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DOI:
10.1016/j.msksp.2023.102861

Document Version
Publisher's PDF, also known as Version of record

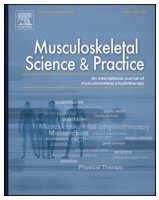
Citation for published version (Harvard):
Thoomes, E, Cleland, JA, Falla, D, de Pauw, R, Maissan, F & Graaf, MD 2023, 'Measurement properties of a computer adaptive device, the Senscoordination 3D Cervical Trainer, to assess cervical range of motion in people with neck pain', *Musculoskeletal Science and Practice*, vol. 67, 102861.
https://doi.org/10.1016/j.msksp.2023.102861

Musculoskeletal Science and Practice 67 (2023) 102861

Contents lists available at ScienceDirect

Musculoskeletal Science and Practice

journal homepage: www.elsevier.com/locate/msksp



Original article

Measurement properties of a computer adaptive device, the Senscoordination 3D Cervical Trainer, to assess cervical range of motion in people with neck pain

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A B S T R A C T

Introduction: Clinicians commonly assess cervical range of motion (ROM) in patients with neck pain. Recently, a new instrument has been developed, the Senscoordination 3D Cervical Trainer (SCT), designed to measure neck ROM in addition to joint position error, static and dynamic balance performance, and performance on a 'neuro muscular control test'. This study aims to assess the interrater reliability, concurrent validity, and responsiveness of the SCT using the CROM device as a comparator.

Methods: One hundred patients with non-specific neck pain were included and their active cervical ROM was measured in a random order by two raters in succession using both devices simultaneously at baseline and after personalised physiotherapy management, at 12 week follow up. Convergent validity and responsiveness were quantified by a Pearson correlation coefficient. The intraclass correlation coefficient (ICC) was used to calculate the test–retest reliability of the SCT. The smallest detectable change (SDC) was calculated per movement direction and for the total range of motion.

Results: The correlation between the measures obtained with the CROM device and the SCT was high (0.97 or 0.98 depending on direction of movement). Interrater reliability was high for all directions (ICC ranging from 0.81 to 0.97). The SDC ranged from 6.9 for left cervical rotation to 12.2 for right cervical rotation. At the follow up, correlation between the change score on the CROM device and the SCT was high (0.86–0.94 depending on the direction of movement).

Conclusion: The SCT is a valid, reliable and responsive instrument for measuring cervical ROM.

1. Introduction

Neck pain is a common musculoskeletal disorder and affects approximately two-thirds of individuals at some point during their lives (Fejer et al., 2006; Cote et al., 1998; Guez et al., 2002). International epidemiological data shows a point prevalence ranging between 10 and 20% (Fejer et al., 2006) and a 12-month prevalence ranging from 30 to 50% (Hogg-Johnson et al., 2008). Neck pain has a persistent and recurrent nature and most people with neck pain do not experience complete resolution of symptoms (Haldeman et al., 2008). Neck pain often results in disability, functional impairments (Hurwitz et al., 2018) and activity limitation (Hogg-Johnson et al., 2008; Cote et al., 2008).

More than half of all patients with neck pain are referred to a physiotherapist (Borghouts et al., 1999; Vos et al., 2007) and will undergo a physical examination to evaluate physical impairments (Bier et al., 2018; Childs et al., 2008). Visual estimation of range of motion (ROM) is often part of this examination but has proven to be unreliable and is not recommended to assess passive or active range of motion (Williams et al., 2010). The American Physical Therapy Association (APTA) guidelines recommend the use of "easily reproducible activity limitation and participation restriction measures associated with a patient's neck pain to assess the changes in the patient's level of function over the episode of care" (Childs et al., 2008; Blanpied et al., 2017). The Cervical Range Of Motion device (CROM) was one of the measures specifically recommended in this guideline (Childs et al., 2008; Blanpied et al., 2017). Several systematic reviews have concluded that the CROM

