Chapter 8
General discussion
Effectiveness and cost-effectiveness of manual therapy Utrecht

Neck pain is the fourth most important health problem worldwide in terms of years lived with disability. In the general population, most people with neck pain (50%–85%) do not experience a complete resolution of the problem although neck pain generally recedes within one to two weeks. People with neck pain will often receive treatment that is mostly organised in primary care. General practitioners (GP) most commonly refer patients with neck pain to manual therapy or physical therapy (51%), more than they provide advice and prescribe medication (42%). However, there is limited evidence regarding which therapeutic modality anyway is most (cost-)effective and which approach is best in which patient.

In Chapters 3 and 4 we compared manual therapy according to the Utrecht school (MTU) with physical therapy (PT) in terms of efficacy and cost-effectiveness, the NECK project (“Nederlands Effectonderzoek Cervicale Klachten”). In the Netherlands, manual therapy (MT) has shown to be significantly more effective when compared to physical therapy (PT) or continued care by a GP (a ‘wait and see’ policy). As MTU differs from other forms of MT as regards patient assessment and therapeutic application (as described in the general introduction (Chapters 1 and 2) of this dissertation), the efficacy and cost-effectiveness of this particular form of manual therapy needs to be determined. We chose to compare MTU to physical therapy, particularly active exercises. This was a pragmatic choice, because in the Netherlands patients with neck pain are referred by their GP to either manual therapy or physical therapy. The results of this trial showed no overall ‘between group’ differences for MTU and PT in the treatment of patients with sub-acute and chronic non-specific neck pain. However, MTU involved fewer treatments compared to PT. From a societal perspective, MTU was not more cost-effective in comparison with PT in terms of perceived recovery, functional status and QALYs. These results are in line with results described in the latest 2015 Cochrane review on spinal manipulative therapy (SMT) for neck pain. From that review, it is evident that manual therapy, mobilization and/or manipulation are not superior to other treatments. The same outcome was reported in earlier Cochrane reviews on low back pain. What are the possible explanations for this finding? It is now an open question as to whether both interventions are equally effective, or that they are equally ineffective. Both groups showed a 3-point (30%) improvement on the numerical rating scale for pain. This is considered clinically relevant. In a meta-analysis of low back pain studies, Artus and colleagues identified a similar pattern of substantial improvement as seen in our NECK project, noting a rapid reduction of pain and functioning for a range of interventions in the first weeks followed by a plateau of unchanged complaints. There was no evidence for superiority for any particular intervention, and only modest differences between the interventions. Artus and colleagues concluded that other factors than treatment related factors might influence the improvement in pain and functioning.

There are several possible explanations for efficacy, such as an intervention effect (specific effect) or non-specific factors, such as natural history, regression to the mean and non-specific effects of treatment.

Regarding specific treatment factors, it can be argued that diagnosis by therapists who use SMT in the treatment of patients with neck and back pain is usually based on assessment with low to moderate diagnostic reliability and validity. On the basis of results described in systematic reviews on this issue we can conclude that there is low inter-rater reliability on ‘passive intervertebral motion assessment’ of the spine, as well as the upper and lower extremities. The question then arises as to how a decision to treat an individual patient is reached, if based on a diagnosis with a low reliability and/or validity. Although MTU is founded on a different approach to patient assessment with high reliability (Kappa 0.8-1) it is essentially authority-based and the validity of tests has not been investigated.

Another explanation for the comparable course of different interventions may be the underlying mode of action of the treatment. Traditionally, mobilizing and manipulative techniques have been based on (bio)mechanical principles appropriate to the motion assessment of the joints, spinal column or extremities. Increased mobility, or at least a change in motion function, would then explain the effectiveness of the manual therapy approach (SMT, mobilization, manipulation). However, there is actually few, and conflicting, evidence on the diagnostic and prognostic value of spinal (segmental) stiffness. It can be argued that no difference
in effectiveness between interventions is demonstrated because other therapies such as exercise therapy also can affect spinal mobility or stiffness.

