Type of date extracted included interventions, demographics, time to follow-up, mean and SD for pain, disability, and quality of life (QOL) baseline, follow-up, and change scores. The Neck Disability Index (NDI) scores were recorded and adapted to percentage scores before analysis. The following pain outcomes were recorded as “pain at rest”: average pain intensity, current pain intensity, pain or pain at rest.  **Methods:** The two independent reviewers assessed the methodological quality of the trial using the PEDro Scale. Trials were deemed “high quality” if they score a six or higher on the scale. Only the interventions that were relevant to the present study were included for analysis. The study recorded follow-up as either immediate post treatment, short term (less than three months), intermediate (three months to a year) and long term (greater than one year). In order to preserve integrity of follow-up assessments, results were excluded from analysis if therapy for one group was discontinued prior to assessment. (e.g. MT discontinued but ET continued). Means and standard deviations were taken as-is or calculated from confidence intervals if unavailable. Authors were contacted for any Missing data or calculations were made using available data. Mean Difference (MD), standardized mean difference (SMD, 95% CI) were calculated using random effects model to account for heterogeneity of the included trials. Cut-off values for SMD were as follows: 0 to 0.2: very small; from 0.2 to 0.5: small; from 0.5 to 0.8: moderate; and from 0.8: strong. Likewise, the same values were used for negative increments. Significance level was calculated to p<0.05. Sensitivity analysis was accomplished with two techniques. First, by using high-quality studies within the meta-analysis and comparing/contrasting their results. Separately, sensitivity analyses was performed on the effect of imputed SDs. These two methods were implemented to determine if manipulating these values affected the results of the study. |
| **Setting**  [e.g., locations such as hospital, community; rural; metropolitan; country] |
| The evidence included in this study was obtained in outpatient clinics. |
| **Participants**  [N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]  Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article. |
| There were 1169 articles screened. Of which, 7 studies were included in the study. The range of participants per study was between 30-350 and totalled 936 participants. The mean age was between 29-51 and 65% of the patients were female. Patients were diagnosed with neck pain. Duration of neck pain varied from short-term, long-term, or a mixture. 5 of the 7 studies included patients with long duration neck pain. No other demographic information was recorded or presented. There was no mention of dropout or baseline comparisons. |
| **Intervention Investigated**  [Provide details of methods, who provided treatment, when and where, how many hours of treatment provided] |
| *Control* |
| The control group consisted of ET alone.  When the authors embarked on this journey, they intended for the “control” to be exercise therapy (ET) and manual therapy (MT) as treatments on their own. In reality, all seven included studied had MT as a supplement to ET and therefore compared ET versus ET plus MT. This forced the control of this study to be ET alone and the experimental group to include ET plus MT. Any conclusions drawn from this point forward would only be able to asses what (if any) added benefit MT adds to ET as compared to ET alone. They are unable to draw conclusions regarding MT by itself.  Exercises consisted of neck and upper body strength, flexibility, and stability training. Some studies incorporated a HEP for all or part of the study. |
| *Experimental* |
| The experimental group consisted of both ET and MT.  Exercises consisted of neck and upper body strength, flexibility, and stability training. Manual therapies consisted of passive or active assisted movements, mobilizations, spinal manipulations, and soft tissue techniques such as Maitland, Mulligan, and Cyriax. Interventions ranged from 8-20 sessions and spanned 2 to 12 weeks. Sessions varied from 15min to an hour in duration. Some studies incorporated a HEP for all or part of the study. |
| **Outcome Measures**  [Give details of each measure, maximum possible score and range for each measure, administered by whom, where] |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Test** | **Purpose of Assessment** | **# of Studies Included** | **Score Range** | **When** | | | Visual Analogue Scale (VAS) | Pain | 5 of 7 | 0-10cm | Immediate Post Treatment (2-12 weeks), 6months, 12 months | | | Numeric Rating Scale (NRS) | Pain | 2 of 7 | 0-10 (subjective) | Immediate Post Treatment (2-12 weeks), 6months, 12 months | | | Neck Disability Index (NDI) | Disability | 4 of 7 | 0-100 | Immediate Post Treatment (2-12 weeks), 6months, 12 months | | | Northwick Park Questionnaire (NPQ) | Disability | 1 of 7 | 0-100 | Immediate Post Treatment (2-12 weeks), 6months, 12 months | | | Short Form (36) with physical and mental component  (SF-36 PCS and MCS) | Quality of Life | 3 of 7 | 0-100 | Immediate Post Treatment (4-12 weeks), 6months, 12 months | | | Short Form (12) with physical and mental component  (SF-12 PCS and MCS) | Quality of Life | 1 of 7 | 0-100 | Immediate Post Treatment (4-12 weeks), 6months, 12 months | |
