Statistical Analysis Plan

The effect of a combination of physical training, specific exercises and pain education compared with pain education alone in patients with chronic neck pain: a randomized control trial with a 4-month follow-up

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This is the analysis plan for the multicentre randomised control study looking at the effect of training and exercises in chronic neck pain patients that is being conducted in Jutland and Funen, Denmark. This plan will be used as a work description for the analyses of the data collected.

1. Study introduction

1.1 Synopsis

Most adults experience some form of neck pain during their lifetime. The 12-month prevalence of neck pain is 30% - 50% and for activity-limiting neck pain it is up to 11% (1). In Denmark, 21% of patients referred to primary care physiotherapy have neck pain (2). In comparable countries such as the Netherlands and Sweden, the prevalence of chronic neck pain is 14% (3) and 16% (4). Patients with chronic neck pain often have physical disability, psychological problems and lower quality-of-life.

Specific exercises for patients with chronic neck pain can be effective in reducing pain (5-7) and physical training aimed at improving general physical fitness and reducing fear of movement is recommended (8-10). Danish guidelines recommend pain education as part of the management strategies for chronic pain patients (10). A systematic review indicates that a combination of cognitive behavioural therapy and physiotherapy including neck exercises is effective in the management of patients with chronic neck pain due to trauma (11). Although patient education, exercises and physical fitness training are often used as treatment in daily practice, the combined treatment effect of these modalities is unknown.

1.2 Aim, hypotheses and objectives:

The overall goal of this research focused on a multimodal physiotherapy programme is to improve health-related quality-of-life (HRQoL) of patients with chronic neck pain.

This study tests the hypothesis that patients with chronic neck pain treated with pain education combined with neck exercises and general training (active), will report greater improvement in HRQoL compared with those treated with pain education only (control).

The control group received:
- educational programme focusing on pain education, mindfulness, goal setting, activating participation in social and work-related contexts

The intervention group received the same educational programme as above plus:
- specific progressive exercises programme, focusing on function of the anterior and posterior neck muscles, neuromuscular scapula control, neck-eye coordination, standing balance
- general fitness training based on a graded activity approach

A study protocol has already been published (12). To meet the required sample size of chronic neck pain patients, the inclusion criteria were adjusted after publishing the protocol. Thus, we included patients with chronic neck pain of either traumatic or non-traumatic origin.
2. Outcomes

2.1 Primary outcome
The primary outcome is the change from baseline to the 4-month follow-up in HRQol, measured by Physical Component Score of Short Form 36 (SF36-PCS). According to the protocol, a change of a group mean difference of 5 SF36-PCS points is considered as a minimal clinically important difference (13).

2.2 Secondary outcomes
The secondary outcomes are used to interpret the results from the primary outcome in a clinical and patient perspective. The analyses of these outcomes are supportive, explanatory and/or hypothesis generating, which is why multiple comparisons are not considered a problem (14).

The following secondary outcomes are examined at baseline and 4 months’ follow-up:

**Physical test:**
- a) neck function:
  - cervical range of motion in flexion, extension, rotation and side bending
  - sensorimotor test: gaze stability and eye movement test
  - muscle function: craniocervical flexion test and cervical extensor test
- b) hyperexcitability for pain: pressure pain threshold test bilateral at anterior tibial muscle, infraspinatus muscle and intersegmental level C5/C6
- c) physical fitness: Aastrand one point submaximal cycle test

**Patient-reported outcomes:**
- d) health related quality of life: Short Form 36 Mental Component Score (SF36-MCS), EuroQol (EQ-5D-3L) and EuroQol VAS
- e) physical function:
  - neck pain and function: Neck Disability Index (NDI),
  - patient perceived level of function: Patient Specific Functioning Scale (PSFS)
  - patient perceived level of worrying: Pain Bothersomeness (PB)
- f) psychological factors:
  - kinesiophobia: TAMPA scale of Kinesiophobia (TSK)
  - depression: Beck Depression Inventory-II (BDI)
  - post-traumatic stress: Impact of Event Scale (IES) (for participants with a traumatic onset only)
- g) patient perceived effect of the intervention: Global Perceived Effect (GPE)

2.3 Descriptive outcomes and adherence
The baseline descriptive outcomes have been published earlier (xx).

Adherence to the exercise programme is registered by the treating physiotherapist as number of sessions attended by the participant in the pain education and exercise sessions. For treatment-related variables, adherence is classified in accordance with the following criteria:
- Good (as defined per protocol) adherence for the participants is 75% participation in the treatment sessions. This is obtained with participation in at least 3 of 4 pain education session and 6 of 8 instruction sessions.
• Moderate adherence is defined with 50% - 75% participation (2-3 of 4 pain education sessions and 4-6 of 8 instruction sessions).
• Poor adherence is registered as less than 50% participation in the sessions (0-1 of 4 pain education sessions and 0-3 of 8 instruction sessions).

