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# BMJ Open

## Measurement properties of pressure biofeedback unit for the assessment of deep cervical flexor muscles: a systematic review protocol

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4 **MEASUREMENT PROPERTIES OF PRESSURE BIOFEEDBACK UNIT FOR THE**  
5 **ASSESSMENT OF DEEP CERVICAL FLEXOR MUSCLES: A SYSTEMATIC REVIEW**  
6 **PROTOCOL**  
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## ABSTRACT

**Introduction:** Neck pain is the fourth cause of years lived with disability worldwide, and it accounts for high economic and societal burden. Altered activation of the neck muscles is a common musculoskeletal impairment presented by patients with neck pain. The craniocervical flexion test with a pressure biofeedback unit has been widely used in clinical practice to assess the function of deep neck flexor muscles. This systematic review will assess the measurement properties of the pressure biofeedback unit for assessing deep cervical flexor muscles.

**Methods and analysis:** This review will follow the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement. We will systematically search the following databases: MEDLINE (via PubMed), EMBASE, PEDro, Cochrane Central Register of Controlled Trials (CENTRAL), Scopus and Science Direct. Studies of any design that have investigated and reported at least one measurement property of the pressure biofeedback unit for assessing the deep cervical flexor muscles during the craniocervical flexion test will be included. All measurement properties will be considered as outcomes. Two reviewers will independently rate the risk of bias of individual studies using the CONsensus-based Standards for the selection of health Measurement Instruments (COSMIN) checklist. A structured narrative synthesis will be used for data analysis. Quantitative findings for each measurement property will be summarized. The overall rating for a measurement property will be classified as “positive”, “indeterminate”, or “negative”. The overall rating will be accompanied with a level of evidence.

**Ethics and dissemination:** Ethical approval and patient consent are not required since this is a systematic review based on published studies. Findings will be submitted to a peer-reviewed journal for publication.

**Trial registration number:** This protocol has been registered with the International Prospective Register of Systematic Reviews (PROSPERO), registration number (CRD42017062175).

**STRENGTHS AND LIMITATIONS:**

- Comprehensive and exhaustive search for relevant studies from several databases;
- An update of the evidence on measurement properties of a widely used clinical test: the pressure biofeedback unit for the assessment of deep cervical flexor muscles;
- A strength of this review is its use of the internationally recognized and validated COSMIN checklist to assess the methodological quality of the included studies;
- The proposed systematic review will adhere to the PRISMA guidelines, ensuring consistency and uniformity in reporting and the full systematic review.
- A limitation of the review is that it will only include papers published in English.

## INTRODUCTION

Neck pain is the fourth cause of years lived with disability worldwide, and it accounts for high economic and societal burden.<sup>1,2</sup> In the general population, 16.7 to 75.1% of adults will experience an episode of neck pain in any given year.<sup>3,4</sup> Patients may present with recurrent neck pain,<sup>5,6</sup> and the prognosis of recovery is poor.<sup>5</sup> Between 50 and 75% of people who experienced neck pain still present with symptoms one to five years after the onset of these symptoms.<sup>6</sup>

Altered activation of the neck muscles is a common musculoskeletal impairment presented by patients with neck pain.<sup>7</sup> Compared to asymptomatic individuals, patients with chronic neck pain present with: increased activity of superficial neck flexors and reduced activity of the deep neck flexors;<sup>8</sup> poor muscle endurance;<sup>9,10</sup> altered kinematics of the cervical spine;<sup>11</sup> delayed feedforward activity;<sup>12</sup> and impaired proprioception.<sup>13-15</sup> These impairments are likely to contribute to the maintenance of symptoms in patients with chronic neck pain.<sup>16</sup>

As the clinical presentation of patients with neck pain is not homogeneous, clinical assessment of neck muscle function is important for identifying musculoskeletal impairments and tailoring treatment to the patients' needs.<sup>17</sup> Several tests have been designed to evaluate different aspects of neck muscle performance.<sup>18-23</sup> Among those tests, the craniocervical flexion test with the pressure biofeedback unit has been developed to evaluate the ability of an individual to selectively recruit the deep neck flexors (*longus capitis* and *longus colli*) while maintaining low activity levels of the superficial neck flexors (e.g. *sternocleidomastoid*, *anterior scalene*) during an active craniocervical flexion in supine lying.<sup>23</sup> This test has been widely used in clinical practice to assess the function of deep neck flexor muscles.<sup>8,23,24</sup>

To conduct the craniocervical flexion test with pressure biofeedback unit, the patient is positioned in supine crook lying with the head in a neutral starting position, followed by an active head nodding action, during which the patient tries to sequentially target five progressive stages, from 22 to 30 mmHg.<sup>24</sup> This test is performed with an extrinsic air-

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3 filled pressure biofeedback unit placed behind the neck. This device provides feedback  
4 and direction for the patient to perform the test, and enables an objective and  
5 quantitative assessment of the patient performance.<sup>23</sup> Evaluation of the test involves  
6 different components: performance of the craniocervical flexion action (contracting  
7 adequately the deep cervical flexors without compensatory activity of the superficial  
8 flexors), isometric endurance of the deep cervical flexors at test stages that the patient  
9 is able to achieve with the correct craniocervical flexion action, and assessment of the  
10 quality and range of craniocervical rotation in the sagittal plane, which should  
11 proportionally increase as the stages of the test progresses.<sup>8,23</sup>  
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21 Ideally, the measurement properties (e.g. reliability, validity, and responsiveness) of an  
22 instrument or test, for instance the craniocervical flexion test with pressure  
23 biofeedback unit, should be assessed before its full implementation in clinical practice.<sup>25</sup>  
24 Selecting instruments with proper measurement properties is fundamental for well-  
25 conducted clinical trials.<sup>26</sup> Hence, systematic reviews of measurement properties are  
26 useful for identifying instruments and tools with the highest reliability, validity and  
27 responsiveness scores.<sup>27</sup>  
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35 A previous systematic review<sup>28</sup> evaluated the measurement properties of methods to  
36 measure muscle function in patients with non-specific neck pain. In this review, the  
37 intra-observer reliability was the only measurement property assessed.<sup>28</sup> This review  
38 was conducted over 10 years ago, included only four studies, and used a checklist  
39 adapted from two previous studies.<sup>29,30</sup> Since then, the number of published studies  
40 evaluating measurement properties of craniocervical flexion test has increased. In  
41 addition, new tools have been developed for assessing the methodological quality of  
42 individual studies exploring the measurement properties of instruments (i.e.  
43 Consensus-based Standards for the selection of health Measurement Instruments –  
44 COSMIN).<sup>25</sup> It is likely that a new review evaluating the measurement properties of the  
45 craniocervical flexion test with pressure biofeedback unit will provide relevant insights  
46 into the state of research in this field. This systematic review will assess the  
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3 measurement properties of the pressure biofeedback unit for assessing deep cervical  
4 flexor muscles.  
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## 10 **METHODS**

### 11 **Protocol and Registration**

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14 This protocol was reported in accordance with the Preferred Reporting Items for  
15 Systematic Reviews and Meta-Analyses Protocols (PRISMA-P).<sup>31</sup> The systematic review  
16 has been registered with PROSPERO (CRD42017062175).  
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### 22 **Eligibility criteria**

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24 We will include studies if they meet the following criteria:

- 25 - Studies of any design (e.g. Cross-sectional studies or randomized clinical trials);
- 26 - Articles that have investigated and reported at least one measurement property
- 27 (i.e. validity, reliability or responsiveness) of the pressure biofeedback unit for
- 28 assessing the deep cervical flexor muscles during the craniocervical flexion test;
- 29 - Articles published in English;
- 30 - Assessing participants older than 18 years old;
- 31 - Articles available in full text;
- 32 - Studies with both asymptomatic and symptomatic individuals (including those
- 33 with acute, subacute and chronic neck pain with or without nerve root
- 34 compromise; neck-related shoulder pain; whiplash-associated disorders; and
- 35 neck disorders associated with headache).
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48 Studies assessing only the effectiveness of interventions, but not reporting  
49 measurement property outcomes of pressure biofeedback unit for assessing motor  
50 control of deep cervical flexor muscles will be excluded.  
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## Outcomes

All measurement properties will be considered as outcomes in this systematic review. We will adopt the COSMIN terminology and definitions of measurement properties.<sup>32</sup> Reliability is defined as the extent to which scores for patients who have not changed are the same for repeated measurement under several conditions; validity is the degree to which an outcome instrument measures the construct(s) it purports to measure; and responsiveness is the ability of an outcome instrument to detect change over time in the construct to be measured.<sup>32</sup> Among these properties, reliability and validity are further subdivided. For example, reliability is further classified into reliability, internal consistency and measurement error; validity comprises content validity, construct validity and criterion validity.<sup>32</sup> For the purposes of this review, we will include all outcome measures used in assessing psychometric properties reported by included studies.