Another unanswered question is whether the mechanical stimulus provided by SMT, which acts in a purely mechanical manner, can explain the outcome of the intervention. There seems to be a clear paradigm shift occurring in the explanatory model towards an important role for neurophysiological processes at both the spinal and supraspinal level. Because they start with a mechanical stimulus, manual techniques may play a role in this interaction, acting as a trigger in a cascade of neurophysiologic events. The same neurophysiological responses occur upon stimulation of soft tissue and nerves, which can explain the similarities in outcomes between SMT and other treatments such as exercises or massage therapy. Placebo and psychosocial variables also produce the same neurophysiological responses. Research showed that subjective and physiological responses can be changed by influencing one’s expectations. Functional magnetic resonance imaging (fMRI) studies have shown that during placebo treatment in which patients anticipate on pain (relief) there is increased activity in the brain such as the orbitofrontal cortex and the dorsolateral prefrontal cortex, regions involved in expectation and emotional factors. For spinal mobilization there is no supporting evidence for an effect on segmental vertebral movement, but evidence suggests the involvement of an endogenous pain inhibition system mediated by the central nervous system. Possible neurophysiological responses affecting areas other than the specific region of treatment may explain why ‘local’ therapies have an impact on central pain reduction. Clearly, the neurophysiological response is also a ‘black box’ that needs to be further unravelled.

Another explanation for the similarities in effectiveness across treatments might be the lack of a good understanding of the cause of the pain. As long as we are not able to identify the cause of pain, we are also not able to provide an adequate treatment targeting the cause of pain. A better understanding, on theoretical grounds or through basic research, of the mode of action of an assessment or treatment would be helpful in the selection of patients who will respond positively to a specific intervention. Conclusions based on theory or basic research can then be further tested for efficacy in clinical trials.

The effects of manual therapy on patients are still measured using non-specific outcomes, such as global perceived effect (GPE), function, and pain, and not with outcomes appropriate and representative for manual therapeutic interventions. The question is whether these instruments actually exist, and if they exist, whether they would help identify aspects relevant to the patient. The segmental motion tests of the spine on which the therapy is often based are, as previously mentioned, only weakly to moderately reliable and valid, with the exception of testing for pain. These tests can therefore not be used as evaluative tools to assess whether the interventions have produced the effect intended by the therapist.

In addition, there are also non-specific factors that may explain the course of neck pain. The improvements could be interpreted as natural recovery. In a previous trial carried out by Hoving et al., MT appeared to be substantially more effective than usual care (mainly based on a “wait and see” policy) as provided by general practitioners (GPs) for patients with subacute and chronic neck pain. We found comparable results with manual therapy as Hoving et al. and, therefore, do not consider that natural recovery is fully responsible for improvements seen in our study.

It is also plausible that our results differ from the natural course based on results from a cohort study in Norway. In this Norwegian study on the natural course, pain remained unchanged over the one year follow-up for subjects with pain of equal intensity in the neck and low back areas at baseline, and for subjects with 4 or more musculoskeletal pain sites. In our study and the Norwegian study, adjusted mean pain did not drop below a score of 2 on the numeric rating scale for pain at any time during the follow-up period. However, the population in the NECK study scored 2.1 points higher at baseline. By contrast, in our study about 20% of patients had both neck and back pain to 11% in the Norwegian study, around 65% had 3 or more musculoskeletal pain sites to 22% in the Norwegian study and 30% had 4 or more musculoskeletal complaints to 11% in the Norwegian study. The patients in our study population were also mostly middle-aged (average 49 years in our study and 44 years in the Norwegian study), the group that generally shows the poorest outcome for neck pain. A rapid reduction in acute symptoms in the first weeks after the start of the intervention appears to be consistent with the natural course. In the case of
persistent/chronic complaints, a rapid reduction of symptoms is unexpected and may reasonably be attributed to the intervention. Considering the above, it seems likely that both treatments evaluated in the NECK study, MTU and PT, are effective in the treatment of non-specific neck pain. If there is no difference in effectiveness or cost-effectiveness between interventions, therapy choice will depend on the patient’s own preference and the clinical expertise of the therapist.

While trials focus especially on the differences between the experimental and control/comparator interventions, identify associations or mediators with non-specific factors, including expectations (outcome expectations, but also process expectations), satisfaction, treatment setting or the patient-therapist relationship may help to improve understanding of the results of clinical trials and thus to further optimize possible interventions.