The participants in the active group register their compliance of home exercise training in a training diary.

3 Design
The study was conducted as a two-group randomised controlled trial. The study was multi-centred, stratified by recruitment location and by onset of neck pain, being traumatic or non-traumatic. The participants were recruited from both primary (eight physiotherapy clinics) and secondary health care (two hospital spine centres, one municipal rehabilitation centre and one hospital outpatient clinic). The recruitment period was March 2012 to September 2014.

The trial was registered in www.ClinicalTrials.gov identifier NCT01431261. The Regional Scientific Ethics Committee of Southern Denmark approved the study (S-20100069). The study conformed to The Declaration of Helsinki 2008 (15) by fulfilling all general ethical recommendations.

3.1 Sample size
The power and sample size calculation was based on the primary outcome, SF36-PCS. For a two-sample pooled t-test of a mean difference with a two-sided significance level of 0.05, assuming a common Standard Deviation of 10, a sample size of 86 per group was required to obtain a power of at least 90% to detect a group mean difference of 5 PCS points (13). To adjust for an estimated 15% withdrawal during the 4-month study period, we included 100 patients in each group.

3.2 Randomisation - allocation - blinding
After the baseline assessment, the participants were randomly assigned to either the active or control group. The randomisation sequence was created using SAS (SAS 9.2 TS level 1 M0) statistical software and stratified by centre with a 1:1 allocation using random block sizes of 2, 4, and 6. The allocation sequence was concealed from the researcher assessing participants in sequentially numbered, opaque, sealed and stapled envelopes. After revealing the content of the envelope, both participants and the treating physiotherapists were aware of the allocation and the corresponding treatment. Outcome assessors and data analysts were kept blinded. Prior to the outcome assessments, the participants were asked by the research assistants not to mention the treatment to which they were allocated.

Prior to breaking the code, the authors of this study will conduct two interpretations of the results on the basis of a blinded review of the data from the primary endpoint (changes from intervention A compared with changes from intervention B), one assuming that A is the active intervention, and the other assuming that B is the active intervention. Not until the authors have agreed that there will be no further changes in the interpretation, will the randomisation code be opened, to ensure that bias in the interpretation is reduced.
3.3 Study population - settings
All participants were recruited via announcements at the local clinic or centre, by their treating physiotherapist or at their first contact with the clinic or centre. The interventions took place at the same clinic / centre as where the participants were recruited.

Participants in primary health care were referred by general practitioners to physiotherapy treatment. The recruitment and interventions in primary care took place in physiotherapy clinics in the middle and eastern part of Jutland, Denmark.

Participants in secondary health care were referred by general practitioners, chiropractors or specialised medical doctors to the involved centres. The recruitment and interventions in secondary care took place in outpatient clinics in southern Jutland and on Funen: Spine Centre of Southern Denmark Hospital Lillebælt, Spine Centre of Regional Hospital Silkeborg, Rehabilitation Centre of the Odense Municipality, and Neurological Outpatient Clinic at Hospital of Southwest Jutland. Both spine centres and the rehabilitation centre of Odense Municipality are specialised in treating patients with musculoskeletal dysfunctions. The neurological outpatient clinic is specialised in treating neurological patients and headache patients.

Inclusion criteria were minimum age of 18 years; neck pain for at least 6 months with either traumatic or non-traumatic onset; reduced neck function reduced as determined by a score of at least 10 on the Neck Disability Index; diagnostic procedures completed (e.g. medical investigations, diagnostic imaging); ability to read and understand Danish and to participate in the exercise programme. Participants could have pain from other body regions as long as the primary pain area was situated in the neck region. Exclusion criteria were neuropathies/ radiculopathies (clinically tested by: positive Spurling test; relief on cervical traction and positive plexus brachialis tests on the affected side)(16); ongoing experimental or progressive medical treatment; unstable social and/or working conditions; pregnancy; known current fractures; depression as determined by a Beck Depression Index score > 29, or other known co-existing medical conditions that could restrict participation in the exercise programme.

The classification ‘traumatic’ versus ‘non-traumatic’ was based upon the participants’ self-reported cause of their neck pain as traumatic or not. Trauma could relate to a traffic accident or any other physically traumatic event.

Figure 1 will be used as the flow diagram of the study.

3.4 Procedures
Participants were tested by two different assessors at five different locations on Funen and in Jutland. The physical tests were performed in the same order for all participants, starting with the least physically demanding test. The self-reported questionnaires were completed during the same test session, after the physical tests but before performing the physical fitness test. Before enrolling in the study, the participants signed an informed consent form.