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https://doi.org/10.1016/j.msksp.2023.102861
Received 31 March 2023; Received in revised form 14 September 2023; Accepted 18 September 2023
Available online 21 September 2023

is both a reliable and valid instrument for measuring active neck movement (Williams et al., 2010; de Koning et al., 2008; Gugliotti et al., 2021). The construct validity of the CROM has been assessed using radiographs, a single inclinometer and opto-electronic systems (de Koning et al., 2008) and the CROM is considered to be the most appropriate clinical instrument for assessing ROM in patients with non-specific neck pain (Williams et al., 2010; de Koning et al., 2008). Moreover, normative values are available per gender and age category (Youdas et al., 1992; Thoomes-de Graaf et al., 2020). However, the responsiveness or the minimal important change (MIC) have not been assessed for the CROM.

Although the CROM is appropriate to measure ROM and can be used to evaluate the effect of an intervention, it cannot be used to assist the treatment itself. It is not designed to be worn during active or passive treatment interventions and the patient is not able to see the inclinometers used to record ROM. Recently, a new instrument has been developed, the Senscoordination 3D Cervical Trainer™ (SCT), which is designed to measure neck ROM in addition to joint position error (JPE), static and dynamic balance performance, and performance on a 'neuro muscular control test' as designed by the manufacturer. Furthermore, in contrast to the CROM, the SCT has potential to be used as a therapeutic intervention since the device incorporates video gaming which in turn can potentially be used to facilitate exercise to increase ROM and improve the control of neck movement. Since the SCT is computer orientated with incorporated software developed by the manufacturer, outcomes could potentially be used to automatically calculate change scores and thus monitor patient progress.

In a first step to evaluate measurement properties of the SCT, this study aimed to assess the interrater reliability, concurrent validity (using the CROM as the comparator instrument) and responsiveness of the SCT. The outcome of this study could potentially inform the assessment of other SCT measures such as JPE and neuro muscular control tests.

2. Methods

2.1. Design

This is a validity, reliability, and responsiveness study which is part of a cohort study CROMM-study) (Thoomes-de Graaf et al., 2020; Thoomes-de Graaf et al., 2019), including patients with non-specific neck pain treated in a physiotherapy setting. The Medical Ethics Center in Rotterdam approved the study (MEC-2018-129). The study was registered in the Netherlands Trial Register as NTR7463. Informed written consent was obtained from all patients and the study was conducted according to the Declaration of Helsinki. This study adheres to the Guidelines for Reporting Reliability and Agreement Studies (GRRAS) (Kottner et al., 2011).

2.2. Participants

Patients were recruited from a primary care physiotherapy clinic between July 2018 and January 2019. Patients with non-specific neck pain classified as Grade I or II, as described by the Neck Pain Task Force, were eligible if they were over 18 years of age and adequately understood Dutch (Guzman et al., 2009). Patients were excluded if they presented with serious pathology (e.g., infection, cancer, fracture or rheumatoid arthritis) or previous cervico-thoracic surgery. A minimum number of 100 patients were recruited which is considered acceptable (Mokkink et al., 2022), especially since most studies validating cervical range of motion measures were performed on 30 patients.

2.3. Raters

Two raters (MdG and ET) performed all measurements following a standardized measurement protocol. Both are experienced (>10 years) manipulative physiotherapists.

2.4. Self-reported measures

2.4.1. Baseline measurement

All participants received an automated online questionnaire that included demographic characteristics (age, gender, duration of complaints, occupation, etc.), a Numeric Pain Rating Scale (NPRS) and the Neck Disability Index (NDI). Additionally, patients were asked if they felt restricted in their neck movement (and if so, in which direction). All forms were available online, using Limesurvey™ software. Both researchers and software holders safely stored data within a content management system separately from research data to ensure anonymity.