| **Main Findings**  [Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable. You may summarize results in a table but you must explain the results with some narrative.] |
| The main findings of the article can be broken up into pain, disability and quality of life. In regard to pain, the pooled SMDs demonstrated insignificant differences on mean change scores for pain intensity at each of the follow up interval (immediate post-treatment, intermediate-term, long-term). Further, the authors downgraded the GRADE quality of evidence due to lack of blinding and long-term follow-up data. With regard to disability, the authors again noted insignificant differences in mean change scores, downgraded the GRADE level of evidence of neck disability outcomes to moderate for the intermediate-term and low for the immediate post treatment and long-term follow-ups citing a lack of blind, inconsistent and incomplete data. Finally, the findings regarding quality of life echoed much of the above statements. Pooled SMDs demonstrated non-significant between-group differences in mean change scores, GRADE level evidence was reduced to moderate at intermediate-term follow-up, low at immediate-post treatment and long-term follow-up. Again, for causes related to a lack of blinding, inconsistency and incomplete data.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Follow-Up** | **Pain at Rest** | **Disability** | **QOL – Physical** | **QOL – Mental** | | Intermediate-Post Treatment | Pooled SMD \_0.15 (95% CI e0.30 to 0.00)  in favor of combined treatment | Pooled SMD 0.02 (95% CI e0.26 to 0.30)  in favor of exercise therapy only | Pooled SMD 0.14 (95% CI e0.20 to 0.48)  in favor of combined treatment | Pooled SMD 0.22 (95% CI e0.04 to 0.47)  in favor of combined treatment | | 6 Months | Pooled SMD e0.05 (95%  CI \_0.35 to 0.24) in favor of  combined treatment | Pooled SMD 0.01 (95% CI  e0.19 to 0.21) in favor of  exercise therapy only | Pooled SMD 0.06 (95%  CI \_0.14 to 0.26)  in favor of combined treatment | Pooled SMD 0.05 (95% CI \_0.15 to 0.25)  in favor of combined treatment | | 12 Months | SMD 0.15 (95% CI e0.17 to 0.46)  in favor of exercise therapy only | SMD \_0.09 (95% CI e0.41 to 0.22)  in favor of combined treatment | Pooled SMD 0.17 (95% CI \_0.15 to 0.49)  in favor of combined treatment | Pooled SMD 0.05 (95% CI \_0.27 to 0.37)  in favor of combined treatment | |
| **Original Authors’ Conclusions**  [Paraphrase as required. If providing a direct quote, add page number] |
| The authors’ conclusions are that a combined treatment of MT and ET does not appear to be more effective than ET alone in reducing neck pain, neck disability, or quality of life for adults with grade I or II neck pain. They came to this conclusion by way of finding very small to insignificant between-group differences in effect sizes for their primary outcomes. The authors stated that if there are specific effects associated with MT, these benefits are very minimal to the overall treatment effect of combining the two treatments. The authors cite the lack of trials investigating this topic and the subsequent poor quality of included studies as reasons for the insignificant results. However, given the recency of the included studies, they appear hopeful this is representative of increased interest in the subject matter and therefore, the potential for future research to support or refute their findings. |
| **Critical Appraisal** |
| **Validity**  [Summarize the internal and external validity of the study. Highlight key strengths and weaknesses. Comment on the overall evidence quality provided by this study.] |
| Using the AMSTAR quality measurement tool to assess the methodological quality, I scored this systematic review with an 8/11 points. This score indicates that this review is of medium quality (5-8pts) systematic review. Strengths of the review include duplicate study selection and extraction, a comprehensive literature search, the authors’ unbiased and scientific approach to their analysis and conclusions, and the appropriateness of their methods to pool data. The weaknesses of the review were that there were a low number of trials, the included trials were of poor quality, and very little details (specifically demographic information) from the trials were included. Although the results are minimal, what little information that is extrapolated can be generalized due to the large degree of variability of the patient demographics and treatment lengths. |
| **Interpretation of Results**  [This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.] |
