

# Guideline for Reporting Interventions on Spinal Manipulative Therapy: Consensus on Interventions Reporting Criteria List for Spinal Manipulative Therapy (CIRCLe SMT)

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## ABSTRACT

**Objective:** The aim of the Consensus on Interventions Reporting Criteria List for Spinal Manipulative Therapy (CIRCLe SMT) study was to develop a criteria list for reporting spinal manipulative therapy (SMT).

**Methods:** A Delphi procedure was conducted from September 2011 to April 2013 and consisted of international experts in the field of SMT. The authors formed a steering committee and invited participants, selected initial items, structured the comments of the participants after each Delphi round, and formulated the feedback. To ensure content validity, a large number of international experts from different SMT-related disciplines were invited to participate. A workshop was organized following the consensus phase, and it was used to discuss and refine the wording of the items.

**Results:** In total, 123 experts from 18 countries participated. These experts included clinicians (70%), researchers (93%), and academics working in the area of SMT (27%), as well as journal editors (14%). (*Note:* The total is more than 100% because most participants reported 2 jobs.) Three Delphi rounds were necessary to reach a consensus. The criteria list comprised 24 items under 5 domains, including (1) rationale of the therapy, (2) description of the intervention, (3) SMT techniques, (4) additional intervention/techniques, and (5) quantitative data.

**Conclusions:** A valid criteria list was constructed with the aim of promoting consistency in reporting SMT intervention in scientific publications. (*J Manipulative Physiol Ther* 2017;40:61-70)

**Key Indexing Terms:** *Manipulation, Spinal; Publications; Randomized Controlled Trials*

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## INTRODUCTION

A randomized controlled trial (RCT) is considered the most robust design to study the effectiveness of treatments. Accurate reporting of RCTs is important for critical appraisal of study validity, adequate interpretation of the results, and for optimal implementation of the findings in clinical practice. In that regard, the CONSolidated Standard Of Reporting Trials Statement (CONSORT) was designed to improve the reporting of trials and has been modified for nonpharmacologic trials.<sup>1</sup>

Descriptions of the study design and method often constitute a substantial part of reports of RCTs, whereas the intervention is often described in a few sentences.<sup>2,3</sup> Glasziou<sup>4</sup> indicated that many RCT reports often lack crucial details about the intervention. To best interpret the results of individual studies, it is important to have more detailed information about the “who, what, when, and

where” of the intervention, especially given that interventions are typically tailored to meet individual needs.<sup>4</sup> Development of a criteria list for the reporting of interventions has been undertaken for a variety of conservative interventions, including acupuncture and homeopathy for musculoskeletal complaints.<sup>5-7</sup> Descriptions and classifications of mobilizations and/or manipulations have been published,<sup>8,9</sup> but no item list for reporting spinal manipulative therapy (SMT) has yet been developed. Creating such a list seems essential given the fact that many different techniques are used in SMT.<sup>10</sup>

The potential benefits of good reporting are significant,<sup>11</sup> and this also applies to a detailed description of the intervention. For example, such reporting improves the completeness and transparency of the research reports, which enables a more accurate interpretation of the RCT. In addition, it allows clinicians and researchers to replicate the intervention. The specific characteristics of the application of SMT techniques are critical to adequate interpretation of the outcomes of RCTs and make them applicable to clinical practice. Therefore, CIRCLe SMT (Consensus on Interventions Reporting Criteria List for Spinal Manipulative Therapy) aims to develop a minimum set of items for the description of SMT in RCTs by obtaining consensus via a Delphi procedure among experts in the field of SMT.

## METHODS

The article “Guidance for Developers of Health Research Reporting Guidelines” was used for this project.<sup>12</sup> A Delphi process was used as the facilitation technique for reaching consensus.<sup>13</sup> This project was exempted from ethics review under Dutch law.