## Search strategy

The search strategy was designed through consultation with a health sciences faculty librarian. Our search will include the following databases: MEDLINE (via PubMed), EMBASE, PEDro, Cochrane Central Register of Controlled Trials (CENTRAL), Scopus and Science Direct. All databases will be searched from their inception to present time using a published search filter for finding studies on measurement properties.<sup>33</sup> MEDLINE full-search strategy is described in Table 1.

## Data extraction

Two reviewers (FXA and MSS) will independently screen titles and abstracts for eligibility. A third reviewer (MPC) will resolve any disagreement. The full text of potentially eligible articles will be screened independently by two reviewers (FXA and MSS). Data from included studies will be extracted independently by the two reviewers, using a piloted data collection form. Data will then be compared for accuracy, and disagreements will be solved by consensus. The following information will be extracted from the included studies: study design, sample characteristics, measurement

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3 properties (e.g. validity, reliability or responsiveness) assessed by included studies, and  
4 results of the measurements' properties.  
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### 8 9 **Risk of bias within included studies**

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11 Two reviewers (FXA and GEF) will independently rate the risk of bias of individual  
12 studies using the COSMIN checklist.<sup>25</sup> The COSMIN checklist is a validated critical  
13 appraisal tool designed for the systematic evaluation of the methodological quality of  
14 studies on the measurement properties.<sup>27</sup> The checklist consists of nine domains  
15 concerning measurement properties. The number of items for each domain varies from  
16 5 to 18. Each item deals with design characteristics and statistical methods used and  
17 reported by authors. Each item will be scored based on a four-point rating scale as  
18 "excellent", "good", "fair", or "poor". The lowest rating score of a domain will be used for  
19 attributing the quality score for that specific domain. For each study, only applicable  
20 domains to the study being assessed will be used for assessing the quality of the study.  
21 Disagreements between reviewers will be resolved by a third reviewer (MPC).  
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### 32 **Synthesis of results**

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34 A structured narrative synthesis will be used for data analysis. Quantitative findings for  
35 each measurement property will be summarized. The overall rating for a measurement  
36 property will be classified as "positive", "indeterminate", or "negative". The overall  
37 rating will be accompanied with a level of evidence (strong, moderate, limited,  
38 conflicting, unknown – Table 2) as proposed by Terwee et al.<sup>34</sup> The criteria used to  
39 assign levels of evidence for the quality of each measurement property will follow the  
40 framework proposed by the Cochrane Back and Neck Review Group.<sup>35</sup>  
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49 We will conduct a narrative synthesis of subgroups, if applicable, based on the sample  
50 characteristics (i.e. asymptomatic or symptomatic), and type of disorder (e.g. acute,  
51 subacute and chronic non-specific neck pain; acute, subacute and chronic neck pain  
52 with nerve root compromise; neck-related shoulder pain; whiplash-associated  
53 disorders; and neck disorder associated with headache).  
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## ETHICS AND DISSEMINATION

Ethical approval and patient consent are not required since this is a systematic review based on published studies. This protocol has been registered on the international PROSPERO and the systematic review will be conducted according to the PRISMA statement. The results of this systematic review will be submitted to a peer-reviewed journal for publication and may be presented at national and international meetings.

## AUTHORS' CONTRIBUTIONS

FXA is the leading researcher, responsible for conceiving the study, and designing the protocol. All authors have contributed to the conception and design of the study protocol, development of the search strategy, the establishment of the inclusion and exclusion criteria, data extraction criteria, analyses and interpretation. FXA and MSS will screen title, abstracts and full text for eligibility. MSS and GEF will extract data. FXA GEF will rate the methodological quality of individual studies. MPC will resolve any disagreement between reviewers. GEF and MSS will provide the statistical analysis plan of the study and will conduct the data analysis. FXA, MSS, GEF will write the first version of the paper. MPC, DCR and MFS will provide critical revision of the paper. All authors read and approved this protocol for publication.

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**COMPETING INTEREST**

None declared.

For peer review only

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TABLE 1. Search strategy in MEDLINE (via Pubmed).

1#	((((( (patient outcome assessment [Mesh]) OR ((outcome and process assessment [Mesh]))) OR treatment outcome [Mesh] OR instrumentation[sh] OR methods[sh] OR "Validation Studies"[pt] OR "Comparative Study"[pt] OR "psychometrics"[MeSH] OR psychometr*[tiab] OR clinimetr*[tw] OR clinometr*[tw] OR "outcome assessment (health care)"[MeSH] OR "outcome assessment"[tiab] OR "outcome measure*" [tw] OR "observer variation"[MeSH] OR "observer variation"[tiab] OR "Health Status Indicators"[Mesh] OR "reproducibility of results"[MeSH] OR reproducib*[tiab] OR "discriminant analysis"[MeSH] OR reliab*[tiab] OR unreliab*[tiab] OR valid*[tiab] OR "coefficient of variation"[tiab] OR coefficient[tiab] OR homogeneity[tiab] OR homogeneous[tiab] OR "internal consistency"[tiab] OR (cronbach*[tiab] AND (alpha[tiab] OR alphas[tiab])) OR (item[tiab] AND (correlation*[tiab] OR selection*[tiab] OR reduction*[tiab])) OR agreement[tw] OR precision[tw] OR imprecision[tw] OR "precise values"[tw] OR test-retest[tiab] OR (test[tiab] AND retest[tiab]) OR (reliab*[tiab] AND (test[tiab] OR retest[tiab])) OR stability[tiab] OR interrater[tiab] OR inter-rater[tiab] OR intrarater[tiab] OR intra-rater[tiab] OR intertester[tiab] OR inter-tester[tiab] OR intratester[tiab] OR intra-tester[tiab] OR interobserver[tiab] OR inter-observer[tiab] OR intraobserver[tiab] OR intra-observer[tiab] OR intertechnician[tiab] OR inter-technician[tiab] OR intratechnician[tiab] OR intra-technician[tiab] OR interexaminer[tiab] OR inter-examiner[tiab] OR intraexaminer[tiab] OR intra-examiner[tiab] OR interassay[tiab] OR inter-assay[tiab] OR intraassay[tiab] OR intra-assay[tiab] OR interindividual[tiab] OR inter-individual[tiab] OR intraindividual[tiab] OR intra-individual[tiab] OR interparticipant[tiab] OR inter-participant[tiab] OR intraparticipant[tiab] OR intra-participant[tiab] OR kappa[tiab] OR kappa's[tiab] OR kappas[tiab] OR repeatab*[tw] OR ((replicab*[tw] OR repeated[tw]) AND (measure[tw] OR measures[tw] OR findings[tw] OR result[tw] OR results[tw] OR test[tw] OR tests[tw])) OR generaliza*[tiab] OR generalisa*[tiab] OR concordance[tiab] OR (intraclass[tiab] AND correlation*[tiab]) OR discriminative[tiab] OR "known group"[tiab] OR "factor analysis"[tiab] OR "factor analyses"[tiab] OR "factor structure"[tiab] OR "factor structures"[tiab] OR dimension*[tiab] OR subscale*[tiab] OR (multitrait[tiab] AND scaling[tiab] AND (analysis[tiab] OR analyses[tiab])) OR "item discriminant"[tiab] OR "interscale correlation*" [tiab] OR error[tiab] OR errors[tiab] OR "individual variability"[tiab] OR "interval variability"[tiab] OR "rate variability"[tiab] OR (variability[tiab] AND (analysis[tiab] OR values[tiab])) OR (uncertainty[tiab] AND (measurement[tiab] OR measuring[tiab])) OR "standard error of measurement"[tiab] OR sensitiv*[tiab] OR responsive*[tiab] OR (limit[tiab] AND detection[tiab]) OR "minimal detectable concentration"[tiab] OR interpretab*[tiab] OR ((minimal[tiab] OR minimally[tiab] OR clinical[tiab] OR clinically[tiab]) AND (important[tiab] OR significant[tiab] OR detectable[tiab]) AND (change[tiab] OR difference[tiab])) OR (small*[tiab] AND (real[tiab] OR detectable[tiab]) AND (change[tiab] OR difference[tiab])) OR "meaningful change"[tiab] OR "ceiling effect"[tiab] OR "floor effect"[tiab] OR "Item response model"[tiab] OR IRT[tiab] OR Rasch[tiab] OR "Differential item functioning"[tiab] OR DIF[tiab] OR "computer adaptive testing"[tiab] OR "item bank"[tiab] OR "cross-cultural equivalence"[tiab] ) ) ) ) )
2#	((((( (pressure biofeedback unit[Title/Abstract] OR pressure biofeedback units[Title/Abstract] OR unit, pressure biofeedback[Title/Abstract] OR units, pressure biofeedback[Title/Abstract] OR stabilizer[Title/Abstract] OR stabilizers[Title/Abstract] OR stabiliser[Title/Abstract] OR stabilisers[Title/Abstract] OR biofeedback[Title/Abstract] OR biofeedbacks[Title/Abstract] OR craniocervical flexion test[Title/Abstract] OR cranio-cervical flexion test[Title/Abstract] OR cranio cervical flexion test[Title/Abstract] ) ) ) ) )
3#	((((( (Muscle, Neck[Title/Abstract] OR Muscles, Neck[Title/Abstract] OR Neck muscle[Title/Abstract] ) ) ) OR Neck muscles[MeSH Terms] ) ) OR ( ( neck[MeSH Terms] ) OR Necks[Title/Abstract] OR deep cervical flexor*[Title/Abstract] OR rectus capit*[Title/Abstract] OR longus colli[Title/Abstract] OR longus capiti [Title/Abstract] ) )
4#	1# AND 2# AND 3#



TABLE 2. Quality criteria for measurement properties.