4. Analysis
The effect of the intervention is determined as between-group difference in change in the primary outcome SF36-PCS from baseline to the 4-month follow-up. The secondary outcomes are between group
differences in neck function, sensorimotor function, hyperexcitability for pain, physical fitness, HRQol, self-reported physical functioning, psychological factors and global patient perceived effect of the intervention allowing for in-depth interpretation.

All statistical analyses will be performed on the basis of the intention-to-treat principle, e.g. participants will be analysed in the intervention group to which they were randomly allocated. In the primary analyses, missing data will be replaced by ‘Baseline Observation Carried Forward’ (BOCF) technique. Secondly, to relate the results to adherence, a per protocol analysis will also be performed. The per protocol population is defined as the participants who have completed the intervention to which they were allocated, according to the principles described in section 2.3.

All analyses will be checked for normality by visual inspection of histograms and a test for unequal variance between groups. To determine any differences in the demographic and baseline outcome values between the two groups, we will construct the appropriate point estimate (i.e., mean, median or proportion) with its 95% C.I. Multilevel modelling will be performed for all continuous data to determine if there are any differences between the two groups for the outcome variables after adjusting for baseline variables that were found to be unbalanced (Table 3). Logistic regression analyses will be used for binary variables to calculate Odds Ratio (Table 4). Ordinal regression analyse will be used for nominal and ordinal variables (Table 5). All the analyses will be performed using the Statistical Package for Social Sciences (version 22.0.0, IBM, USA)

4.5 Discontinued the interventions
Withdrawals and the reason for their withdrawal (if identified) will be registered by the leading project physiotherapist.

4.6 Dropouts
Dropouts are defined as those who were not assessed at the 4-month follow up. All dropout participants are included in the ITT analysis with baseline observation carried forward procedure.

5. Implementation of Analysis Plan
All analyses will be performed by the same statistician and independently be repeated by the principal investigator. Differences between the analyses will be discussed and uncertainties clarified.

The following procedure will be followed:

1. A database model will be lined up in collaboration between the statistician (EB) and principal investigator (IR). This model must be approved by the supervisors of the study (BJK and KS).
2. The database manager (IR) will code each treatment arm into ‘group treatment A’ and ‘group treatment B’ but will not be aware of the status (active or control) of the groups.
3. Blinded data will be delivered to the statistician (EB) according to the data base model.
4. Primary and secondary analyses will be conducted blinded from allocation to treatment arm.
5. Results will be presented to the co-authors of the manuscript. The authors will agree upon two interpretations based on the analysis of the primary outcome data: one assuming that group A will be the active group, and the other assuming that B will be the active group. The two interpretations will be
discussed and consensus will be reached regarding clinical interpretation of the results. On agreement, all members of the author group will approve and sign the interpretations (17).

References

13.Carreon LY, Glassman SD, Campbell MJ, Anderson PA. Neck Disability Index, short
form-36 physical component summary, and pain scales for neck and arm pain: the
minimum clinically important difference and substantial clinical benefit after cervical
14.The European Agency for the Evaluation of Medicinal Products C. Points to consider
on multiplicity issues in clinical trials. EMEA. 2002.
15.World Medical A. World Medical Association Declaration of Helsinki: ethical
of the diagnostic accuracy of provocative tests of the neck for diagnosing cervical
Blinded interpretation of study results can feasibly and effectively diminish
Figures

Figure 1 Flow chart of the participants

Inclusion, baseline assessment

Excluded (n= )
- Not meeting inclusion criteria (n= )
- Declined to participate (n= )
- Other reasons (n= )

Randomized (n= )

Allocation

Pain education (n= )
- Received allocated intervention (n= )
- Did not receive allocated intervention (give reasons) (n= )

Pain education, training and exercises (n= )
- Received allocated intervention (n= )
- Did not receive allocated intervention (give reasons) (n= )

Follow-Up

Lost to follow-up (n= )
Discontinued intervention (give reasons) (n= )

Lost to follow-up (n= )
Discontinued intervention (give reasons) (n= )

Analysis

Analysed at 4-month follow up (n= )
- Excluded from analysis (n= )

Analysed at 4-month follow up (n= )
- Excluded from analysis (n= )