Although RCTs are the gold standard in assessing the effectiveness of interventions, translation of their results into clinical practice may be challenging. In many RCTs, patients with neck pain receive the same treatment. However, individuals with neck pain are not a homogeneous group and the underlying constraints (impairments) or mechanisms of neck pain, or coping with pain, may be different. Subgroups may exist that require different treatments in order to achieve optimal results. However, as long as we are not able to identify these subgroups clinical practice remains ‘trial and error’ and results of clinical trials are difficult to generalise in daily practice.

Pooled data tend, by definition, towards the neutralization of individual differences. In RCTs often general inclusion criteria are used, while more specific inclusion criteria would do more justice to clinical practice. Based on clinical reasoning a therapist will select, in shared decision with the patient, an appropriate intervention for an individual patient, a choice that often involves the selection by the therapist of one of several possible options, options that are more extensive than those allowed by a RCT protocol. It is therefore not unreasonable to be cautious when interpreting and implementing results from RCTs with broad inclusion criteria and reviews on the effectiveness of a treatment for an individual patient.

Another aspect that may reduce the generalizability of RCTs is the involvement of patients in an RCT who are willing to participate in a randomized trial and the possible differences to a patient population in clinical practice. After an initially successful start of the NECK project, enrolment remained far behind the target. Various strategies were devised to improve enrolment (information for GPs, regularly sending reminders), and it was eventually decided to post an article about the study in several local newspapers, indicating that patients with neck pain could join the study. A mix of recruitment strategies, as used in the NECK project, does not appear to affect treatment outcomes, on the condition that adjustments are made for baseline differences.

Inadequate recruitment and enrolment in a study can lead to reduction of external validity, so monitoring for recruitment is important. During the inclusion period, it was difficult to recruit the number of patients calculated based on the feasibility study. This does not appear to be unusual, especially in primary care studies, as less than a third (31%) of the trials in an overview by McDonald et al. achieved their original recruitment target, around half (53%) were awarded an extension and early recruitment problems were identified in 77 (63%) trials. It is possible that some patients enrolled in the study would otherwise have placed no demands on medical care. This could have biased our cost-effectiveness study. Future cost-effectiveness studies should consider these limitations and conduct subgroup analyses to evaluate the impact of recruitment strategy on the results.

In the NECK project we chose for a pragmatic study with restrictions in the treatment protocol. In the PT intervention it was not allowed to apply manual techniques on spinal joints, although is not unusual in that setting. This possibly resulted in some limitations in treatment options compared to usual care. This is the first effectiveness study on MTU, so we organized a single modality care trial to compare MTU as a hands-on therapy (mainly passive for the patient) with a contrasting intervention, mainly exercise-based PT (active for the patient). Although single modality trials and reviews are necessary, practitioners have voiced concerns that they do not accurately represent clinical practice, or possibly, best practice for patients. Several reviews have supported the use of combined mobilization, manipulation and exercise to improve short-term pain reduction, global perceived effect and patient satisfaction in acute and chronic neck pain. Both interventions
in the NECK project were ‘mono therapies’, applied following a protocol in order to obtain adequate contrast. Treatment probably achieves more efficiency when practitioners are free in their choices. Adjusted for demographic characteristics and features of the health problem patients with a free choice needed on average 2.3 fewer treatments per calendar year than referred patients and more often reached their treatment goals. Clinical generalizability is threatened due to the intervention standardization in an RCT. The question is whether it is realistic to assume that a single form of treatment (such as manual therapy, exercises or pain education) is sufficient to reduce pain experience and limitations in functioning in patients. A multimodal approach seems to be indicated, which implicated that in MTU active exercises and pain education should be part of the therapy, in addition to the current homework exercises.

Although from a societal perspective there was no clear difference in cost-effectiveness between MTU and PT, MTU involved fewer treatments. It seems obvious that the costs are lower if fewer treatments are needed. However, when using a societal perspective this does not appear to be the case. Apparently the lower costs of the fewer treatment sessions seem compensated by higher costs of other health care utilization or higher indirect costs. The interpretation of these results depends on the viewpoint taken (e.g. patient, healthcare provider, insurance company, policymaker). Although there was no difference in total costs, the costs of the MTU intervention were lower. This might be important to insurance companies and patients, the latter especially when they have to bear these costs themselves.