| The results of the study offer little value. In some respects, I believe this shows the researchers provided an unbiased review of an area of literature that is lacking quantity and quality trials. I think the review was disrupted from the start when the authors were unable to find any reviews that looked at the treatment of manual therapy separate from exercise therapy without other confounding treatments (such as cold/hot packs and electrotherapy) clouding the true effects of the given intervention. However, I believe the results indicate that the most appropriate approach at this particular time is to treat patients with a multi-modal approach that targets a variety of pain-modulating mechanisms, while continually monitoring and seeking to improve the patients function and quality of life. |
| **Applicability of Study Results**  [Describe the relevance and applicability of the study to your clinical question and scenario. Consider the practicality and feasibility of the intervention in your discussion of the evidence applicability.] |
| The systematic review by Fredin et al. is highly applicable to the clinical question due to the relevance between the clinical question and the authors research question. Both the SR and the clinical question sought to determine if there is a treatment effect related to manual therapy, and how that effect compares to the effects of exercise therapy in an adult population with neck pain. The dilemma for both the SR and the clinical question is that the body of literature required to make generalizations on this topic does not yet exist. Both exercise therapy and manual therapy techniques are practical and widely used interventions in physical therapy rehabilitation. |

**(2) Description and appraisal of (Manual Therapy, Therapeutic Patient Education, and Therapeutic Exercise, an Effective Multimodal Treatment of Non-Specific Chronic Neck Pain) by (Beltran-Alacreu et al., 2015)**

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| **Aim/Objective of the Study/Systematic Review:** |
| The aim of the study was to determine the effectiveness of a multimodal treatment approach for disability associated with nonspecific chronic neck pain. The authors were specifically interested in how therapeutic exercise (TEX) and therapeutic education (TPE) affected disability in short and medium term. |
| **Study Design**  [e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]  Note: For systematic review, use headings ‘search strategy’, ‘selection criteria’, ‘methods’ etc. For qualitative studies, identify data collection/analyses methods. |
| The study by Beltran-Alacreu e al. is a single-blind randomized controlled trial where individuals with nonspecific chronic neck pain (CNP) were recruited. After meeting the eligibility criteria, participants were randomly allocated by a therapist to one of three groups by a computer-generated random allocation list. Group 1 was the control, which consisted of manual therapy alone; group 2 (experimental group 1) was subject to manual therapy (MT) AND therapeutic patient education (TPE), and group 3 (experimental group 2) received MT, TPE, and therapeutic exercise (TEX). Each protocol lasted 4 weeks with two treatments per week for a total of 8 sessions. The sessions were one-to-one, and outcomes were measured a baseline, 4 weeks, 8 weeks, and 16 weeks. Roles within the study were divided among therapists. Four therapists were assessors and two therapists provided all interventions. The assessors discussed all study details including inclusion/exclusion criteria, made appointments, and prepared documents. One therapist kept the schedule that the assessors were blinded to, and the procedural therapists provided all treatments. Assessors collected all baseline and follow-up data to which the therapists were blinded, and patients were instructed to not discuss interventions with the assessors. |
| **Setting**  [e.g., locations such as hospital, community; rural; metropolitan; country] |
| Ambulatory primary health care facility in Madrid, Spain. This facility is located on are near the campus of La Salle University. |
| **Participants**  [N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]  Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article. |
| 52 Men and women were recruited from La Salle University at an ambulatory primary health care facility in Coslada, Madrid. The study was publicly advertised on the university campus and university staff, students, and relatives were allowed to participate. Their ages ranged from 18 to 65 years old and they were required to have had neck pain for at least 12 weeks (deemed to be chronic at this stage). The participants were comparable at baseline across all demographics and outcomes with exception of mean pain duration being notably higher in the control group. Of the 45 participants in the study, only 2 were lost to follow up by the end of week 16. |
| **Intervention Investigated**  [Provide details of methods, who provided treatment, when and where, how many hours of treatment provided] |