### Steering Committee

In September 2011, the project team formed a steering committee that was responsible for the construction of the list of items, selection of participants, construction of the Delphi questionnaires, analysis of the responses of the participants, and handling the feedback from the participants after each round.

### Phase I

**Selection of Items.** Items to be included in the questionnaires were selected on the basis of articles on mobilization and manipulation techniques,<sup>14-18</sup> systematic reviews<sup>10</sup> and textbooks on SMT,<sup>19-22</sup> and other guidelines for description of interventions.<sup>6,7,9,23-25</sup>

A scheme consisting of relevant domains that were thought to influence treatment outcome was established.

In a pilot study, participants with various clinical backgrounds were invited to evaluate these items and to formulate additional items to ensure that all potentially

relevant items would be included in the initial draft of the criteria list to be used in the first Delphi round.

**Selection of Participants.** To ensure content validity, a large number of international experts from different disciplines were invited to participate, including authors of RCTs or systematic reviews in the field of SMT from the previous 5 years; participants of the International Forum XI on Low-Back Pain Research in Primary Care in Melbourne, Australia (2011); and clinical experts identified by the steering committee.

### Phase II: Procedure Delphi Rounds

During the Delphi procedure, the project team used structured questions. Additionally, participants were invited to give comments on the suggested items and suggestions for additional items. Consensus was defined as 70% of the participants or more answering “yes” on an item.

**Round 1.** First, demographics of the participants were ascertained (eg, type of profession), and questions about participation in (planning) RCTs or systematic reviews concerning SMT in the last 5 years were posed. For each item, the project team asked the participants if that item should be included in the final criteria list. In addition, the participants were asked whether manipulation and mobilization techniques should be described in the same terms or separately.

**Round 2.** On the basis of the results from Round 1, questions were rephrased and presented for the second round. To compile a minimum criteria list, the project team asked the participants to state whether they thought inclusion of an item was “absolutely required” or “desirable.” In addition, participants were asked to indicate whether a global description would suffice for an item or if a detailed description was necessary.

**Workshop Meeting.** Items that were identified from the second round were discussed during a workshop at the International Low-Back Pain Forum XII in Odense, Denmark, in 2012. Moreover, the wording was refined where necessary. Also, an example of good reporting of SMT was formulated by the participants.

**Round 3.** Based on the outcomes of Rounds 1 and 2, the steering committee formulated 3 possible choices to determine which items should be included in the final list: (1) because of the small number of items chosen (by consensus) as “absolutely required,” the first option was to use all of the original items from Round 1 and disregard the results of Round 2; (2) include items that were considered important in Round 2 by at least 50% of the participants; or (3) include items that were considered important in Round 2 by at least 70% of participants. A list with the 3 options was presented, and participants were asked to rank these options. The first choice (highest preference) was assigned 3 points, the second choice 2, and the third 1 point. The option with the highest score was used to compose the final criteria list.