Generalizability of results of trials to clinical practice is important. Reports of RCTs should include an adequate description of the study population, the outcomes and the intervention. Lack of consistent reporting or the absence of information in RCTs on the intervention, i.e., the type of manipulation or mobilization of the spine, makes the interpretation of the results difficult. We developed a reporting guideline (CIRLe SMT) for manipulation and mobilisation as an extension of the CONSORT statement. The goal was to develop a criteria list for the reporting of SMT with the purpose of increasing the transparency and interpretability of results from RCTs and other scientific publications. This will also facilitate study comparison, reproducibility and inclusion in systematic reviews. The specific characteristics of the application of SMT techniques are critical to adequate interpretation of the outcomes of RCTs and to making them applicable in clinical practice. A valid criteria list was constructed using a Delphi process, containing 24 items in 5 domains, which should promote consistency in reporting SMT interventions in scientific publications as an extension of the CONSORT Statement and the extension for non-pharmaceutical trials. A limitation of our research could be that we may not have included all relevant experts in the Delphi rounds. We invited authors of published RCTs or systematic reviews on SMT and/or those who attended the low back and neck pain Forum in Australia in 2011. This group has a strong focus on SMT research, and the majority of participants are also active in clinical practice. However, the target population (clinicians) may have been underrepresented. The focus of the participants on SMT could also be considered a limitation. It may be of interest to learn what experts from other fields of medicine (e.g. GPs, orthopaedic specialists, neurologists) would like to know about the methods of treatment. A better understanding of the methods used could lead to better communication with referrers and to targeted referral, something that happens very little at the moment in manual therapy in the Netherlands. In the period from 2007 to 2011 one fifth of patients with neck pain were referred by the GP, 70% to PT and only 8% to manual therapy. Referrers have individual perceptions, such as knowledge and beliefs about manual therapy, that can either lead to barriers or may facilitate referral to manual therapy.

The experts did not include the assessment of mobilization or manipulation in the Delhi procedure as a domain in the CIRLe SMT reporting guidance. In general, the results of assessment of mechanical dysfunction of the spine determine the therapeutic intervention. However, regarding intersegmental and overall movement testing, research shows strong evidence for only poor to fair inter- and intra-examiner reliability. The reliability overall is not improved based on examiners’ discipline, experience level, consensus on procedure used, training just before the study, or use of symptomatic subjects. The general conclusion is therefore that manual examination is not valid for the diagnosis of zygapophyseal joints. The fact that the assessment was not included in the reporting guidance is therefore understandable. Although evidence suggests otherwise, most practitioners (54.0%) are reasonably confident that they would reach a correct diagnosis of impairments, function or motion segment using manual examination. If the manual therapeutic
diagnosis is not valid, it is also doubtful whether the mechanism of the effect of treatment can be regarded as valid as mentioned before. This might explain the lack of differences between the various treatments for neck pain, as discussed above.

Descriptions and classifications of mobilizations and/or manipulations seem essential given the fact that many different techniques are used in SMT8. One of the reasons for the absence of a reporting guideline for SMT could be the lack of international standardization of terminology and definitions for manipulation and mobilization-based therapies for the spine. Interestingly, the experts participating in the CIRCLe SMT guideline described the intervention techniques for mobilizations and manipulations using the same parameters. It is possible that the difference between the techniques is based on the relative dosage of these parameters; there might be more similarities than differences between both techniques.

It is our hope that the international community (journals, clinicians, education institutes) adopts this list of criteria and that they are endorsed by scientific journals. If SMT interventions are more accurately described in publications of RCTs, recommendations in clinical guidelines can be more specific and the results of these trials can be better implemented in clinical practice. We encourage journal endorsement of our item list, as it has been shown that lists of this type help improve the quality and completeness of reporting in medical journals43-46, especially when journals endorse guidelines46. We also encourage ‘umbrella’ organizations (e.g. International Federation of Orthopaedic Manipulative Therapists, European Chiropractic Union, and national associations related to SMT) to endorse the criteria list to help facilitate implementation in research practice and educational programs.