Property	Rating	Quality criteria
<b>Reliability</b>		
Internal consistency	+	Cronbach's alpha(s) $\geq 0.70$
	?	Cronbach's alpha not determined or unidimensionality unknown
	-	Cronbach's alpha(s) $< 0.70$
Reliability	+	ICC/ weighted Kappa $\geq 0.70$ OR Pearson's r $\geq 0.80$
	?	Neither ICC / weighted Kappa, nor Pearson's r determined
	-	ICC / weighted Kappa $< 0.70$ OR Pearson's r $< 0.80$
Measurement error	+	MIC $>$ SDC OR MIC outside the LoA
	?	MIC not defined
	-	MIC $\leq$ SDC OR MIC equals or inside LoA
<b>Validity</b>		
Content validity	+	All items are considered to be relevant for the construct to be measured, for the target population, and for the purpose of the measurement AND the questionnaire is considered to be comprehensive
	?	Not enough information available
	-	Not all items are considered to be relevant for the construct to be measured, for the target population, and for the purpose of the measurement OR the questionnaire is considered not to be comprehensive
Construct validity – Structural validity	+	Factors should explain at least 50% of the variance
	?	Explained variance not mentioned
	-	Factors explain $< 50\%$ of the variance
- Hypothesis testing	+	Correlations with instruments measuring the same construct $\geq 0.50$ OR at least 75% of the results are in accordance with the hypotheses AND correlations with related constructs are higher than with unrelated constructs
	?	Solely correlations determined with unrelated constructs
	-	Correlations with instruments measuring the same construct $< 0.50$ OR $< 75\%$ of the results are in accordance with the hypotheses OR correlations with related constructs are lower than with unrelated constructs
- Cross-cultural validity	+	No differences in factor structure OR no important DIF between language versions
	?	Multiple group factor analysis not applied AND DIF not assessed
	-	Differences in factor structure OR important DIF between language versions
- Criterion validity	+	Convincing arguments that gold standard is "gold" AND correlation with gold standard $\geq 0.70$
	?	No convincing arguments that gold standard is "gold"
	-	Correlation with gold standard $< 0.70$
<b>Responsiveness</b>		
Responsiveness	+	Correlation with changes on instruments measuring the same construct $\geq 0.50$ OR at least 75% of the results are in accordance with the hypotheses OR AUC $\geq 0.70$ AND correlations with changes in related constructs are higher than with unrelated constructs
	?	Solely correlations determined with unrelated constructs
	-	Correlations with changes on instruments measuring the same construct $< 0.50$ OR $< 75\%$ of the results are in accordance with the hypotheses OR AUC $< 0.70$ OR correlations with changes in related constructs are lower than with unrelated constructs

Legend: MIC, minimal important change; SDC, smallest detectable change; LoA, limits of agreement; ICC, intraclass correlation coefficient; DIF, differential item functioning; AUC, area under the curve; +, positive rating

TABLE 3. Levels of evidence for the quality of the measurement property.

Level	Rating	Criteria
Strong	+++ or ---	Consistent findings in multiple studies of good methodological quality OR in one study of excellent methodological quality
Moderate	++ or --	Consistent findings in multiple studies of fair methodological quality OR in one study of good methodological quality
Limited	+ or -	One study of fair methodological quality
Conflicting	+/-	Conflicting findings
Unknown	?	Only studies of poor methodological quality

Legends: +, positive rating; -, negative rating; ?, indeterminate rating

For peer review only

**PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol\***

Section and topic	Item No	Checklist item	Page number
<b>ADMINISTRATIVE INFORMATION</b>			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	NA
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	9
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	NA
Support:			
Sources	5a	Indicate sources of financial or other support for the review	
Sponsor	5b	Provide name for the review funder and/or sponsor	NA
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	
<b>INTRODUCTION</b>			
Rationale	6	Describe the rationale for the review in the context of what is already known	4, 5
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	5
<b>METHODS</b>			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting,	6

		time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	6
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	6
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	7
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	7
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	7
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	6, 7
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	6, 7
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	8
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	8
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as $I^2$ , Kendall's $\tau$ )	8
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	8
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	8
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication	NA

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		bias across studies, selective reporting within studies)	
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	NA

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**\* It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

*From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.*

# BMJ Open

## Measurement properties of the craniocervical flexion test: a systematic review protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-019486.R1
Article Type:	Protocol
Date Submitted by the Author:	05-Dec-2017
Complete List of Authors:	Araujo, Francisco Ferreira, Giovanni ; Universidade Federal de Ciencias da Saude de Porto Alegre, Physical Therapy Department Scholl Schell, Maurício ; Universidade Federal de Ciencias da Saude de Porto Alegre Castro, Marcelo; Neuromusculoskeletal Assessment and Clinical Biomechanics Laboratory (LaBClin) Silva, Marcelo; Universidade Federal de Ciencias da Saude de Porto Alegre, Physical Therapy Department Ribeiro, Daniel; School of Physiotherapy
<b>Primary Subject Heading</b>:	Rehabilitation medicine
Secondary Subject Heading:	Occupational and environmental medicine
Keywords:	Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY, REHABILITATION MEDICINE, SPORTS MEDICINE

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Manuscripts

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3 **Measurement properties of the craniocervical flexion test: a systematic**  
4 **review protocol**  
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**ABSTRACT:**

**Introduction:** Neck pain is the first cause of years lived with disability worldwide, and it accounts for high economic and societal burden. Altered activation of the neck muscles is a common musculoskeletal impairment presented by patients with neck pain. The craniocervical flexion test with pressure biofeedback unit has been widely used in clinical practice to assess function of deep neck flexor muscles. This systematic review will assess the measurement properties of the craniocervical flexion test for assessing deep cervical flexor muscles.

**Methods and analysis:** This is a protocol for a systematic review that will follow the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement. MEDLINE (via PubMed), EMBASE, PEDro, Cochrane Central Register of Controlled Trials (CENTRAL), Scopus and Science Direct will be systematically searched from inception. Studies of any design that have investigated and reported at least one measurement property of the craniocervical flexion test for assessing the deep cervical flexor muscles will be included. All measurement properties will be considered as outcomes. Two reviewers will independently rate the risk of bias of individual studies using the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) checklist. A structured narrative synthesis will be used for data analysis. Quantitative findings for each measurement property will be summarized. The overall rating for a measurement property will be classified as “positive”, “indeterminate”, or “negative”. The overall rating will be accompanied with a level of evidence.

**Ethics and dissemination:** Ethical approval and patient consent are not required since this is a systematic review based on published studies. Findings will be submitted to a peer-reviewed journal for publication.

**Trial registration number:** This protocol has been registered with the International Prospective Register of Systematic Reviews (PROSPERO), registration number (CRD42017062175).



**STRENGTHS AND LIMITATIONS:**

- Comprehensive and exhaustive search for relevant studies from several databases;
- A new summary of the evidence on measurement properties of a widely used clinical test: the craniocervical flexion test with the pressure biofeedback unit for the assessment of deep cervical flexor muscles;
- This review used the internationally recognized, validated COSMIN checklist to assess the methodological quality of the included studies when assessing the quality of the craniocervical flexion test;
- The proposed systematic review will adhere to the PRISMA guidelines, ensuring consistency and uniformity in reporting and the full systematic review;
- A limitation of the review is that it will only include papers published in English.