2.4.1.1. Neck pain intensity. A Numeric Pain Rating Scale (NPRS) was used to quantify neck pain intensity experienced over the past 24 h, where 0 represents "no pain" and 10 "the worst pain possible" (Pool et al., 2007; Kovacs et al., 2008). The NPRS is appropriate to assess pain intensity (Jensen et al., 1986; Hjermstad et al., 2011) and is recommended in clinical practice guidelines for neck pain (Blanpied et al., 2017; Kamper et al., 2010).

2.4.1.2. Perceived neck pain and disability. The NDI is designed to measure "activity limitations" during activities of daily living (ADL) in patients with neck pain and was derived from the Oswestry Disability Index for low back pain (Schellingerhout et al., 2011, 2012). The 10 items of the NDI have 6 response categories (range 0–5, total score range 0–50). There is moderate evidence for the responsiveness of the NDI (AUC = 0.79; 95%CI 0.68, 0.89) using the Global Rating of Change (GRC) as a comparator (Young et al., 2009). The Dutch version of the NDI was used which is reliable, valid and responsive (Schellingerhout et al., 2011; Jorritsma et al., 2012a).

2.4.2. Follow-up measurements

All patients received an automated online questionnaire including the NPRS, NDI and the GPE-scale, 12 weeks after baseline measurements were collected. Within this period the patients received personalised physiotherapy treatment (their usual care) for one or more sessions; therapy sessions were not standardized but instead were tailored to the individual. Additionally, patients were asked if they still felt restricted in their neck movement (and in which direction) and/or if this had changed since the start of their treatment. If increasing ROM was a goal of their treatment, patients were asked if they felt this goal was achieved, rating this on a 7-point Likert scale. Patients were also asked about their experience regarding the measurement using an open-ended response option.

2.4.2.1. Global perceived effect-scale. The Global Perceived Effect (GPE)-scale is a 7-point Likert scale asking if the patient's condition has improved or deteriorated since the start of treatment ("Could you please state the amount of change concerning your recovery compared to when you first started treatment?"). This scale ranges from "worse than ever" to "completely recovered" (completely recovered, much improved, slightly improved, no change, slightly worse, much worse and worse than ever). The GPE-scale has good test-retest reliability and correlates well with changes in pain and disability (Kamper et al., 2010). Despite controversy on the role of global rating items, the GPE scale has frequently been used as an anchor in responsiveness studies (Weenink et al., 2014; Luijsterburg et al., 2008; Jorritsma et al., 2012b; Soer et al., 2012; Demoulin et al., 2010).

2.5. Instruments

2.5.1. Cervical range of motion measuring (CROM) device

The CROM device measures cervical ROM using three separate inclinometers attached to a frame identical to spectacles; one inclinometer uses a gravity needle in the sagittal plane to assess flexion/extension,

one inclinometer uses a gravity needle in the frontal plane to assess lateral flexion and one inclinometer uses a magnetic needle to assess rotation.

2.5.2. Senscoordination 3D cervical Trainer™ (SCT)

The SCT is a commercially available "off the shelf" device, complete with custom software designed by the manufacturer (Sensamove, The Netherlands, https://www.sensamove.com/nl/cervical-trainer/). The SCT incorporates a 9 degrees of freedom sensor which combines signals from a 3-axis accelerometer, a 3-axis gyroscope and a 3-axis magnetometer and then translates the 9 separate data points to an orientation vector in *x, y* and *z* coordinates and an angle of rotation around the direction of the vector. It is positioned with an adjustable strap and aligned centrally on the forehead just above the bridge of the nose. Automatic calibration occurs when turning the device on; the SCT does not require re-calibration other than a resetting of measurement values to "0l" at the start of a new measurement session. The SCT was used as is advised by the manufacturer without modification other than attaching it to the CROM device to ensure simultaneous measurements.

All authors explicitly declare having no conflict of interest with the SCT or CROM.