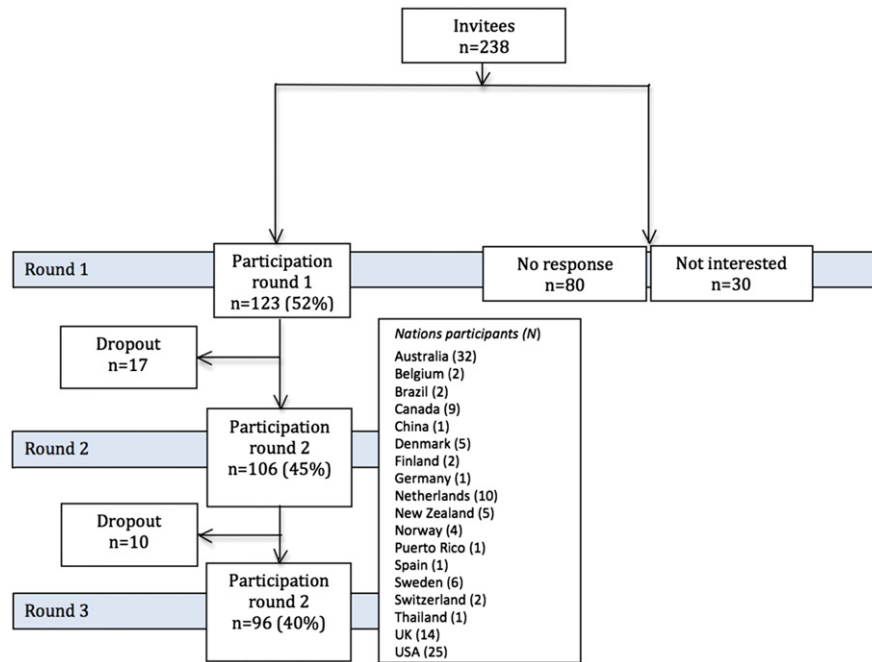


Fig 1. Flowchart of participants in Delphi procedure CIRCLe SMT project.

### Final Criteria List

On the basis of the Delphi procedure and workshop, the final criteria list was composed. Items were modified, if necessary, by the steering committee according to the input of the participants in the Delphi rounds and the comments received during the workshop.

## RESULTS

### Participants

In total, 238 experts were invited via e-mail, and 123 (52%) completed the first round. Figure 1 depicts the flow of the study. The experts were from 18 countries (Fig 1) and included clinicians (70%), researchers in the field of musculoskeletal pain (93%), and academics working in the area of SMT (27%), as well as journal editors (14%). (Note: The total is more than 100% because most reported more than 1 job.) Among the clinicians, there were 42 manual therapists, 19 chiropractors, 6 osteopaths, and 18 with another profession. In total, 55% had participated in an RCT, with 41% of those in 3 or more trials, and 50% had participated in a systematic review, with 44% of those in 4 or more reviews.

### Round 1

In total, 48 items in 6 domains were included in the first round (Fig 2). The majority of the participants (66%) stated that manipulation and mobilization techniques should be described separately. Eleven items were excluded from this round (Fig 2).

### Round 2

Of those invited, 86% completed the second round. In the first round, 4 items were considered to reach consensus, namely, active movement tests, passive movement tests, pain sensitivity tests, and additional techniques/interventions. However, no consensus was reached as to whether their description should be global or detailed. Hence, these items were presented in the second round again.

### Workshop Meeting

In total, 19 participants joined the workshop in Odense, Denmark. During the workshop, items from the second round were discussed and rephrased, if suggested by the participants. The included items were then processed in a sample text of reporting SMT.

### Round 3

Of the participants, 78% completed Round 3. The results of this round were as follows: Option 1 (ie, all items from Round 1) received 198 points, option 2 (ie, 50% cutoff) had 215 points, and option 3 (70% cutoff) had 163 points.

The items that were excluded by choosing option 2 were as follows:

- **Rationale of the therapy:** (1) Qualification of practitioners; (2) Supposed theoretical and/or underlying mechanism of the therapy;
- **Description of the intervention:** (3) Method for increasing adherence to the protocol;