| *Control* |
| All participants received eight treatment sessions (twice per week) in a one-month timeframe. The duration of the manual therapy portion was approximately 25 minutes. Sessions were spaced apart by 48-72 hours and the interventions were provided by two physical therapists.  The control group received various MT techniques with the purpose being to restore normal function and pain reduction of the cervical region. The protocol incorporated specific passive motion at the facet joints and global mobilization of the cervical spine. In addition, a HVLA thrust was applied to the dorsal region. The authors provided a supplemental digital document that described the mobilizations. The mobilization techniques included; oscillatory traction, craniocervical traction, upper cervical flexion mobilization, lateral glide mobilization, APUCM (anterior-posterior upper cervical mobilization), side glide, a retraction technique, and a dorsal HVLA (of the mid-thoracic spine). |
| *Experimental* |
| Those allocated in the experimental groups received the manual therapy in addition to the following interventions.  Experimental group 1 (MT and TPE)  Patients in this group received TPE that was based on a biobehavioral approaches divided into three parts: Cognitive, operant, and respondent. Purpose of the approach was to change pain perception and reduce beliefs associated with pain and disability while offering coping strategies and self-efficacy activities. These sessions were 20 minutes each.  Experimental group 2 (MT,TPE and TEX)  Patients in this group received everything above, in addition to therapeutic exercise in the form of stability training of the cervical region and neural self-mobilization exercises. Exercises emphasized deep-flexor and extensor strengthening. Patients were asked to cease activity if pain was provoked. This exercise program was progressive and supervised by a physiotherapist. |
| **Outcome Measures**  [Give details of each measure, maximum possible score and range for each measure, administered by whom, where] |
| Primary measure was the Neck Disability Index (NDI) as compared to baseline and 16-week follow-up. NDI is a 10-item scale where each item is rated between 0 and 5 where higher scores indicate higher disability. MCID = 7 points.1   |  |  | | --- | --- | | **Score** | **Disability Level** | | 0-4 | None | | 5-14 | Mild | | 15-24 | Moderate | | 25-34 | Severe | | 35-50 | Complete |   Secondary measures include the Tampa Scale of Kinesiophobia (TSK) which is an 11-item self-report questionnaire with 4-point scoring system graded between “Strongly Disagree” to “Strongly Agree”. Scores range from 11 to 44 and higher scores signify increased fear of movement or reinjury.  Another measure included was the Fear Avoidance Beliefs Questionnaire (FABQ) which consists of 16 items with sub scale scores of 0-7 points. These are graded from “Completely Disagree to “Completely agree.” Again, higher scores indicate increase fear and avoidance.  The Visual Analog Fatigue Scale (VAFS) was included to measure endurance and sensation of fatigue in the deep neck cervical flexors following the Neck Flexor Muscle Endurance (NFME) test. The VAFS is 100mm horizontal line marked with “no fatigue” and “worst fatigue ever experienced” on either end. The patient then marks where their perceived level of fatigue is along the line.  \*These outcomes were measured by the assessors. |
| **Main Findings**  [Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable. Use a table to summarize results if possible.] |
| |  |  |  |  | | --- | --- | --- | --- | | **Mean Difference (95% CI) , Effect Size (d) , and P Value (P) – Summary findings of Table 4**1 | | | | | **TSK-11 (0-44)** | **Baseline VS Post-treatment** | **Baseline VS 8 week** | **Baseline VS 16 week** | | *Control* | 4, d= 0.7 | 3, d= 0.6 | 3, d=0.5 | | *Exp Group 1* | 8, d= 1.6 | 8, d= 1.4 | 8, d= 1.2 | | *Exp Group 2* | 2, d= 0.4 | 5, d= 1, | 6, d= 1 | | **FABQ (0-96)** |  | | | | *Control* | 1, d= 0 | 7, d= 0.5 | 4, d=0.2 | | *Exp Group 1* | 11, d= 0.5 | 13, d= 0.7 | 14, d= 0.7 | | *Exp Group 2* | 11, d= 0.7 | 14, d= 0.9 | 16, d= 1.1 |  |  |  |  |  | | --- | --- | --- | --- | | **TSK-11 (0-44)** | **Baseline VS Post-treatment** | **Baseline VS 8 week** | **Baseline VS 16 week** | | *Control vs Exp1* | P = 0.009 | P = 0.006 | P = 0.01 | | *Control vs Exp1* | P = 0.5 | P = 0.01 | P = 0.02 | | *Exp1 vs Exp2* | P = 0.2 | P = 1 | P = 1 | | **FABQ (0-96)** |  | | | | *Control vs Exp1* | P = 0.01 | P = 0.1 | P = 0.01 | | *Control vs Exp1* | P = 0.01 | P = 0.08 | P = 0.004 | | *Exp1 vs Exp2* |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | **NDI (Wilcoxon Values)** | | | | | | **NDI (0-50)** | **Baseline VS Post-treatment** | **Baseline VS 8 week** | **Baseline VS 16 week** | **Friedman ANOVA** | | *Control* | 0.001 | 0.006 | 0.007 | <0.001 | | *Exp Group 1* | 0.001 | 0.001 | 0.001 | <0.001 | | *Exp Group 2* | 0.001 | 0.001 | 0.001 | <0.001 | |