2.6. Measurement procedure

Patients were seated on a chair with a backrest and seat height of 45 cm. Their feet were resting on the ground (see Fig. 1). Participants performed flexion, extension, right and left rotation, and right and left lateral flexion once prior to the test. The devices were simultaneously positioned on the patient's head and then calibrated prior to the test with the patient's head in a neutral position: the SCT is calibrated electronically and the axial gravity needle of the CROM is manually set to 0°. End range positions were held for 5 s and degrees were manually recorded per movement by the rater and automatically recorded by the SCT. The patients were instructed to *slowly* move to what they felt to be their end range of movement once and hold that position for 5 s while the raters recorded degrees of ROM for the CROM manually while those for the SCT were recorded electronically by the software. There was no set order of movement, and an online randomiser determined the testing sequence.

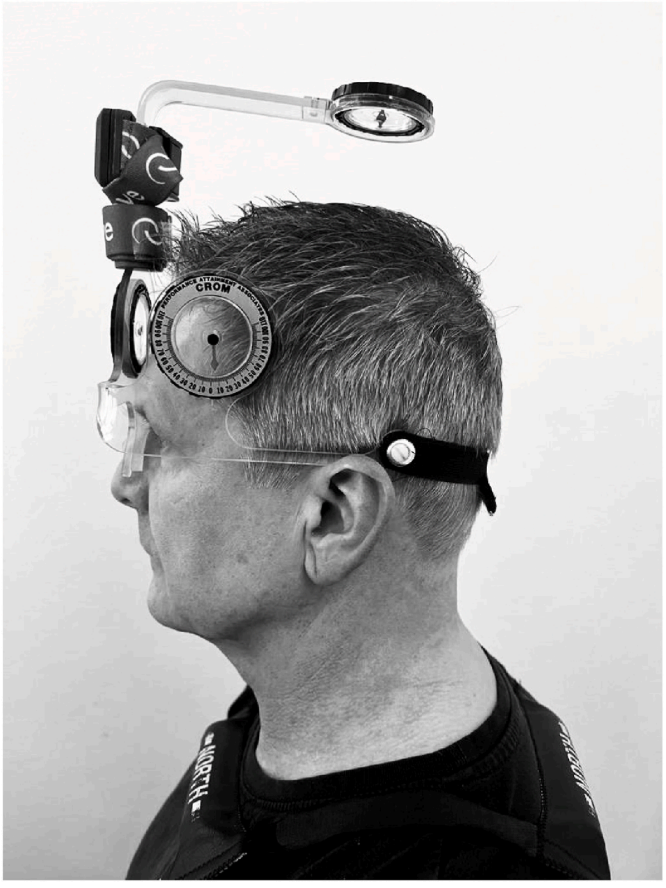

Fig. 1. Test position with the SCT attached to the CROM for simultaneous measurement.

2.6.1. Validity and responsiveness

One rater recorded the measurement of the CROM and the SCT at the same time (since the SCT records the degrees automatically).

2.6.2. Test-retest measurement

All patients were measured twice using the SCT by the different raters. There was no set order of testing between raters and an online randomiser determined the order. The second measurement was performed after 5 min during which time the patient remained seated. The test conditions were identical for each measure.

2.7. Statistical analysis

All statistical analyses were performed with SPSS Version 29 (IBM Corporation, Armonk, NY). All data were checked for normality using a stem-and-leaf plot, Q-Q plot, and whisker box. Nonparametric tests were used if data were not normally distributed. Descriptive statistics were used to calculate frequencies.

2.7.1. Validity

Convergent validity was quantified by the Pearson correlation coefficient. Correlations were rated as follows: $r < 0.30$ as low/insignificant; $0.30 \leq r < 0.45$ as moderate; $0.45 \leq r < 0.60$ as substantial and $r \geq 0.60$ as high (Burnand et al., 1990). High correlations ($r \geq 0.60$) were expected between instruments based on a similar construct (Mokkink et al., 2010). Analysis was performed for all movement directions and the combined total ROM of all movement directions.