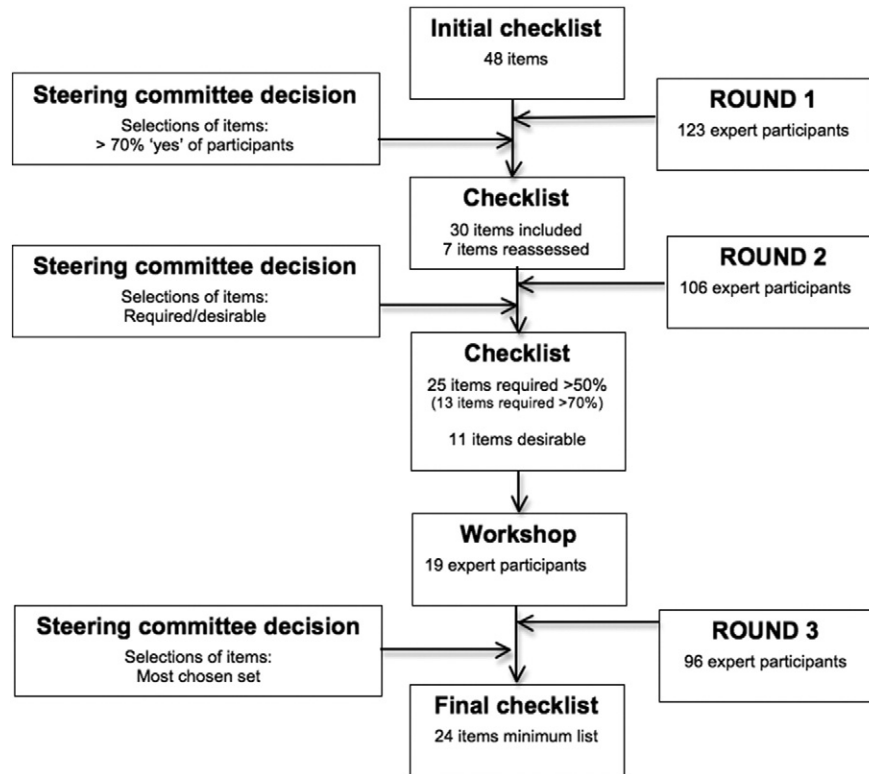


Fig 2. Flowchart of selected items CIRCLe SMT criteria list during the Delphi process.

- **Patient assessment:** (4) Active movement tests; (5) Passive movement tests; (6) Pain sensitivity tests;
- **Description of SMT techniques:** (7) Type of movement component of the technique (eg, traction, translation, angulation, spin); (8) Amplitude of the technique; (9) Target of force (the location of the intended force) of the technique; (10) Manually assisted procedures allowed (eg, table adjustments, instrument adjustments); and
- **Quantitative data:** (11) Treatment duration per session (in minutes).

The procedure was completed in April 2013.

#### Final Version CIRCLe SMT Criteria List

The 5 domains of the CIRCLe SMT list and the 24 items with the explanations on the need for adequate reporting and the operationalization of the items are presented. In Figure 3, the domains and the items are summarized.

#### Rationale of the Therapy

**Reference to Descriptions of the Therapy in Articles, Handbooks, or Professional Documents.** To be able to replicate the trial or implement the performed treatment in clinical practice, the fullest possible description of the underlying concepts that

are the basis for the therapeutic constructs should be stated, including references to literature and to documents pertaining to the trial.

**Type of Practitioner(s).** Spinal manipulative therapy is characterized by different conceptions and styles/types. The overall styles, types, or approach on which the treatment is based should be described to contextualize the trial within the range of current clinical practices.

**Years in Practice.** To clarify potential variations and expertise bias and to help improve the applicability of the results, it is informative to report the years of practice of the care providers involved in the trial.

**Special Training of the Practitioner(s) for the Trial.** It is necessary to describe whether participating care providers received any specific training for the trial.

#### Description of the Intervention

**Settings of the SMT Intervention (eg, Primary, Secondary, Tertiary Care).** To be clinically useful, the result should be relevant to a definable group of patients in a particular clinical setting (ie, they must be externally valid). There needs to be a description of where the treatment was delivered, even if in general terms (ie, in private practices or in a hospital setting).