| **Original Authors’ Conclusions**  [Paraphrase as required. If providing a direct quote, add page number] |
| The authors found the FABQ follow-up scores statistically significant in the experimental groups but not in the control. Both experimental and control groups demonstrated reduced disability in the short and medium terms. However, a greater effect was seen in the experimental groups than in the control. While the NDI change scores were higher in the experimental group versus the control, scores between the two experimental groups were similar. Therefore, the inclusion of therapeutic exercise and/or therapeutic education in conjunction with manual therapy provides greater effect than manual therapy alone. The authors also found that experimental group 2 had a minimal improvement over experimental group 1 in terms of disability. Lastly, The VAFS and FME for the experimental groups showed better outcomes than the control, although not clinically significant. |
| **Critical Appraisal** |
| **Validity**  [Summarize the internal and external validity of the study. Highlight key strengths and weaknesses. Comment on the overall evidence quality provided by this study.] |
| The validity of the article was assessed using the PEDro scale where it scored a 9 out 11. This is an excellent score that deems the article to have a low risk of bias. Strengths of the article include blinding of therapists in regard to procedures versus assessment, subject allocation, and scheduling. The investigators also did a great job acquiring follow-up data with very minimal drop off and they provided both point measure and measures of variability for key outcomes. Weaknesses of the study include a lack of participant data prior to enrollment (co-morbidities, failed treatment attempts, etc), and the inclusion criteria allowed for a wide variety of participants. This limitation helps with the generalization of the results in populations with chronic non-specific neck pain (which was the aim of the study), but it would be useful to be able to separate subgroups within the study population to see how the interventions affected specific neck injuries (e.g. Whiplash). |
| **Interpretation of Results**  [This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.] |
| I agree with much of the interpretations presented by the authors. For the NDI, P <0.01 for all follow-up periods, making the results statistically significant in all groups throughout the entirety of the testing period. My interpretation of this is that manual therapy alone, and certainly in conjunction with TPE and TEX, has a positive impact on disability in patients with chronic neck pain. With respect to the FABQ and TSK-11 outcomes, the effect size of the experimental groups shows statistical significance as the effect sizes are greater than 0.3. In the FABQ, at the 16-week follow up there was no significant effect size within the control group. Whereas the experimental groups shared effect sizes greater than 0.3 from the first treatment all the way through to week 16. Similarly, in the TSK-11, the experimental groups had substantially larger effect sizes compared to the control and the results were similar between the two experimental groups. My interpretation of this data is that there is an early, and long-standing benefit to therapeutic education with or without therapeutic exercise. It would have been interesting to see how the results would have differed if experimental group 2 utilized TEX instead of TPE so that we could make conclusions regarding the effectiveness of TPE versus TEX. |
| **Applicability of Study Results**  [Describe the relevance and applicability of the study to your clinical question and scenario. Consider the practicality and feasibility of the intervention in your discussion of the evidence applicability.] |
| As briefly mentioned, I would have liked to see a study that isolated manual therapy from therapeutic exercise, or at a minimum, offered TEX in addition to MT without the addition of TPE. While the results regarding TPE are fascinating, the mere implementation of TPE in the treatment intervention is a confounding variable that impairs the relevancy of this article to the stated clinical question. The therapeutic education component is actually cited as a reason why the Fredin et al. systematic review did not include the Beltran-Alacreu RCT in their systematic review. Regardless, I cannot draw comparisons between manual therapy and TEX especially because the outcomes between experimental groups were very similar. If the pain or disability results of experimental group 2 were substantially higher than experimental group 1, it may be reasonable to draw inferences that the added intervention of therapeutic exercise was the cause for difference. However, this was not the case. |

**SYNTHESIS AND CLINICAL IMPLICATIONS**

[Synthesize the results, quality/validity, and applicability of the two studies reviewed for the CAT. Future implications for research should be addressed briefly. Limit: 1 page.]