2.7.2. Interrater reliability

Rater 1 and rater 2 independently measured the participants that reported feeling unchanged between measurements. A student t-test was used to assess if there were systematic differences between rater 1 and rater 2. The intraclass correlation coefficient (ICC) was used to calculate the test–retest reliability of the SCT, i.e., the extent to which the same test results are obtained for repeated assessments when no real change is expected. ICC can range from 0.00 (no stability/agreement) to 1.00 (perfect stability/agreement) (Nunally JC, 1994). An ICC of 0.70 is acceptable (Nunally JC, 1994; Terwee et al., 2007). When there were no systematic differences, a two-way mixed model was used and if there were systematic differences, a two-way random effects model was used. Analysis was performed for all movement directions and for the combined total ROM. For the combined total ROM, a Bland Altman plot will be presented.

2.7.3. Measurement error

Test-retest data was used to assess the measurement error. To assess the change beyond the measurement error, the Smallest Detectable Change (SDC) was calculated using $1.96 * SD_{diff}$ in case of no systematic errors. We used $SEM_{agreement}$ in case of systematic differences to calculate the SDC ($1.96 \sqrt{2} * SEM_{agreement}$) (Terwee et al., 2007). The SDC was calculated for each movement direction and for the total ROM. Ideally the MIC should be higher than the SDC (de Vet et al., 2006).

2.7.4. Responsiveness

Hypothesis testing for responsiveness was based on the concept that the correlation between the change score of related constructs (CROM)

must be higher than with less related constructs (GPE). Hypothesis testing was quantified by the Pearson correlation coefficient. Correlation coefficients between the SCT change score and the change score of the CROM were expected to be above 0.50 (since they measure the same construct) whereas correlation coefficients between the SCT change score and the GPE were expected to be lower than 0.50 (since they measure different constructs) (de Vet et al., 2011; Mokkink et al., 2021). Furthermore, patients reporting improvement of their functional restrictions were expected to have a significantly higher change score on the SCT than patients who did not report any improvement.

3. Results

A total of 100 consecutive patients agreeing to participate were included at baseline (see Fig. 2). Their mean age was 52.6 (14.5) years and 75% were women. Demographic characteristics of the patients are reported in Table 1.

3.1. Validity

The Pearson correlation coefficient between the CROM device and the SCT was high (0.97 or 0.98 depending on the direction of movement). Correlation for the total ROM was 0.99 (See Table 2).

3.2. Interrater reliability

A total of 90 patients indicated they felt no important change had occurred between the first and second measure. Selected patients for the analysis of interrater reliability did not differ from patients not selected (Table 1). No systematic differences were found between rater 1 and rater 2, except for lateral flexion right (mean difference −2.1, p = 0.001). The ICC for all movement directions was high, ranging from 0.81 to 0.97 (see Table 3).

For the combined total ROM, a Bland Altman plot is presented in Fig. 3. ANOVA regression analysis resulted in a mean of −0.028 (p = 0.261) indicating no proportional bias.

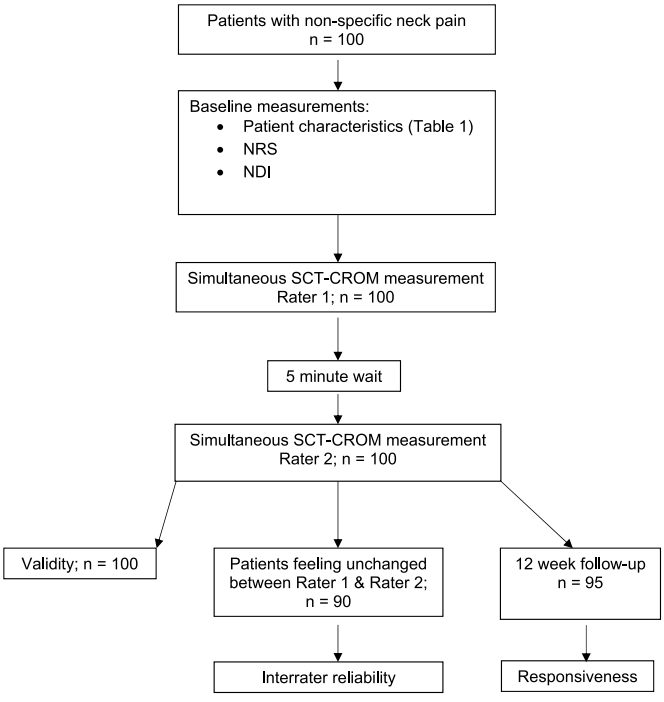

Fig. 2. Participant flow through the study.