**Standardization of the Interventions.** Spinal manipulative therapy could be defined as a complex intervention, as there

<b>1. Rationale of the therapy</b>	
1.1	Reference to descriptions of the therapy in articles, handbooks or professional documents
1.2	Type of practitioner(s) (e.g. chiropractor, manual therapist, osteopath)
1.3	Years in SMT practice of the practitioner(s)
1.4	Special training for the trial of the practitioner(s)
<b>2. Description of the intervention</b>	
2.1	Settings of the SMT intervention (e.g. primary, secondary, tertiary care)
2.2	Standardization of the interventions
2.3	Description of the frequency of treatment sessions to be modified if the protocol allows
2.4	Criteria for tailoring the interventions to individual participants
2.5	Criteria for treatments to be discontinued
2.6	Method of assessment of adherence to the protocol
<b>3. Description of SMT techniques</b>	
3.1	Direction of force of the technique
3.2	Velocity of the technique
3.3	Thrust technique
3.4	Number of treated motion segments
3.5	Number of repetitions of the technique
3.6	Level of treated motion segments
3.7	Number of treated regions
3.8	Patient's position
<b>4. Additional techniques/interventions</b>	
4	Additional techniques/interventions applied to the SMT group
<b>5. Quantitative data</b>	
5.1	Treatment period and the follow up period
5.2	Treatment frequency per week/ month
5.3	Treatment dosage
5.4	Number of treatments of the intervention
5.5	Number of care providers performing the intervention

**Fig 3.** CIRCLe SMT checklist of information to include when reporting interventions in a clinical trial of SMT.

are several interacting components both independently and interdependently. A highly specific protocol would provide a word-for-word, session-by-session script for the therapist to follow with every patient. A flexible treatment protocol would provide a general framework within which to operate but would not constrain the selection of specific activities or topics.<sup>26</sup> Both treatment protocols are possible; therefore, the treatment protocol should be adequately described.

**Description of the Frequency of Treatment Sessions to Be Modified if the Protocol Allows.** The planned number and frequency of treatments should be clearly documented. Deviations from the protocol during the study should be described in the Results section, including, where relevant, the reasons for this deviation.

**Criteria for Tailoring the Interventions to Individual Patients.** Describing the details of the process of tailoring the treatment for individual patients is necessary for enabling replication, whereby the algorithm might be done as a figure, flowchart, or a table rather than as text. It is important to use relevant standardized terminology (eg, items of our list) in the study protocol to facilitate documentation of the interventions and to determine the amount of individualization in the intervention.

**Criteria for Treatments to Be Discontinued.** Criteria for discontinuation of therapy should be preset. These criteria may depend on the symptoms of the patient or the complaint's course.

**Method of Assessment of Adherence to the Protocol.** Assessing treatment adherence is essential to appraising the feasibility and reproducibility of the intervention in clinical practice. Therefore, the method of assessment of adherence to the protocol should be described.

### Description of SMT Techniques

**Direction of Force of the Technique.** The direction in which the therapist applies the force should be described using standard anatomical and biomechanical terminology.

**Velocity of the Technique.** The velocity should be recorded in general terms (eg, slow or fast).

**Thrust Technique (Name/System).** A description of whether or not a thrust technique is used should be given (including name or system), as well as the position in which the restricted barrier is provided.

**Number of Treated Motion Segments/Joints.** The number of treated motion segments of the spine should be described. If the number varies among patients, the mean and range should be reported.

**Number of Repetitions of the Technique.** The number of repetitions of each applied technique should be mentioned by mean and range.

**Level of Treated Motion Segments/Joints.** When the study is on a specific level (eg, C0-C1 or L5-S1), the level should be specified with the description of how the segments were localized.

**Number of Treated Regions.** It is suggested that the number of treated regions, at least the subregions (eg, upper, middle, and lower cervical regions), be described.

**Patient's Position.** A description of the position of the patient should be included (eg, supine, prone, side-lying). This includes any repositioning of a region of the body, such as positioning the patient in rotation or side bending.