## 1. INTRODUCTION:

Neck pain is the first cause of years lived with disability worldwide, and it accounts for high economic and societal burden.<sup>1,2</sup> In the general population, 16.7 to 75.1% of adults will develop an episode of neck pain in any given year.<sup>3,4</sup> Patients may present recurrent neck pain,<sup>5,6</sup> and the prognosis of recovery is poor.<sup>5</sup> Between 50 and 75% of people who experienced neck pain still present with symptoms one to five years after onset of symptoms.<sup>6</sup>

Altered activation of the neck muscles is a common musculoskeletal impairment presented by patients with neck pain.<sup>7</sup> Compared to asymptomatic individuals, patients with neck pain exhibit increased activity of superficial neck flexors and reduced activity of the deep neck flexors;<sup>8</sup> poor muscle endurance;<sup>9,10</sup> altered kinematics of the cervical spine;<sup>11</sup> delayed feedforward activity;<sup>12</sup> and impaired proprioception.<sup>13-15</sup> These impairments are likely to contribute to maintenance of symptoms in patients with chronic neck pain.<sup>16</sup>

As the clinical presentation of patients with neck pain are not homogeneous, clinical assessment of neck muscle function is important for identifying musculoskeletal impairments and tailoring treatment to patients' needs.<sup>17</sup> Several tests have been designed to evaluate different aspects of neck muscle performance.<sup>18-23</sup> Among those tests, the craniocervical flexion test with pressure biofeedback unit has been developed to evaluate the ability of an individual to selectively recruit the deep neck flexors (*longus capitis* and *longus colli*) while maintaining low activity levels of the superficial neck flexors (e.g. *sternocleidomastoid*, *anterior scalene*) during an active craniocervical flexion in supine lying.<sup>23</sup> This test has been widely used in clinical practice to assess function of deep neck flexor muscles.<sup>8,23,24</sup>

To conduct the craniocervical flexion test with pressure biofeedback unit, the patient's head is positioned in neutral, with patient in supine crook lying. The test consists of an active head nodding movement. During this movement, the patient attempts to target five different pressure levels, from 22 to 30 mmHg.<sup>24</sup> This test is performed with an extrinsic air-filled pressure biofeedback unit placed

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3 behind the neck. This device provides feedback and direction for the patient to  
4 perform the test, and enables an objective and quantitative assessment of the  
5 patient performance.<sup>23</sup> The performance of the test is assessed through the  
6 following components: how well the patient performs the active head nodding and  
7 achieves that by contracting the deep cervical flexors without contraction of  
8 superficial flexors), muscle endurance (through isometric contraction) of deep  
9 cervical flexors at each test stages with appropriate craniocervical flexion  
10 contraction, and quality and range of craniocervical movement in the sagittal plane  
11 (which is expected to increase as the patient progress through the five different  
12 pressure levels).<sup>8,23</sup>  
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21 Ideally, the measurement properties (e.g. reliability, validity, and  
22 responsiveness) of an instrument or test, for instance the craniocervical flexion  
23 test with pressure biofeedback unit, should be assessed before its full  
24 implementation in clinical practice.<sup>25</sup> Selecting instruments with proper  
25 measurement properties is fundamental for well-conducted clinical trials.<sup>26</sup> Hence,  
26 systematic reviews of measurement properties are useful for identifying  
27 instruments and tools with the highest reliability, validity and responsiveness  
28 scores.<sup>27</sup>  
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36 A previous systematic review<sup>28</sup> evaluated the measurement properties of  
37 methods to measure muscle function in patients with non-specific neck pain. In  
38 this review, the intra-observer reliability was the only measurement property  
39 assessed.<sup>28</sup> This review was conducted over 10 years ago, included only four  
40 studies and used a checklist adapted from two previous studies.<sup>29,30</sup> Since then, the  
41 number of published studies evaluating measurement properties of craniocervical  
42 flexion test has increased. In addition, new tools have been developed for assessing  
43 methodological quality of individual studies exploring measurement properties of  
44 instruments (i.e. Consensus-based Standards for the selection of health  
45 Measurement Instruments – COSMIN).<sup>25</sup> It is likely that a new review evaluating  
46 the measurement properties of the craniocervical flexion test with pressure  
47 biofeedback unit will provide relevant insights on the state of research in this field.  
48 This systematic review will critically appraise and summarize the quality of the  
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3 measurement properties of the craniocervical flexion test for assessing deep  
4 cervical flexor muscles.  
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## 7 8 **2. METHODS:**

### 9 10 **2.1. Protocol and Registration**

11 This is a protocol for a systematic review that was reported in accordance  
12 with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses  
13 Protocols (PRISMA-P).<sup>31</sup> The systematic review has been registered with  
14 PROSPERO (CRD42017062175).  
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### 18 19 **2.2. Eligibility criteria**

20 We will include studies if they meet the following criteria:  
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- 22 - Studies of any design (e.g. Cross-sectional studies or randomized clinical  
23 trials);
- 24 - Articles that have investigated and reported at least one measurement  
25 property (i.e. validity, reliability or responsiveness) of the craniocervical  
26 flexion test for assessing the deep cervical flexor muscles;
- 27 - Articles published in English;
- 28 - Assessing participants older than 18 years old;
- 29 - Articles available in full text;
- 30 - Studies with both asymptomatic and symptomatic individuals (including  
31 those with acute, subacute and chronic neck pain with or without nerve  
32 root compromise; neck-related shoulder pain, whiplash-associated  
33 disorders and neck disorders associated with headache).  
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44 Studies assessing only the effectiveness of interventions, but not reporting  
45 measurement property outcomes of pressure biofeedback unit for assessing motor  
46 control of deep cervical flexor muscles will be excluded.  
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### 51 52 **2.3. Outcomes**

53 All measurement properties will be considered as outcomes in this  
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3 systematic review. We will adopt the COSMIN terminology and definitions of  
4 measurement properties.<sup>32</sup> Reliability is defined as the extent to which scores for  
5 patients who have not changed are the same for repeated measurement under  
6 several conditions; validity is the degree to which an outcome instrument  
7 measures the construct(s) it purports to measure; and responsiveness is the ability  
8 of an outcome instrument to detect change over time in the construct to be  
9 measured.<sup>32</sup> Among these properties, reliability and validity are further  
10 subdivided. For example, reliability is further classified into reliability, internal  
11 consistency and measurement error; validity comprises content validity, construct  
12 validity and criterion validity.<sup>32</sup> For the purposes of this review, we will include all  
13 outcome measures used assessing psychometric properties that are reported by  
14 included studies.  
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#### 26 **2.4. Search strategy**

27 The search strategy was designed through consultation with a health  
28 sciences faculty librarian. Our search will include the following databases:  
29 MEDLINE (via PubMed), EMBASE, PEDro, Cochrane Central Register of Controlled  
30 Trials (CENTRAL), Scopus and Science Direct. All databases will be searched from  
31 their inception to present time using a published search filter for finding studies on  
32 measurement properties.<sup>33</sup> MEDLINE full-search strategy is described in Table 1.  
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#### 41 **2.5. Data extraction**

42 Two reviewers (FXA and MSS) will independently screen titles and  
43 abstracts for eligibility. A third reviewer (MPC) will resolve any disagreement. The  
44 full text of potentially eligible articles will be screened independently by two  
45 reviewers (FXA and MSS). Data from included studies will be extracted  
46 independently by the two reviewers, using a piloted data collection form. Data will  
47 then be compared for accuracy, and disagreements will be solved by consensus.  
48 The following information will be extracted from the included studies: study  
49 design, sample characteristics, measurement properties (e.g. validity, reliability or  
50 responsiveness) assessed by included studies, craniocervical flexion test  
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3 procedures and results of the measurements properties.  
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## 8 **2.6 Risk of bias within included studies**

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10 Two reviewers (FXA and GEF) will independently rate the risk of bias of  
11 individual studies using the COSMIN checklist.<sup>25</sup> The COSMIN checklist is a  
12 validated critical appraisal tool designed for the systematic evaluation of the  
13 methodological quality of studies on the measurement properties.<sup>27</sup> The checklist  
14 consists of nine domains concerning measurement properties. The number of  
15 items for each domain varies from 5 to 18. Each item deals with design  
16 characteristics and statistical methods used and reported by authors. Each item  
17 will be scored based on a four-point rating scale as "excellent", "good", "fair", or  
18 "poor". The lowest rating score of a domain will be used for attributing the quality  
19 score for that specific domain. For each study, only applicable domains to the study  
20 being assessed will be used for assessing the quality of the study. Disagreements  
21 between reviewers will be resolved by a third reviewer (MPC).  
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## 33 **2.7 Synthesis of results:**

34 A structured narrative synthesis will be used for data analysis. Quantitative  
35 findings for each measurement property will be summarized. The overall rating for  
36 a measurement property will be classified as "positive", "indeterminate", or  
37 "negative". The overall rating will be accompanied with a level of evidence (strong,  
38 moderate, limited, conflicting, unknown – Table 2) as proposed by Terwee et al.<sup>34</sup>  
39 The criteria used to assign levels of evidence for the quality (Table 3) of each  
40 measurement property will follow the framework proposed by the Cochrane Back  
41 and Neck Review Group.<sup>35</sup>  
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Table 3