Table 1
Demographic characteristics of the included participants.

	Validity cohort N = 100	Reliability cohort N = 90	Responsiveness N = 95
Gender (male) (%)	25 (25.0)	22 (24.4)	23 (24.2%)
Age, Mean (SD)	52.6 (14.5)	52.3 (14.6)	52.5 (14.3)
Duration of neck pain in weeks Median (IQR)	20.0 (8.0–100.0	20.0 (6.0–100.0)	20.0 (8.0–100.00)
Acute/subacute	45 (45.0)	40 (44.5)	42 (44.2)
Chronic	55 (55.0)	50 (55.6)	53 (55.8)
Prior history with neck pain (yes) (%)	79 (79.0)	72 (80.0)	76 (80%)
Ability to work despite neck pain: No, completely unable	1 (1.0)	1 (1.1)	1 (1.1)
No, but I do not work at all	22 (22.0)	21 (23.3)	20 (21.1)
Yes, it's possible to perform my ordinary work activities	60 (60.0)	54 (60.0)	58 (61.1)
Yes, but I have to adjust	17 (17.0)	14 (15.6)	16 (16.8)
NDI baseline score Mean (SD)	24.1 (12.2)	24.0 (12.2)	23.6 (11.4)
Initial pain (NRS) Mean (SD)	4.7 (2.4)	4.6 (2.4)	4.6 (2.4)

Abbreviations: NDI: Neck Disability Index, NRS: Numeric Rating Scale, IQR: Inter quartile range, SD: Standard deviation.

Table 2
Correlation between CROM and SCT for the total ROM and for each movement direction.

	Mean CROM (SD)	Mean SCT (SD)	Pearson correlation (95% CI)	Significance
Total ROM (°)	291.6 (56.0)	298.8 (57.8)	0.99 (0.99–1.00)	*p < 0.01*
Flexion (°)	48.2 (11.5)	50.5 (12.4)	0.98 (0.96–0.98)	*p < 0.01*
Extension (°)	56.7 (14.0)	57.6 (13.6)	0.97 (0.96–0.98)	*p < 0.01*
Rotation left (°)	59.5 (11.7)	61.0 (12.4)	0.98 (0.97–0.99)	*p < 0.01*
Rotation right (°)	60.1 (13.5)	61.3 (13.8)	0.98 (0.98–0.99)	*p < 0.01*
Lateral flexion left (°)	33.7 (9.5)	34.4 (9.6)	0.97 (0.96–0.98)	*p < 0.01*
Lateral flexion right (°)	33.5 (10.2)	34.7 (10.4)	0.97 (0.96–0.98)	*p < 0.01*

Abbreviations: ROM: range of motion; CROM: cervical range of motion measurement; SCT: Senscoordination 3D Cervical Trainer.

Table 3
Agreement between both raters.

	ICC (95%CI)	SDC
Total ROM	0.97 (0.96–0.98)	26.3
Flexion	0.93 (0.90–0.96)	9.3
Extension	0.94 (0.91–0.96)	9.3
Rotation left	0.96 (0.94–0.98)	6.9
Rotation right	0.90 (0.85–0.93)	12.2
Lateral flexion left	0.88 (0.83–0.92)	9.4
Lateral flexion right	0.81 (0.71–0.88)	11.8

Abbreviations: ROM: range of motion; SDC: smallest detectable change.