**Table 1.** CIRCLe SMT Checklist of Information to Include When Reporting Interventions in a Clinical Trial of SMT

All Included Items Required According to Delphi Round 1		
	Checklist	Example Reporting
<b>1. Rationale of the therapy</b>		
1.1	Reference to descriptions of the therapy in articles, handbooks, or professional documents	Manipulation according to Hays <sup>11</sup>
1.2	Type of practitioner(s) (eg, chiropractor, manual therapist, osteopath)	Four chiropractors
1.3	Years in SMT practice of the practitioner(s)	All with a minimum experience of 5 years
1.4	Special training for the trial of the practitioner(s)	Therapists received 2 training sessions, for a total of 3 hours, to become familiar with the protocol.
<b>2. Description of the intervention</b>		
2.1	Settings of the SMT intervention (eg, primary, secondary, tertiary care)	Treatment was conducted in the private practices of the participating therapists.
2.2	Standardization of the interventions	Treatment period consisted of a total 6 weeks. In the initial 3 weeks, 2 treatments per week were performed, followed by 1 treatment per week for the subsequent 3 weeks. Each treatment session lasted, on average, 30 minutes. Detailed information on the protocol is available at: <a href="http://www.protocol@trial.com">http://www.protocol@trial.com</a> . Manipulations with high velocity were not allowed.
2.3	Description of the frequency of treatment sessions to be modified if the protocol allows	Treatment was left to the discretion of the practitioner, and therapy was discontinued prematurely if recovery, based on predetermined objectives, was achieved or at the desire of the patient. Similarly, therapy could be prolonged beyond that protocolized, if thought to be necessary by the practitioner, in consultation with the patient.
2.4	Criteria for tailoring the interventions to individual participants	Tailoring for individual participants is allowed on the basis of adverse effects of the intervention on the participant.
2.5	Criteria for treatments to be discontinued	The treatment stops when, during the course of the intervention, the participant meets the exclusion criteria of the trial.
2.6	Method of assessment of adherence to the protocol	All protocol deviations were registered by practitioners using standard forms.
<b>3. Description of SMT techniques</b>		
3.1	Direction of force of the technique	Force was directed posterior to anterior.
3.2	Velocity of the technique	High velocity

3.3	Thrust technique	Thrust
3.4	Number of treated motion segments	In the low cervical (C4-C7) and high thoracic (Th1-Th4) spine
3.5	Number of repetitions of the technique	The procedure was repeated until an audible click was heard. The procedure was repeated 6 times for each segment.
3.6	Level of treated motion segments	In the low cervical (C4-C7) and high thoracic (Th1-Th4) spine
3.7	Number of treated regions	In the low cervical (C4-C7) and high thoracic (Th1-Th4) spine
3.8	Patient's position	In the prone position
<b>4. Additional techniques/interventions</b>		
4	Additional techniques/interventions applied to the SMT group	In addition to the manipulative/mobilization treatment, one-on-one, core stability training for 15 minutes, based on an initial individualized assessment, was conducted under supervision, with a warming up; strength exercises for lower back and abdominal muscles with submaximal resistance with slow speed; and after every 10 repetitions, a rest moment and 3 rehearsals, conducted within painless range, followed by stretching and cooling down, all according the protocol of Flippo. <sup>13</sup> In addition, advice on activities of daily living and prevention was given in each session based on individual assessment.
<b>5. Quantitative data</b>		
5.1	Treatment period and the follow-up period	The mean treatment period was 5 weeks (range 2-10 weeks). In total, 40% of the participants, completed treatment within 3 weeks. In 10 participants (12%), deviations from the protocol were registered in terms of content of the treatment. The follow-up period was 6 months.
5.2	Treatment frequency per week/month	On average, 6 treatments were delivered (range 3-10), while proceeded 1 treatment per week.
5.3	Treatment dosage	The mean treatment period was 5 weeks (range 2-10 weeks). On average, 6 treatments were delivered (range 3-10), with a mean treatment time of 30 minutes.
5.4	Number of treatments of the intervention	On average, 6.1 (SD 3.2) treatments were delivered (range 3-10).
5.5	Number of care providers performing the intervention	In total, 11 care providers participated. There was no statistically significant difference between the numbers of treatments delivered per practitioner.