We will conduct a narrative synthesis of subgroups, if applicable, based on the sample characteristics (i.e. asymptomatic or symptomatic), and type of disorder (e.g. acute, subacute and chronic non-specific neck pain; acute, subacute

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3 and chronic neck pain with nerve root compromise; neck-related shoulder pain;  
4 whiplash-associated disorders; and neck disorder associated with headache).  
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### 10 **3. ETHICS AND DISSEMINATION:**

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12 Ethical approval and patient consent are not required since this is a  
13 systematic review based on published studies. This protocol has been registered  
14 on the international PROSPERO and the systematic review will be conducted  
15 according to the PRISMA statement. The results of this systematic review will be  
16 submitted to a peer-reviewed journal for publication and will be also possibly  
17 presented at national and international meetings.  
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26 **Authors' contributions:** FXA is the leading researcher, responsible for conceiving  
27 the study, and designing the protocol. All authors have contributed to the  
28 conception and design of the study protocol, development of the search strategy,  
29 the establishment of the inclusion and exclusion criteria, data extraction criteria,  
30 analyses and interpretation. FXA and MSS will screen title, abstracts and full text  
31 for eligibility. MSS and GEF will extract data. FXA and GEF will rate the  
32 methodological quality of individual studies. MPC will will resolve any  
33 disagreement between reviewers. GEF and MSS will provide the statistical analysis  
34 plan of the study and will conduct the data analysis. FXA, MSS, GEF will write the  
35 first version of the paper. MPC, DCR and MFS will provide critical revision of the  
36 paper. All authors read and provided final approval of this protocol to be  
37 published.  
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51 are supported by a scholarship from Coordenação de Aperfeiçoamento de Pessoal  
52 de Nível Superior (CAPES – Brazil). However, CAPES is not involved in any other  
53 aspect of this study protocol.  
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5 **Competing interest:** None declared.  
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For peer review only



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TABLE 1. Search strategy in MEDLINE (via Pubmed).

1#	( ( ( ( ( (patient outcome assessment [Mesh]) OR ((outcome and process assessment [Mesh]))) OR treatment outcome [Mesh] OR instrumentation[sh] OR methods[sh] OR "Validation Studies"[pt] OR "Comparative Study"[pt] OR "psychometrics"[MeSH] OR psychometr*[tiab] OR clinimetr*[tw] OR clinometr*[tw] OR "outcome assessment (health care)"[MeSH] OR "outcome assessment"[tiab] OR "outcome measure*" [tw] OR "observer variation"[MeSH] OR "observer variation"[tiab] OR "Health Status Indicators"[Mesh] OR "reproducibility of results"[MeSH] OR reproducib*[tiab] OR "discriminant analysis"[MeSH] OR reliab*[tiab] OR unreliab*[tiab] OR valid*[tiab] OR "coefficient of variation"[tiab] OR coefficient[tiab] OR homogeneity[tiab] OR homogeneous[tiab] OR "internal consistency"[tiab] OR (cronbach*[tiab] AND (alpha[tiab] OR alphas[tiab])) OR (item[tiab] AND (correlation*[tiab] OR selection*[tiab] OR reduction*[tiab])) OR agreement[tw] OR precision[tw] OR imprecision[tw] OR "precise values"[tw] OR test-retest[tiab] OR (test[tiab] AND retest[tiab]) OR (reliab*[tiab] AND (test[tiab] OR retest[tiab])) OR stability[tiab] OR interrater[tiab] OR inter-rater[tiab] OR intrarater[tiab] OR intra-rater[tiab] OR intertester[tiab] OR inter-tester[tiab] OR intratester[tiab] OR intra-tester[tiab] OR interobserver[tiab] OR inter-observer[tiab] OR intraobserver[tiab] OR intra-observer[tiab] OR intertechnician[tiab] OR inter-technician[tiab] OR intratechnician[tiab] OR intra-technician[tiab] OR interexaminer[tiab] OR inter-examiner[tiab] OR intraexaminer[tiab] OR intra-examiner[tiab] OR interassay[tiab] OR inter-assay[tiab] OR intraassay[tiab] OR intra-assay[tiab] OR interindividual[tiab] OR inter-individual[tiab] OR intraindividual[tiab] OR intra-individual[tiab] OR interparticipant[tiab] OR inter-participant[tiab] OR intraparticipant[tiab] OR intra-participant[tiab] OR kappa[tiab] OR kappa's[tiab] OR kappas[tiab] OR repeatab*[tw] OR ((replicab*[tw] OR repeated[tw]) AND (measure[tw] OR measures[tw] OR findings[tw] OR result[tw] OR results[tw] OR test[tw] OR tests[tw])) OR generaliza*[tiab] OR generalisa*[tiab] OR concordance[tiab] OR (intraclass[tiab] AND correlation*[tiab]) OR discriminative[tiab] OR "known group"[tiab] OR "factor analysis"[tiab] OR "factor analyses"[tiab] OR "factor structure"[tiab] OR "factor structures"[tiab] OR dimension*[tiab] OR subscale*[tiab] OR (multitrait[tiab] AND scaling[tiab] AND (analysis[tiab] OR analyses[tiab])) OR "item discriminant"[tiab] OR "interscale correlation*" [tiab] OR error[tiab] OR errors[tiab] OR "individual variability"[tiab] OR "interval variability"[tiab] OR "rate variability"[tiab] OR (variability[tiab] AND (analysis[tiab] OR values[tiab])) OR (uncertainty[tiab] AND (measurement[tiab] OR measuring[tiab])) OR "standard error of measurement"[tiab] OR sensitiv*[tiab] OR responsive*[tiab] OR (limit[tiab] AND detection[tiab]) OR "minimal detectable concentration"[tiab] OR interpretab*[tiab] OR ((minimal[tiab] OR minimally[tiab] OR clinical[tiab] OR clinically[tiab]) AND (important[tiab] OR significant[tiab] OR detectable[tiab]) AND (change[tiab] OR difference[tiab])) OR (small*[tiab] AND (real[tiab] OR detectable[tiab]) AND (change[tiab] OR difference[tiab])) OR "meaningful change"[tiab] OR "ceiling effect"[tiab] OR
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	"floor effect"[tiab] OR "Item response model"[tiab] OR IRT[tiab] OR Rasch[tiab] OR "Differential item functioning"[tiab] OR DIF[tiab] OR "computer adaptive testing"[tiab] OR "item bank"[tiab] OR "cross-cultural equivalence"[tiab] ) ) ) )
2#	(( (( ( pressure biofeedback unit[Title/Abstract] OR pressure biofeedback units[Title/Abstract] OR unit, pressure biofeedback[Title/Abstract] OR units, pressure biofeedback[Title/Abstract] OR stabilizer[Title/Abstract] OR stabilizers[Title/Abstract] OR stabiliser[Title/Abstract] OR stabilisers[Title/Abstract] OR biofeedback[Title/Abstract] OR biofeedbacks[Title/Abstract] OR craniocervical flexion test[Title/Abstract] OR crano-cervical flexion test[Title/Abstract] OR crano cervical flexion test[Title/Abstract] OR crano cervical flexion[Title/Abstract] ) ) ) )
3#	(( (( ( ( Muscle, Neck[Title/Abstract] OR Muscles, Neck[Title/Abstract] OR Neck muscle[Title/Abstract] ) ) ) OR Neck muscles[MeSH Terms] ) ) ) OR ( ( neck[MeSH Terms] ) OR Necks[Title/Abstract] OR deep cervical flexor*[Title/Abstract] OR rectus capit*[Title/Abstract] OR longus colli[Title/Abstract] OR longus capiti [Title/Abstract] ) ) )
4#	1# AND 2# AND 3#

TABLE 2. Quality criteria for measurement properties.