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| Both studies included in the CAT reflect a paucity of high-quality evidence that is appropriate to answer the clinical question. While both studies began with a high degree of relevancy to the clinical question, for different reasons the study designs were modified in a way that did not provide much insight to the stated problem. In the Fredin et al. systematic review, the authors intended to compare manual therapy versus exercise therapy but were unable to support their research with any studies that contrasted the two treatment therapies. Instead, they were obligated to include 7 studies that utilized manual therapy as an adjunct to exercise therapy. These articles were then found to have moderate to low GRADE quality scores due to a lack of blinding and incomplete follow-up data. Conversely, the RCT by Beltran-Alacreu et al. used manual therapy as the control and layered upon therapeutic education and therapeutic exercise to compare the additive effects of the three treatments. The issue with this study design is that there was no “true” control that reflects the standard or practice or “typical” physiotherapy. It is widely recognized that the amount and type of manual therapy included in a physical/physiotherapists treatment plan varies greatly by the clinician and country that the therapy is provided. It is not reasonable to regard manual therapy as the standard of practice across the world (nor did the authors do this), however, utilizing manual therapy as a control is not a representation of typical care. Nevertheless, the results of this study indicated that there is a significant benefit of combined treatment of MT, TPE as well as MT, TPE, and TEX when evaluating disability and fear avoidance. Patients in these experimental groups exhibited large effect sizes (>0.3) across all follow-up periods.  Based on the two studies described above, while taking into consideration the relevancy, risk of bias and overall quality of the articles, I can conclude that the present data is not in support of the use of manual therapy as a standalone treatment for adult patients with neck pain. The research supports the use of a multi-modal approach that includes manual therapy, alongside therapeutic education. The Beltran-Alacreu et al. study demonstrated that there is not a substantial benefit to adding therapeutic exercise beyond what is seen with combined treatment of MT and TPE. However, a combined approach of all three techniques provided an effect size >0.1 at the 16-week follow-up when evaluating fear avoidance as measured by the FABQ and TSK-11 tests. Therefore, my clinical recommendation would be to utilize all three techniques in patient care in order to get the most out of your patient encounters.  To conclude this CAT, I would like to draw one final comparison and offer recommendations for future research. In the Fredin et al. systematic review, one of the conclusions is that manual therapy did not add benefit to a program utilizing exercise therapy. While in the Beltra-alacreu randomized controlled trial, one of the conclusions is that both experimental interventions were significantly more beneficial than manual therapy alone. If you contrast the findings of these articles against each other, it is reasonable to infer that manual therapy may have very little benefit, if any. However, this claim cannot be confirmed or denied without the inclusion of high-quality studies that specifically contrast manual therapy to exercise therapy for a given patient population without confounding treatments, such as TPE. Therefore, future research will require high quality RCTs with the aim of studying the difference between these two treatment methods while intentionally refraining from including other therapies that could affect the overall results. |

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[List all references cited in the CAT]

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