Psychosocial variables and subgrouping

Psychosocial factors of patients can have prognostic value in outcome success of interventions2,47,48. If such factors can be determined in patients with neck pain at the start of manual therapy or physical therapy treatment, the treatment can be tailored to individual patients. It is therefore important whether these psychosocial factors have a predictive value in addition to clinical and demographic variables. Psychological factors that are believed to play a role were examined in a study reported in chapter 6, namely outcome expectations, credibility, health locus of control and fear avoidance beliefs. In addition, patient characteristic as locus of control can be changed with a cognitive behavioural therapy49. Patients with an external locus of control might benefit more from a passive therapy with an active role of the therapist, as in MTU, while patients with an internal locus of control would benefit more from an active exercise therapy, as in PT.

The main findings showed that outcome expectancy, in patients with non-specific sub-acute and chronic neck pain, has additional predictive value for treatment success above and beyond clinical and demographic variables. None of the other variables (locus of control and fear avoidance beliefs) showed relevant predictive values. There were no significant interactions between psychosocial variables and the interventions on any of the outcome measures or measurement moments. Multiple studies have shown that in addition to other aspects (such as female gender, older age, high job demands, low social/work support), poor mental health, somatisation (a tendency to worry about common somatic symptoms), persistent anxiety and depression are important in the development of chronicity in neck pain. In an individual approach to problems it is important to recognise these factors and analyse whether a particular form of therapy targeting these factors is more effective than untargeted, more general therapy. In our study, a number of these patient characteristics were studied in a secondary analysis of the RCT described in chapters 6.

Due to the strict inclusion and exclusion criteria that were applied, our RCT probably included a relatively homogeneous patient group to increase the generalizability of the study results, which on the other hand may affect the generalizability of the results to clinical practice. In particular, participation in the RCT may have played a role in the high expectations found in the study (on average 22 points out of a maximum of 27). Participants chose to participate in the study or were specifically referred by their general practitioner probably based on expressed expectations. Patients completed the expectations questionnaire immediately after the first treatment in the presence of the therapist. Although patients were asked to place the questionnaire in a sealed envelope to prevent the therapist seeing the answers, there may have been a collection bias. If patients complete questionnaires in front
of a therapist, this may lead to higher scores. The scores on outcome expectancy were high, as expected in voluntary participation, with little variation in the scores. On the other hand, it could be argued that not only participants in RCTs, but patients seeking care in general have high prior expectations. Patients show better adherence when they are motivated, and they are more motivated when they have positive expectations. It has been shown repeatedly that patients with good adherence tend to have better outcomes than patients with poor adherence, even if they receive a placebo treatment. It is possible that therapies that require effort on the part of the patient, e.g. exercise, have a stronger mediator effect in expectancy than medication.

In addition, there is little research on outcome expectations in patients with neck pain treated by manual therapy. Research has shown that expectations may change during the intervention period and that an inventory should therefore not only be carried out at the beginning of the treatment, but also over the course of the treatment period. This will allow new treatment strategies to be initiated during the course of the treatment and patient expectations can be adjusted to the results at that time. In the secondary analysis on expectancy (Chapter 6) partly for pragmatic reasons, we did not include measurements of expectancy during follow-up. The Credibility/Expectancy Questionnaire used in our study is a general questionnaire that is not tailored specific for neck pain or specific symptoms or limitations of activities and participation. This might have biased the results of the outcome expectancy or credibility, because the expectations are not directly linked to the clinical symptoms of the patient. It has been shown that patient expectations can have an influence on outcomes. Therefore, it was a strength of our study to compare the expectations of the two intervention groups at baseline to identify potential bias. Measurement at baseline of outcome expectations is recommended in future randomized studies, because it is a potential prognostic factor. Comparison of the expectations of the groups at baseline is important, and the analysis should be adjusted for potential confounding if the baseline expectations are not similar.

Fear avoidance beliefs has been selected as a clinical prediction rule based on determinants of success for thoracic manipulation in neck pain (FABQ subscale of physical activity less than 12 points, FABQ subscale work less than 10-points). In our study, however, fear had no predictive value for both interventions. The intervention studied by Cleland and colleagues used high velocity thrust (HVT) techniques that are clearly different compared to the mobilizations by low-grade passive movement used in the NECK project. From a patient’s perspective, these HVT techniques, which involve a short rapid movement at the end position of the joint and an audible “crack”, could lead to a more prominent role for fear and explain the difference between both studies.