Property	Rating	Quality criteria
Reliability		
Internal consistency	+	Cronbach's alpha(s) $\geq 0.70$
	?	Cronbach's alpha not determined or unidimensionality unknown
	-	Cronbach's alpha(s) $< 0.70$
Reliability	+	ICC/ weighted Kappa $\geq 0.70$ OR Pearson's r $\geq 0.80$
	?	Neither ICC / weighted Kappa, nor Pearson's r determined
	-	ICC / weighted Kappa $< 0.70$ OR Pearson's r $< 0.80$
Measurement error	+	MIC $>$ SDC OR MIC outside the LoA
	?	MIC not defined
	-	MIC $\leq$ SDC OR MIC equals or inside LoA
Validity		

Content validity	+	All items are considered to be relevant for the construct to be measured, for the target population, and for the purpose of the measurement AND the questionnaire is considered to be comprehensive
	?	Not enough information available
	-	Not all items are considered to be relevant for the construct to be measured, for the target population, and for the purpose of the measurement OR the questionnaire is considered not to be comprehensive
Construct validity - Structural validity	+	Factors should explain at least 50% of the variance
	?	Explained variance not mentioned
	-	Factors explain < 50% of the variance
- Hypothesis testing	+	Correlations with instruments measuring the same construct $\geq 0.50$ OR at least 75% of the results are in accordance with the hypotheses AND correlations with related constructs are higher than with unrelated constructs
	?	Solely correlations determined with unrelated constructs
	-	Correlations with instruments measuring the same construct < 0.50 OR < 75% of the results are in accordance with the hypotheses OR correlations with related constructs are lower than with unrelated constructs
- Cross-cultural validity	+	No differences in factor structure OR no important DIF between language versions
	?	Multiple group factor analysis not applied AND DIF not assessed
	-	Differences in factor structure OR important DIF between language versions
- Criterion validity	+	Convincing arguments that gold standard is "gold" AND correlation with gold standard $\geq 0.70$
	?	No convincing arguments that gold standard is "gold"
	-	Correlation with gold standard < 0.70
Responsiveness		
Responsiveness	+	Correlation with changes on instruments measuring the same construct $\geq 0.50$ OR at least 75% of the results are in accordance with the hypotheses OR AUC $\geq 0.70$ AND correlations with changes in related constructs are

		higher than with unrelated constructs
	?	Solely correlations determined with unrelated constructs
	-	Correlations with changes on instruments measuring the same construct < 0.50 OR < 75% of the results are in accordance with the hypotheses OR AUC < 0.70 OR correlations with changes in related constructs are lower than with unrelated constructs

Legend: MIC, minimal important change; SDC, smallest detectable change; LoA, limits of agreement; ICC, intraclass correlation coefficient; DIF, differential item functioning; AUC, area under the curve; +, positive rating

TABLE 3. Levels of evidence for the quality of the measurement property.

Level	Rating	Criteria
Strong	+++ or ---	Consistent findings in multiple studies of good methodological quality OR in one study of excellent methodological quality
Moderate	++ or --	Consistent findings in multiple studies of fair methodological quality OR in one study of good methodological quality
Limited	+ or -	One study of fair methodological quality
Conflicting	+/-	Conflicting findings
Unknown	?	Only studies of poor methodological quality

Legends: +, positive rating; -, negative rating; ?, indeterminate rating



**PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol\***

Section and topic	Item No	Checklist item	Page number
<b>ADMINISTRATIVE INFORMATION</b>			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	NA
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	9
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	NA
Support:			
Sources	5a	Indicate sources of financial or other support for the review	NA
Sponsor	5b	Provide name for the review funder and/or sponsor	
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	
<b>INTRODUCTION</b>			
Rationale	6	Describe the rationale for the review in the context of what is already known	4, 5
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	5
<b>METHODS</b>			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting,	6

		time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	6
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	6
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	7
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	7
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	7
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	6, 7
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	6, 7
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	8
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	8
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as $I^2$ , Kendall's $\tau$ )	8
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	8
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	8
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication	NA

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		bias across studies, selective reporting within studies)	
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	NA

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**\* It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

*From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.*

# BMJ Open

## Measurement properties of the craniocervical flexion test: a systematic review protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-019486.R2
Article Type:	Protocol
Date Submitted by the Author:	17-Jan-2018
Complete List of Authors:	Araujo, Francisco; Universidade Federal de Ciencias da Saude de Porto Alegre; Centro Universitario Ritter dos Reis - Campus Canoas Ferreira, Giovanni ; Universidade Federal de Ciencias da Saude de Porto Alegre, Physical Therapy Department Scholl Schell, Maurício ; Universidade Federal de Ciencias da Saude de Porto Alegre Castro, Marcelo; Neuromusculoskeletal Assessment and Clinical Biomechanics Laboratory (LaBClin) Silva, Marcelo; Universidade Federal de Ciencias da Saude de Porto Alegre, Physical Therapy Department Ribeiro, Daniel; University of Otago, School of Physiotherapy
<b>Primary Subject Heading</b>:	Rehabilitation medicine
Secondary Subject Heading:	Occupational and environmental medicine
Keywords:	Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY, REHABILITATION MEDICINE, SPORTS MEDICINE

SCHOLARONE™  
Manuscripts



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3 **Measurement properties of the craniocervical flexion test: a systematic review**  
4 **protocol**  
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**ABSTRACT:**

**Introduction:** Neck pain is the leading cause of years lived with disability worldwide, and it accounts for high economic and societal burden. Altered activation of the neck muscles is a common musculoskeletal impairment presented by patients with neck pain. The craniocervical flexion test with pressure biofeedback unit has been widely used in clinical practice to assess function of deep neck flexor muscles. This systematic review will assess the measurement properties of the craniocervical flexion test for assessing deep cervical flexor muscles.

**Methods and analysis:** This is a protocol for a systematic review that will follow the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement. MEDLINE (via PubMed), EMBASE, PEDro, Cochrane Central Register of Controlled Trials (CENTRAL), Scopus and Science Direct will be systematically searched from inception. Studies of any design that have investigated and reported at least one measurement property of the craniocervical flexion test for assessing the deep cervical flexor muscles will be included. All measurement properties will be considered as outcomes. Two reviewers will independently rate the risk of bias of individual studies using the updated COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) checklist. A structured narrative synthesis will be used for data analysis. Quantitative findings for each measurement property will be summarized. The overall rating for a measurement property will be classified as “positive”, “indeterminate”, or “negative”. The overall rating will be accompanied with a level of evidence.

**Ethics and dissemination:** Ethical approval and patient consent are not required since this is a systematic review based on published studies. Findings will be submitted to a peer-reviewed journal for publication.

**Trial registration number:** This protocol has been registered with the International Prospective Register of Systematic Reviews (PROSPERO), registration number (CRD42017062175).

**STRENGTHS AND LIMITATIONS:**

- Comprehensive and exhaustive search for relevant studies from several databases;

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3 - A new summary of the evidence on measurement properties of a widely used clinical  
4 test: the craniocervical flexion test with the pressure biofeedback unit for the  
5 assessment of deep cervical flexor muscles;  
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9 - This review used the internationally recognized, validated COSMIN checklist to assess  
10 the methodological quality of the included studies when assessing the quality of the  
11 craniocervical flexion test;  
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15 - The proposed systematic review will adhere to the PRISMA guidelines, ensuring  
16 consistency and uniformity in reporting and the full systematic review;  
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19 - A limitation of the review is that it will only include papers published in English.  
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## 1. INTRODUCTION:

Neck pain is the leading cause of years lived with disability worldwide, and it accounts for high economic and societal burden.[1,2] In the general population, 16.7 to 75.1% of adults will develop an episode of neck pain in any given year.[3,4] Patients may present recurrent neck pain,[5,6] and the prognosis of recovery is poor.[5] Between 50 and 75% of people who experienced neck pain still present with symptoms one to five years after onset of symptoms.[6]

Altered activation of the neck muscles is a common musculoskeletal impairment presented by patients with neck pain.[7] Compared to asymptomatic individuals, patients with neck pain exhibit increased activity of superficial neck flexors and reduced activity of the deep neck flexors;[8] poor muscle endurance;[9,10] altered kinematics of the cervical spine;[11] delayed feedforward activity;[12] and impaired proprioception.[13–15] These impairments are likely to contribute to maintenance of symptoms in patients with chronic neck pain.[16]

As the clinical presentation of patients with neck pain are not homogeneous, clinical assessment of neck muscle function is important for identifying musculoskeletal impairments and tailoring treatment to patients' needs.[17] Several tests have been designed to evaluate different aspects of neck muscle performance.[18–23] Among those tests, the craniocervical flexion test with pressure biofeedback unit has been developed to evaluate the ability of an individual to selectively recruit the deep neck flexors (*longus capitis* and *longus colli*) while maintaining low activity levels of the superficial neck flexors (e.g. *sternocleidomastoid*, *anterior scalene*) during an active craniocervical flexion in supine lying.[23] This test has been widely used in clinical practice to assess function of deep neck flexor muscles.[8,23,24]

To conduct the craniocervical flexion test with pressure biofeedback unit, the patient's head is positioned in neutral, with patient in supine crook lying. The test consists of an active head nodding movement. During this movement, the patient