3.3. Measurement error

The SDCs for each movement direction are presented in Table 3. They ranged from 6.9 for left rotation to 12.2 for right rotation and, the

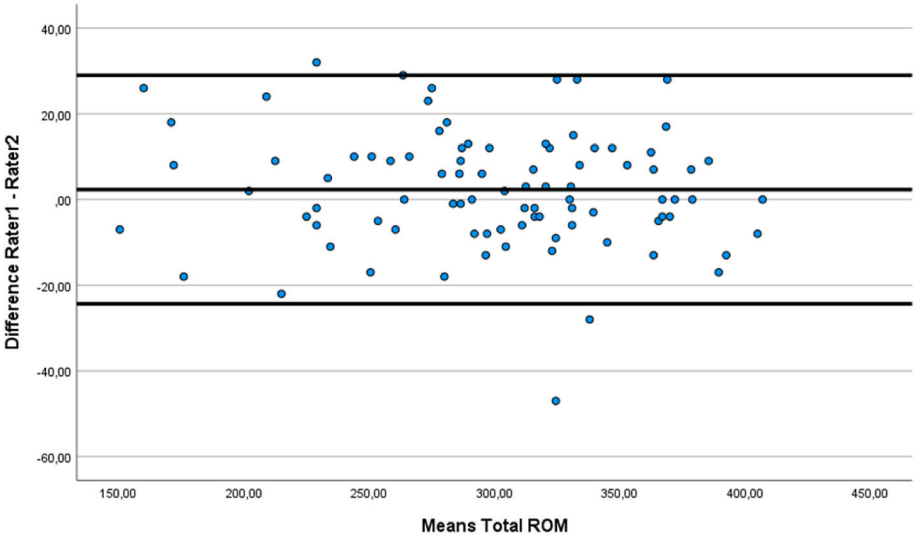

Fig. 3. Bland Altman plot for total ROM.

SDC for the total ROM was 26.3.

3.4. Responsiveness

A total of 95 patients were included in the follow up. The mean total ROM of patients was 330.1° (SD 51.5) when using the CROM at follow up, compared to 338.2° (SD 52.8) when using the SCT. The Pearson correlation between the change score on the CROM device and the SCT was high (0.86–0.94 depending on the direction of movement). Pearson correlations between the SCT change score and the GPE were all beneath 0.50, thereby confirming both hypotheses that the SCT measures the same construct as the CROM device but is less related to the change score on the GPE (see Table 4).

The independent *t*-test confirmed the hypothesis that patients showed a greater change in total ROM on the SCT when they stated they that their neck mobility had improved, resulting in a significant difference between the change score on the total SCT of 16.7° ($p = 0.009$).

4. Discussion

This is the first study to assess the measurement properties of the SCT when compared to the CROM. The SCT was found to have good inter-rater reliability, concurrent validity, and responsiveness.

Both instruments are easy to use, but the SCT has several advantages over the CROM. For one, the SCT software captures cervical ROM digitally which makes for easier reading and recording of the data. Additionally, the SCT software captures and records the end ROM of each individual movement and any subsequent movement of the neck within that range by the patient does not alter the recorded values provided by the software; this facilitates transfer of the data to a patient clinical data management system while the patient is still wearing the SCT device. In contrast, with the CROM device, the clinician needs to record the analogue needle readout after each individual movement, making this a more cumbersome procedure.

Another important consideration is serious gaming which has been described as the use of computer games where the primary goal is not pure entertainment (Rego et al., 2010). The use of serious gaming as a treatment intervention for patients with neck pain using head-mounted displays or using flat-screen computer games has been evaluated in several studies (Wittkopf et al., 2020; Ahern et al., 2020; Gumaa et al., 2019). Recent systematic reviews have reported that serious gaming shows promising results for managing chronic neck pain (Gumaa et al., 2019). However further high-quality research is needed due to the available low-quality evidence (Ahern et al., 2020). Previous studies have investigated serious gaming for the assessment of neck kinematics (Sarig-Bahat et al., 2010; Sarig Bahat et al., 2015) and exercise prescription for the treatment of patients with neck pain (Sarig Bahat et al., 2015). These treatments showed good results (Sarig-Bahat et al., 2010) including reduced disability, patient satisfaction, and improved cervical kinematics in patients with neck pain (Sarig Bahat et al., 2015). As further measurement properties of the SCT are assessed, the potential advantages over the CROM device might become even more apparent given that the SCT can also be used as a form of serious gaming. Based on the current custom software which comes with SCT, the SCT can be used to train JPE as well as static and dynamic balance performance and performance on a cervical 'neuro muscular control test'.