It is possible that there is not only a role for individual patient characteristics, but that the form of treatment also plays a role in outcome success. Our study showed no moderating effect of the treatments (MTU, PT) on the investigated psychosocial variables, but as this was a secondary analysis within an RCT on effectiveness in neck pain. There was no randomization of patient preferences for treatment, a possible suggestion for further research.

To guide clinicians in deciding which intervention to provide, the heterogeneous group of patients with neck pain could be divided into sub-groups based on, for example, symptoms, illness beliefs and patient characteristics. The STarT Back Tool (SBT) was developed for low back pain and was found to be a reliable and valid instrument for the classification of patients in low, medium or high-risk profiles for poor outcome. Stratified treatment for those separate groups seems to be more effective in terms of functioning compared to non-stratified general best-practice management approaches. This type of screening tool does not exist for neck pain, so the study in Chapter 7 aimed to compile a screening tool for neck pain based on three studies conducted in the Netherlands. We explored the ability of this screening tool to identify three risk profiles for patients with neck pain, and the predictive validity of these risk profiles on recovery. This study indicates that low, medium, and high-risk profiles for a poor neck pain prognosis can be distinguished by a short set of items, similar to the SBT. Overall, our study illustrates that the higher the risk profile, the lower the odds for recovery with clinically relevant differences in recovery. The CANS (Complaints of Arm Neck and Shoulder) guideline was released in 2010 in the Netherlands, and recommends that patients with neck pain should be divided into one of three profiles: In profile I, dysfunction in body functions...
and structures are present in the absence of limitations in activities and problems with participation. Profiles II and III refer to patients with activity limitations and participation problems. Classification in profile II requires a clear and identifiable link between the dysfunction of body functions and structures and problems in activities and/or participation, as assessed by both the therapist and the patient. A patient is categorized in profile III if there is a discrepancy between physical disorders and perceived limitations in activity and/or participation, based on judgment of the therapist. In this profile there may be a problem of an inadequate coping with a health problem. Treatment strategy is determined based on a patient’s profile. For profile I, the recommended intervention is limited to advice and education. Patients in profile II are eligible for a more somatic approach and manual or physical therapy may be indicated, while patients in patient profile III are eligible for a more behavioural approach. As far as we are aware, there are no measurement instruments that can justify the choice for one of the patient profiles and no recommendations are suggested in the CANS guidelines. Therefore, clinicians largely rely on their own experience and clinical judgment. A reliable and valid instrument to categorize patients to the various risk profiles would therefore be an important step forward.

Creating clusters of patient characteristics with low, medium and high-risk prognoses reveals differences in the success of outcomes. The instrument developed analogously to the STarT Back Tool (SBT), the ‘STarT Neck Tool (SNT), is partly based on psychosocial constructs. We performed a preliminary study, described in Chapter 7, in which we used questions from three conducted RCTs on neck pain corresponding to the questions of the SBT. The results showed distinct subgroups of low, medium and high-risk profiles and significant differences in outcome success of these profiles. It has taken into account that many assumptions were made about similarity to the SBT constructs and scores in the SNT questionnaire. The SNT was designed as a secondary analysis, enabling us to analyse the effect of targeted treatment based on the classification of the SNT. The results of the study to develop a screening tool for neck pain indicate that these results are worthy of further research. As indicated above, the CANS directive distinguishes between three profiles, while providing no instrument to make this differentiation. The ‘STarT Neck Tool (SNT) also includes three distinct profiles, based in part on psychosocial variables, which can allow this gap in screening to be filled. Validation of the SNT in future prospective research is advised.