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3 attempts to target five different pressure levels, from 22 to 30 mmHg.[24] This test is  
4 performed with an extrinsic air-filled pressure biofeedback unit placed behind the  
5 neck. This device provides feedback and direction for the patient to perform the test,  
6 and enables an objective and quantitative assessment of the patient performance.[23]  
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8 The performance of the test is assessed through the following components: how well  
9 the patient performs the active head nodding and achieves that by contracting the  
10 deep cervical flexors without contraction of superficial flexors), muscle endurance  
11 (through isometric contraction) of deep cervical flexors at each test stages with  
12 appropriate craniocervical flexion contraction, and quality and range of craniocervical  
13 movement in the sagittal plane (which is expected to increase as the patient progress  
14 through the five different pressure levels).[8,23]  
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23 Ideally, the measurement properties (e.g. reliability, validity, and  
24 responsiveness) of an instrument or test, for instance the craniocervical flexion test  
25 with pressure biofeedback unit, should be assessed before its full implementation in  
26 clinical practice.[25] Selecting instruments with proper measurement properties is  
27 fundamental for well-conducted clinical trials.[26] Hence, systematic reviews of  
28 measurement properties are useful for identifying instruments and tools with the  
29 highest reliability, validity and responsiveness scores.[27]  
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37 A previous systematic review[28] evaluated the measurement properties of  
38 methods to measure muscle function in patients with non-specific neck pain. In this  
39 review, the intra-observer reliability was the only measurement property assessed.[28]  
40 This review was conducted over 10 years ago, included only four studies and used a  
41 checklist adapted from two previous studies.[29,30] Since then, the number of  
42 published studies evaluating measurement properties of craniocervical flexion test has  
43 increased. In addition, new tools have been developed for assessing methodological  
44 quality of individual studies exploring measurement properties of instruments (i.e.  
45 Consensus-based Standards for the selection of health Measurement Instruments –  
46 COSMIN).[25] It is likely that a new review evaluating the measurement properties of  
47 the craniocervical flexion test with pressure biofeedback unit will provide relevant  
48 insights on the state of research in this field. This systematic review will critically  
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3 appraise and summarize the quality of the measurement properties of the  
4 craniocervical flexion test for assessing deep cervical flexor muscles.  
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## 8 **2. METHODS:**

### 9 **2.1. Protocol and Registration**

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11 This is a protocol for a systematic review that was reported in accordance with  
12 the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols  
13 (PRISMA-P).[31] The systematic review has been registered with PROSPERO  
14 (CRD42017062175).  
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### 19 **2.2. Eligibility criteria**

20 We will include studies if they meet the following criteria:  
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- 23 - Articles that have investigated and reported at least one measurement  
24 property (i.e. validity, reliability or responsiveness) of the craniocervical flexion  
25 test for assessing the deep cervical flexor muscles;  
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27 - Articles published in English;  
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29 - Assessing participants older than 18 years old;  
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31 - Articles available in full text;  
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33 - Studies with both asymptomatic and symptomatic individuals (including those  
34 with acute, subacute and chronic neck pain with or without nerve root  
35 compromise; neck-related shoulder pain, whiplash-associated disorders and  
36 neck disorders associated with headache).  
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44 Studies assessing only the effectiveness of interventions, but not reporting  
45 measurement property outcomes of pressure biofeedback unit for assessing motor  
46 control of deep cervical flexor muscles will be excluded.  
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### 51 **2.3. Outcomes**

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54 All measurement properties will be considered as outcomes in this systematic  
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3 review. We will adopt the COSMIN terminology and definitions of measurement  
4 properties.[32] Reliability is defined as the degree to which a measurement is free  
5 from measurement error; validity is the degree to which an outcome instrument  
6 measures the construct(s) it purports to measure; and responsiveness is the ability of  
7 an outcome instrument to detect change over time in the construct to be  
8 measured.[32] Among these properties, reliability and validity are further subdivided.  
9 For example, reliability is further classified into reliability, internal consistency and  
10 measurement error; validity comprises content validity, construct validity and criterion  
11 validity.[32] For the purposes of this review, we will include all outcome measures  
12 used assessing psychometric properties that are reported by included studies.  
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#### 23 **2.4. Search strategy**

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25 The search strategy was designed through consultation with a health sciences  
26 faculty librarian. Our search will include the following databases: MEDLINE (via  
27 PubMed), EMBASE, PEDro, Cochrane Central Register of Controlled Trials (CENTRAL),  
28 Scopus and Science Direct. All databases will be searched from their inception to  
29 present time using a published search filter for finding studies on measurement  
30 properties.[33] MEDLINE full-search strategy is described in Table 1.  
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#### 41 **2.5. Data extraction**

42 Two reviewers (FXA and MSS) will independently screen titles and abstracts for  
43 eligibility. A third reviewer (MPC) will resolve any disagreement. The full text of  
44 potentially eligible articles will be screened independently by two reviewers (FXA and  
45 MSS). Data from included studies will be extracted independently by the two  
46 reviewers, using a piloted data collection form. Data will then be compared for  
47 accuracy, and disagreements will be solved by consensus. The following information  
48 will be extracted from the included studies: study design, sample characteristics,  
49 measurement properties (e.g. validity, reliability or responsiveness) assessed by  
50 included studies, craniocervical flexion test procedures and results of the  
51 measurements properties.  
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## 2.6 Risk of bias within included studies

Two reviewers (FXA and GEF) will independently rate the risk of bias of individual studies using the updated COSMIN checklist.[34] The COSMIN checklist is a validated critical appraisal tool designed for the systematic evaluation of the methodological quality of studies on the measurement properties.[27] For each study, only applicable domains to the study being assessed will be used for assessing the quality of the study. Disagreements between reviewers will be resolved by a third reviewer (MPC).

## 2.6. Synthesis of results:

A structured narrative synthesis will be used for data analysis. Quantitative findings for each measurement property will be summarized. The overall rating for a measurement property will be classified as “positive”, “indeterminate”, or “negative”. The overall rating will be accompanied with a level of evidence (strong, moderate, limited, conflicting, unknown – Table 2) as proposed by Terwee et al.[35] The criteria used to assign levels of evidence for the quality of each measurement property (Table 3) will follow the framework proposed by the Cochrane Back and Neck Review Group.[36]

We will conduct a narrative synthesis of subgroups, if applicable, based on the sample characteristics (i.e. asymptomatic or symptomatic), and type of disorder (e.g. acute, subacute and chronic non-specific neck pain; acute, subacute and chronic neck pain with nerve root compromise; neck-related shoulder pain; whiplash-associated disorders; and neck disorder associated with headache).

## 3. ETHICS AND DISSEMINATION:

Ethical approval and patient consent are not required since this is a systematic review based on published studies. This protocol has been registered on the