Not included in the CIRCLe SMT checklist (In CONSORT): *Co-intervention usage*. Co-interventions were recorded by daily logbooks, which the participants were asked to maintain.

### Additional Techniques/Interventions

A clear and detailed description of all additional components, whether carried out by the practitioner or the patient, should be reported so that the factors that might be responsible for any change observed are made known. Additional techniques and interventions refer to, for example, exercises, acupuncture, auxiliary techniques, prescribed self-treatment (including medication usage), and (lifestyle) advice provided by the practitioner. These additions should be described in detail so that readers are well informed about the package of treatment. If appropriate, guidelines or recommendations on reporting of interventions or techniques should be followed, such as for exercises<sup>27</sup> or acupuncture.<sup>5</sup>

### Quantitative Data

**Treatment Period and the Follow-up Period.** Both the treatment period and the follow-up period should be clearly described.

**Treatment Frequency per Week or Month.** The frequency of treatment should be accurately described, for example, if participants have been treated twice a week for the first 2 weeks and then once a week for an additional 4 weeks.

**Treatment Dosage.** Therapy dose can be described in terms of time spent in therapy or in terms of effort expended, or both. Description of time includes minutes per session, sessions per day or week, and number of days or weeks.

**Number of Treatments of the Intervention.** The mean and range should be reported if there is variation among the participants. The frequency and duration of sessions should be described, with mean and range if there are differences among the participants.

**Number of Care Providers Performing the Intervention.** To describe the potential clustering of practitioners and centers, which is essential for accurate statistical analyses, the number of care providers for each trial arm should be documented in detail.

An example of reporting SMT using all items of the criteria list is presented in Table 1.

## DISCUSSION

This is the first study to develop a criteria list for the reporting of SMT, which may serve as an extension of the CONSORT Statement. A similar extension exists for nonpharmacologic interventions; however, a list specific to SMT is lacking. This is deemed important for a number of reasons, namely, SMT is not one entity but, rather, represents a broad description of an intervention. A better description of SMT will make it possible for clinicians to better interpret results and determine to what extent this may influence their clinical practice. Such a guideline also makes it possible to better interpret and compare results

across trials. In that regard, our study represents an important step forward; that is, this work, which is based on a Delphi procedure including a large group of representatives throughout the field of SMT, defines a (minimal) criteria list for reporting trials of SMT. In the end, this encompasses 24 items clustered in 5 domains. This effort represents the first guideline for reporting items to be included in trials of SMT. Although designed for RCTs, this guideline can also be used for study designs.

### Items of the Criteria List

Most of the participants were in favor of describing manipulation and mobilization separately. However, at the end of the Delphi procedure, they selected the same items for manipulation as for mobilization.

There was a preference for keeping track of subjective descriptions of items that can have a positive impact on the clinical practice. For example, the intentions of the practitioner should be recorded as well as the actual treatment applied. The description of SMT techniques is supposed to be in a language that is theoretically neutral. The description should only provide information about where and how the force is applied.<sup>9</sup>

Interestingly, no consensus was reached on diagnosis-related items, even though diagnosis is considered the keystone of therapeutic treatment. A potential explanation for this could be the low-to-moderate reliability of current manual diagnostic tests,<sup>28-31</sup> although clinicians feel confident in their conclusions drawn from them.<sup>32,33</sup>

### Recommendations

Authors of clinical trials in the field of manipulation-based therapy and mobilization-based therapy should use the recommendations presented in this report, together with the items from the CONSORT Statement, with the extension for nonpharmaceutical trials. Spinal manipulative therapy is, in general, a complex intervention with a large number of interacting components. For example, the biomechanical parameters in patients may change with the patients' physical characteristics, clinical condition, and clinical progress. Thus, each related item on the list should be described in as detailed a manner as possible.