The research on psychosocial variables (Chapter 6) and risk profiles for a poor prognosis (Chapter 7) was based on the biopsychosocial model. The predictive values found in the NECK project for patient expectations regarding treatment outcomes confirm the value of this model in the treatment of patients with nonspecific neck pain. Understanding psychological aspects and their relationships with patient characteristics surveyed in clinical practice are important in the choice of therapeutic options for an individual patient. Our findings provide further incentive to explore the outcome expectations at the start of treatment and, when appropriate, possibly influence them. Similarly, the categorization of patients based on a screening tool appears to require a different intervention for patients in the high-risk group than for patients in the low and medium risk groups. Foster stated in a review that the attitude of a therapist can be changed by training, but that this hardly affected changes in clinical performance. Many clinicians closely examine biomedical or biomechanical musculoskeletal complaints. A multimodal approach with a focus on the interactions between biomedical, psychological and social aspects is important for neck pain, although the question is whether physical therapists and manual therapists are adequately equipped for intensive interventions adapted to psychosocial aspects. An important question is whether patients with neck pain at high risk for a poor prognosis would not benefit more from a multidisciplinary approach considering psychosocial aspects involved in this patient group. Although a relatively small group, the individual, social and economic impact might be large. Therapists have to assess whether they can intervene themselves in mild psychosocial problems by behavioural approach, or that they have to refer to physiotherapists or other health care workers as psychologists specialized in psychosocial problems. In low patient expectations it is feasible and practically applicable for a manual or physical therapists to match with the patient about treatment expectations and create higher expectations even without the use of specific interventions such as cognitive behavioural therapy.
When considering the results of the latest reviews on the treatment of neck and back pain\textsuperscript{6-8,65}, and the points of discussion above, the thought arises that setting up new RCTs with may no longer be worthwhile for complaints-based patient groups instead of patient groups based on sub-grouping. Hereby taken into account that most RCTs are relatively small studies, so (small) effects are difficult to distinguish to control interventions or to natural course. Due to the large number of studies already completed, the conclusions of a meta-analysis will not be changed by new results, unless RCTs will be performed with very large numbers of patients. By contrast, fundamental research on the mode of action of manual therapy does seem worthwhile, possibly allowing more specific treatments. More effort will have to be expended on finding individuals who have a greater probability of responding to a specific treatment.

**Recommendations for clinical practice**

Manual therapy according to the Utrecht School (MTU) and physical therapy showed no difference in effectiveness in the treatment of sub-acute and chronic neck pain. Both treatments showed a clinically relevant improvement in pain.

If the intervention is adequately described in literature, possible specific treatment characteristics can be identified through meta-analyses and better implemented in clinical practice. We hope that our article on reporting guidelines for spinal manipulative therapy (SMT Circle) has made a worthwhile contribution to this important goal.

In our study, we could not differentiate between MTU and PT in terms of efficacy based on patient characteristics or psychosocial variables, in other words, there were no specific characteristics that correlated better with a more passive therapeutic approach (MTU) or an active approach (PT). However, patient characteristics do seem to influence the course of the complaints and the treatment effect in both groups, as was found in our study of patient expectations.

In clinical practice, it is advisable to question patients regarding their outcome expectations at the start of the therapy, in order in case of low expectations to intervening on this aspect.

Evidence-Based Medicine (EBM) now plays an increasing role in healthcare. Transparency of individual care is also becoming a requirement, due to social pressure from patient organizations and insurance companies. As David Sackett stated: “Evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.”\textsuperscript{66}

External clinical evidence can be informative, but cannot replace individual assessment of the patient. Clinical expertise also determines whether or not the external evidence is applicable to the individual patient on the basis of the clinical reasoning process of the therapist, besides patient’s values. In addition to clinical characteristics and symptoms, the outcome expectations of a patient have a clear predictive value for the effectiveness of the treatment. A choice of manual therapy or physical therapy treatment in sub-acute and chronic neck pain should be made based on the available evidence, integrated with clinical expertise and expectations and beliefs of the individual patient. As there is no difference in effectiveness between MTU and physical therapy, the choice between the two will mainly be based on the latter two.

**Recommendations for future research**

The CANS guideline in the Netherlands defines distinctive patient profiles whereby stratified therapy is recommended based on the presence of limitations in activity and/or participation and a discrepancy with physical disorders. In addition, coping behaviour with respect to health is of considerable importance. However, no advice on measurement tools to help identify distinct patient factors and stratify therapy is currently available and, to the best of our knowledge, an appropriate instrument to differentiate profiles in neck pain does not yet exist. Therapists are, beside scientific evidence, still expected to act based on their clinical reasoning and their experience.

A tool analogous to the STarT Back Tool could fill this gap. When categorized to patient risk profiles, a difference was found in our study in perceived recovery between low, medium and high-risk groups. These first exploratory study results represent a promising foundation for further research concerning risk profiles for poor neck pain outcomes.
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