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3 international PROSPERO and the systematic review will be conducted according to the  
4 PRISMA statement. The results of this systematic review will be submitted to a peer-  
5 reviewed journal for publication and will be also possibly presented at national and  
6 international meetings.  
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10 **Authors' contributions:** FXA is the leading researcher, responsible for conceiving the  
11 study, and designing the protocol. All authors have contributed to the conception and  
12 design of the study protocol, development of the search strategy, the establishment of  
13 the inclusion and exclusion criteria, data extraction criteria, analyses and  
14 interpretation. FXA and MSS will screen title, abstracts and full text for eligibility. MSS  
15 and GEF will extract data. FXA and GEF will rate the methodological quality of  
16 individual studies. MPC will resolve any disagreement between reviewers. GEF and  
17 MSS will provide the statistical analysis plan of the study and will conduct the data  
18 analysis. FXA, MSS, GEF will write the first version of the paper. MPC, DCR and MFS will  
19 provide critical revision of the paper. All authors read and provided final approval of  
20 this protocol to be published.  
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33 Superior (CAPES – Brazil). However, CAPES is not involved in any other aspect of this  
34 study protocol.  
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40 **Competing interest:** None declared.  
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24 TABLE 1. Search strategy in MEDLINE (via Pubmed).  
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26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57	1# ( ( ( ( ( (patient outcome assessment [Mesh]) OR ((outcome and process assessment [Mesh]))) OR treatment outcome [Mesh] OR instrumentation[sh] OR methods[sh] OR "Validation Studies"[pt] OR "Comparative Study"[pt] OR "psychometrics"[MeSH] OR psychometr*[tiab] OR clinimetr*[tw] OR clinometr*[tw] OR "outcome assessment (health care)"[MeSH] OR "outcome assessment"[tiab] OR "outcome measure*" [tw] OR "observer variation"[MeSH] OR "observer variation"[tiab] OR "Health Status Indicators"[Mesh] OR "reproducibility of results"[MeSH] OR reproducib*[tiab] OR "discriminant analysis"[MeSH] OR reliab*[tiab] OR unreliab*[tiab] OR valid*[tiab] OR "coefficient of variation"[tiab] OR coefficient[tiab] OR homogeneity[tiab] OR homogeneous[tiab] OR "internal consistency"[tiab] OR (cronbach*[tiab] AND (alpha[tiab] OR alphas[tiab])) OR (item[tiab] AND (correlation*[tiab] OR selection*[tiab] OR reduction*[tiab])) OR agreement[tw] OR precision[tw] OR imprecision[tw] OR "precise values"[tw] OR test-retest[tiab] OR (test[tiab] AND retest[tiab]) OR (reliab*[tiab] AND (test[tiab] OR retest[tiab])) OR stability[tiab] OR interrater[tiab] OR inter-rater[tiab] OR intrarater[tiab] OR intra-rater[tiab] OR intertester[tiab] OR inter-tester[tiab] OR intratester[tiab] OR intra- tester[tiab] OR interobserver[tiab] OR inter-observer[tiab] OR intraobserver[tiab] OR intra-observer[tiab] OR intertechnician[tiab] OR inter- technician[tiab] OR intratechnician[tiab] OR intra-technician[tiab] OR interexaminer[tiab] OR inter-examiner[tiab] OR intraexaminer[tiab] OR intra- examiner[tiab] OR interassay[tiab] OR inter-assay[tiab] OR intraassay[tiab] OR intra-assay[tiab] OR interindividual[tiab] OR inter-individual[tiab] OR intraindividual[tiab] OR intra-individual[tiab] OR interparticipant[tiab] OR inter- participant[tiab] OR intraparticipant[tiab] OR intra-participant[tiab] OR kappa[tiab] OR kappa's[tiab] OR kappas[tiab] OR repeatab*[tw] OR ((replicab*[tw] OR repeated[tw]) AND (measure[tw] OR measures[tw] OR
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	findings[tw] OR result[tw] OR results[tw] OR test[tw] OR tests[tw])) OR generaliza*[tiab] OR generalisa*[tiab] OR concordance[tiab] OR (intraclass[tiab] AND correlation*[tiab]) OR discriminative[tiab] OR "known group"[tiab] OR "factor analysis"[tiab] OR "factor analyses"[tiab] OR "factor structure"[tiab] OR "factor structures"[tiab] OR dimension*[tiab] OR subscale*[tiab] OR (multitrait[tiab] AND scaling[tiab] AND (analysis[tiab] OR analyses[tiab])) OR "item discriminant"[tiab] OR "interscale correlation*" [tiab] OR error[tiab] OR errors[tiab] OR "individual variability"[tiab] OR "interval variability"[tiab] OR "rate variability"[tiab] OR (variability[tiab] AND (analysis[tiab] OR values[tiab])) OR (uncertainty[tiab] AND (measurement[tiab] OR measuring[tiab])) OR "standard error of measurement"[tiab] OR sensitiv*[tiab] OR responsive*[tiab] OR (limit[tiab] AND detection[tiab]) OR "minimal detectable concentration"[tiab] OR interpretab*[tiab] OR ((minimal[tiab] OR minimally[tiab] OR clinical[tiab] OR clinically[tiab]) AND (important[tiab] OR significant[tiab] OR detectable[tiab]) AND (change[tiab] OR difference[tiab])) OR (small*[tiab] AND (real[tiab] OR detectable[tiab]) AND (change[tiab] OR difference[tiab])) OR "meaningful change"[tiab] OR "ceiling effect"[tiab] OR "floor effect"[tiab] OR "Item response model"[tiab] OR IRT[tiab] OR Rasch[tiab] OR "Differential item functioning"[tiab] OR DIF[tiab] OR "computer adaptive testing"[tiab] OR "item bank"[tiab] OR "cross-cultural equivalence"[tiab] ) ) ) )
2#	(( (( ( pressure biofeedback unit[Title/Abstract] OR pressure biofeedback units[Title/Abstract] OR unit, pressure biofeedback[Title/Abstract] OR units, pressure biofeedback[Title/Abstract] OR stabilizer[Title/Abstract] OR stabilizers[Title/Abstract] OR stabiliser[Title/Abstract] OR stabilisers[Title/Abstract] OR biofeedback[Title/Abstract] OR biofeedbacks[Title/Abstract] OR craniocervical flexion test[Title/Abstract] OR cranio-cervical flexion test[Title/Abstract] OR cranio cervical flexion test[Title/Abstract] OR cranio cervical flexion[Title/Abstract] ) ) ) )
3#	(( (( ( Muscle, Neck[Title/Abstract] OR Muscles, Neck[Title/Abstract] OR Neck muscle[Title/Abstract] ) ) ) OR Neck muscles[MeSH Terms] ) ) OR ( ( neck[MeSH Terms] ) OR Necks[Title/Abstract] OR deep cervical flexor*[Title/Abstract] OR rectus capit*[Title/Abstract] OR longus colli[Title/Abstract] OR longus capiti [Title/Abstract] ) )
4#	1# AND 2# AND 3#

TABLE 2. Quality criteria for measurement properties.

Property	Rating	Quality criteria
Reliability		
Internal consistency	+	Cronbach's alpha(s) $\geq 0.70$
	?	Cronbach's alpha not determined or unidimensionality unknown

	-	Cronbach's alpha(s) < 0.70
Reliability	+	ICC/ weighted Kappa $\geq$ 0.70 OR Pearson's r $\geq$ 0.80
	?	Neither ICC / weighted Kappa, nor Pearson's r determined
	-	ICC / weighted Kappa < 0.70 OR Pearson's r < 0.80
Measurement error	+	MIC > SDC OR MIC outside the LoA
	?	MIC not defined
	-	MIC $\leq$ SDC OR MIC equals or inside LoA
Validity		
Content validity	+	All items are considered to be relevant for the construct to be measured, for the target population, and for the purpose of the measurement AND the questionnaire is considered to be comprehensive
	?	Not enough information available
	-	Not all items are considered to be relevant for the construct to be measured, for the target population, and for the purpose of the measurement OR the questionnaire is considered not to be comprehensive
Construct validity – Structural validity	+	Factors should explain at least 50% of the variance
	?	Explained variance not mentioned
	-	Factors explain < 50% of the variance
- Hypothesis testing	+	Correlations with instruments measuring the same construct $\geq$ 0.50 OR at least 75% of the results are in accordance with the hypotheses AND correlations with related constructs are higher than with unrelated constructs
	?	Solely correlations determined with unrelated constructs
	-	Correlations with instruments measuring the same construct < 0.50 OR < 75% of the results are in accordance with the hypotheses OR correlations with related constructs are lower than with unrelated constructs
- Cross-cultural validity	+	No differences in factor structure OR no important DIF between language versions

	?	Multiple group factor analysis not applied AND DIF not assessed
	-	Differences in factor structure OR important DIF between language versions
- Criterion validity	+	Convincing arguments that gold standard is "gold" AND correlation with gold standard $\geq 0.70$
	?	No convincing arguments that gold standard is "gold"
	-	Correlation with gold standard $< 0.70$
Responsiveness		
Responsiveness	+	Correlation with changes on instruments measuring the same construct $\geq 0.50$ OR at least 75% of the results are in accordance with the hypotheses OR AUC $\geq 0.70$ AND correlations with changes in related constructs are higher than with unrelated constructs
	?	Solely correlations determined with unrelated constructs
	-	Correlations with changes on instruments measuring the same construct $< 0.50$ OR $< 75\%$ of the results are in accordance with the hypotheses OR AUC $< 0.70$ OR correlations with changes in related constructs are lower than with unrelated constructs

Legend: MIC, minimal important change; SDC, smallest detectable change; LoA, limits of agreement; ICC, intraclass correlation coefficient; DIF, differential item functioning; AUC, area under the curve; +, positive rating

TABLE 3. Levels of evidence for the quality of the measurement property.

Level	Rating	Criteria
Strong	+++ or ---	Consistent findings in multiple studies of good methodological quality OR in one study of excellent methodological quality
Moderate	++ or --	Consistent findings in multiple studies of fair methodological quality OR in one study of good methodological quality
Limited	+ or -	One study of fair methodological quality
Conflicting	+/-	Conflicting findings

Unknown	?	Only studies of poor methodological quality
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Legends: +, positive rating; -, negative rating; ?, indeterminate rating

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**PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol\***

Section and topic	Item No	Checklist item	Page number
<b>ADMINISTRATIVE INFORMATION</b>			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	NA
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	9
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	NA
Support:			
Sources	5a	Indicate sources of financial or other support for the review	NA
Sponsor	5b	Provide name for the review funder and/or sponsor	
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	
<b>INTRODUCTION</b>			
Rationale	6	Describe the rationale for the review in the context of what is already known	4, 5
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	5
<b>METHODS</b>			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting,	6

		time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	6
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	6
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	7
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	7
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	7
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	6, 7
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	6, 7
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	8
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	8
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as $I^2$ , Kendall's $\tau$ )	8
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	8
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	8
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication	NA



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		bias across studies, selective reporting within studies)	
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	NA

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**\* It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

*From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.*