Journal endorsement of our criteria list is encouraged, as it has been shown that such lists help improve the quality and completeness of reporting in medical journals.<sup>34,35</sup> The authors also encourage "umbrella" organizations (eg, the International Federation of Orthopaedic Manipulative Therapists, the European Chiropractic Union) and national associations related to SMT to endorse the criteria list to facilitate its implementation in clinical practice and educational programs.

The control intervention should be described in as much detail as the SMT intervention, if possible, following the



Enhancing the QUALity and Transparency Of health Research (EQUATOR) guidelines.<sup>36</sup>

Finally, the specified length of articles in scientific journals often do not allow for detailed descriptions of interventions. Therefore, it is recommended that additional information be made available by publishing a separate article, preferably a design article describing the complete protocol, including a detailed description of the intervention. Other opportunities would be using an online appendix or link to a website or a publicly available video.

### Limitations and Strengths

As with any Delphi study, a limitation of our study is that the findings are based only on expert opinion. Although a large number of people participated, the idea that a consensus among a group of experts results in the correct and valid criteria list could be debated. The steering committee also may not have included all relevant experts. The invited participants have a strong focus on SMT research, although the majority of participants are also active in clinical practice. However, the target population (clinicians) may have been underrepresented.

It is important to emphasize that the aim of the CIRCL<sup>e</sup> SMT project was to reach consensus on a criteria list for the description of SMT, so not all participants involved to the Delphi process (fully) agree about the items in the final criteria list, but the criteria list is the result of a “communis opinio.”

The strength of the study is the participation of a large group of experts from various backgrounds, and thus the results are likely to be largely transferable. Importantly, we followed a standard procedure in accordance with the guidance for developers of health research reporting guidelines, so the methodologic quality should be viewed to be good.<sup>12</sup>

### CONCLUSIONS

This is the first effort to develop a criteria list designed to improve the reporting of trials of SMT, and this list should be used in conjunction with the CONSORT Statement and its extension for nonpharmaceutical trials. This initiative represents an important step toward improving the quality of reporting SMT and will help clinicians to interpret the results of trials and effectively apply them to clinical practice.

### FUNDING SOURCES AND CONFLICTS OF INTEREST

No funding sources or conflicts of interest were reported for this study.

### CONTRIBUTORSHIP INFORMATION

Concept development (provided idea for the research): R.G., S.M.R., R.A.B.O., R.W.J.G.O., M.W.v.T.

Design (planned the methods to generate the results): R.G., S.M.R., R.A.B.O., R.W.J.G.O., M.W.v.T.

Supervision (provided oversight, responsible for organization and implementation, writing of the manuscript): R.G., S.M.R., R.A.B.O., R.W.J.G.O., M.W.v.T.

Data collection/processing (responsible for experiments, patient management, organization, or reporting data): R.G., S.M.R., R.A.B.O., R.W.J.G.O., M.W.v.T.

Analysis/interpretation (responsible for statistical analysis, evaluation, and presentation of the results): R.G., S.M.R., R.A.B.O., R.W.J.G.O., M.W.v.T.

Literature search (performed the literature search): R.G., S.M.R., R.A.B.O., R.W.J.G.O., M.W.v.T.

Writing (responsible for writing a substantive part of the manuscript): R.G., S.M.R., R.A.B.O., R.W.J.G.O., M.W.v.T.

Critical review (revised manuscript for intellectual content, this does not relate to spelling and grammar checking): R.G., S.M.R., R.A.B.O., R.W.J.G.O., M.W.v.T.

### Practical Applications

- These guidelines focus on the characteristics of reporting of RCTs of SMT and serve as an extension of the CONSORT Statement.
- Good reporting improves the completeness and transparency of reports, and reporting the specific characteristics of the application of SMT techniques makes it possible to better interpret the outcomes and determine their applicability to clinical practice.
- When endorsed by journals, these guidelines have the potential to improve the reporting of clinical trials of SMT.

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