A systematic review aiming to review the evidence for using cervical ROM in patient diagnosis, prognosis, and evaluation of the effects of mobilization/manipulation on cervical ROM, reported there is limited evidence for the diagnostic value of cervical ROM in cervicogenic headache, cervical radiculopathy and cervical spine injury (Snodgrass et al., 2014). They reported conflicting evidence for the prognostic value of cervical ROM, although restricted ROM appeared to be associated with negative outcomes while greater ROM was associated with positive outcomes (Snodgrass et al., 2014). The measurements in the individual studies were performed with a variety of instruments and there was a general tendency that more accurate measurement instruments made for clinically more useful outcomes. Therefore, it is possible that the conclusions presented in this review might change when more reliable measurement tools become available.

Table 4
Correlation between the change score on the CROM and SCT.

	Pearson correlation SCT and CROM (upper & lower 95%CI)	Spearman correlation SCT and GPE
Total ROM	0.94 (0.92–0.96); $p < 0.001$	−0.18; $p = 0.089$
Flexion	0.93 (0.89–0.95); $p < 0.001$	0.03; $p = 0.806$
Extension	0.92 (0.88–0.95); $p < 0.001$	−0.25; $p = 0.013$*
Rotation left	0.88 (0.82–0.92); $p < 0.001$	−0.14; $p = 0.194$
Rotation right	0.90 (0.85–0.93); $p < 0.001$	−0.12; $p = 0.261$
Lateral flexion left	0.90 (0.85–0.93); $p < 0.001$	−0.18; $p = 0.083$
Lateral flexion right	0.86 (0.80–0.91); $p < 0.001$	−0.04; $p = 0.669$

Abbreviations: ROM: range of motion; CROM: cervical range of motion measurement; SCT: Senscoordination 3D Cervical Trainer; GPE: global perceived effect; *: Correlation is significant at the 0.05 level (2-tailed).

4.1. Future research

Normative values for cervical ROM per decade of life, when measured with the CROM, have been proposed in a recent systematic review (Thoomes-de Graaf et al., 2020). Considering the very high correlation between the SCT and the CROM, these values might be applicable to the SCT also. Nevertheless, further research is warranted to confirm this. Future research should also examine the validity of the neuro-muscular control tests incorporated in the custom software provided by the manufacturer of the SCT.

4.2. Strengths and limitations

One of the strengths of this study is the large number of participants for the baseline measurements (n = 100) and the small loss to follow-up (n = 5). Another strength is the adherence to the GRRAS guidelines when designing and reporting this study to ensure methodological rigor. One minor limitation is that the SCT was attached to the CROM frame slightly above the forehead to ensure simultaneous recording of movement, and this is slightly different to its recommended use, which is with an elastic head band directly on the forehead. However, due to its construction (a 9 degrees of freedom sensor combining signals from a 3-axis accelerometer, a 3-axis gyroscope and a 3-axis magnetometer, translating these 9 separate data points to an orientation vector in *x, y* and *z* coordinates and an angle of rotation around the direction of the vector), it is highly unlikely that the attachment to the CROM device frame affected the measurement of the SCT.

5. Conclusion

The SCT is a valid, reliable, and responsive instrument for measuring cervical ROM and is comparable to the CROM.

Funding

No funding was received for this project.

The Medical Ethic Center in Rotterdam approved the study (MEC-2018–129), the study was registered in the Dutch Trial Register (NTR7463).

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