Figure 2 SF36-PCS

SF36 - PCS before and after treatment

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### Tables

#### Table 1 Baseline characteristics

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Active (n)</th>
<th>Control (n)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
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<tr>
<td>Male/female (%, 95% C.I.)</td>
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<tr>
<td><strong>Age</strong></td>
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<tr>
<td>Mean age in years (95% C.I.)</td>
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<tr>
<td><strong>Duration symptoms</strong></td>
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<tr>
<td>Mean in month (95% C.I.)</td>
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<tr>
<td><strong>Education level n (%)</strong>, 95% C.I.)</td>
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<td></td>
</tr>
<tr>
<td>Unskilled or no education</td>
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<tr>
<td>Skilled</td>
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<tr>
<td>Academic</td>
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<tr>
<td><strong>Working situation n (%)</strong>, 95% C.I.)</td>
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<tr>
<td>Unemployed</td>
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<tr>
<td>Working part time</td>
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<tr>
<td>Working full time</td>
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<tr>
<td>Retired</td>
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<tr>
<td>Early retirement</td>
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<tr>
<td>Sick leave</td>
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<td>Under education</td>
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<tr>
<td><strong>Sleep disturbances</strong></td>
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<tr>
<td>Sleeping undisturbed</td>
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<tr>
<td>Disturbed ≤ 3x per night</td>
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<tr>
<td>Disturbed &gt; 3x per night</td>
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</table>

N = number, C.I. = Confidence Interval; p < 0.01

#### Table 2 Treatment-related compliance

<table>
<thead>
<tr>
<th>Adherence /compliance</th>
<th>Active</th>
<th>Control</th>
<th>p-value</th>
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</thead>
<tbody>
<tr>
<td>Adherence participating in educational sessions (%)</td>
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<tr>
<td>Adherence participating in training/exercise sessions (%)</td>
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<tr>
<td>Compliance training/exercises at home (%)</td>
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</tbody>
</table>

N = number, C.I. = Confidence Interval
Table 3 Results Questionnaires and Physical Fitness, Cervical Range of Motion and Pressure Pain Threshold Test

SF36-PCS = Short Form 36 Physical Component Sum; SF36-MCS = Short Form 36 Mental Component Sum; EQ-5D = EuroQol-5 dimensions; NDI = Neck Disability Index; BDI-II = Beck Depression Inventory – II; PB = Pain Bothosomeness; PSFS = Patient Specific Functioning Scale; TSK = Tampa Scale of Kinesiophobia; Phys. Fitn. = Physical Fitness; Cerv.Fl = Cervical Flexion; Cerv.Ex = Cervical Extension; Cerv.RotL = Cervical Rotation Left; Cerv.RotR = Cervical Rotation Right; Cerv.SBL = Cervical Sidebending Left; Cerv.SBR = Cervical Sidebending Right; PPT TAR = Pressure Pain Threshold Tibialis Anterior Right; PPT TAL = Pressure Pain Threshold Tibialis Anterior Left; PPT ISR = Pressure Pain Threshold Infraspinatus Right; PPT ISL = Pressure Pain Threshold Infraspinatus Left; PPT CvR = Pressure Pain Threshold Cervical Right; PPT CvL = Pressure Pain Threshold Cervical Left;

<table>
<thead>
<tr>
<th>Variable</th>
<th>Active improvement Mean (SD)</th>
<th>Control improvement Mean (SD)</th>
<th>Between groups difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF36-PCS</td>
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<tr>
<td>SF36-MCS</td>
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<tr>
<td>EQ-5D</td>
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<tr>
<td>NDI</td>
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<tr>
<td>BDI-II</td>
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<tr>
<td>PB</td>
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<td>PSFS</td>
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<tr>
<td>TSK</td>
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<tr>
<td>PhysFit VO₂ ml/kg/min</td>
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<tr>
<td>Range of Motion Degrees</td>
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<td></td>
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<tr>
<td>Cerv.Fl</td>
<td></td>
<td></td>
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<tr>
<td>Cerv.Ex</td>
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<tr>
<td>Cerv.RotL</td>
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<tr>
<td>Cerv.RotR</td>
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<tr>
<td>Cerv.SBL</td>
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<tr>
<td>Cerv.SBR</td>
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<tr>
<td>Pressure Pain Threshold Kgf</td>
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<td>PPT TAR</td>
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<td>PPT TAL</td>
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<td>PPT ISR</td>
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<td>PPT CvR</td>
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<td>PPT CvL</td>
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### Table 4 Results Gaze Stability and Eye Movement Test

<table>
<thead>
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<th>Variable</th>
<th>Odds Ratio Active</th>
<th>Odds Ratio Control</th>
<th>p-value</th>
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<tbody>
<tr>
<td><strong>Gaze Stability</strong></td>
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<tr>
<td>GS L</td>
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<tr>
<td>GS R</td>
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<td></td>
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<td>GS F</td>
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<td></td>
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<tr>
<td>GS E</td>
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<tr>
<td><strong>Eye Movement Test</strong></td>
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<tr>
<td>EMT</td>
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<tr>
<td>EMT R</td>
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<tr>
<td>EMT L</td>
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</tbody>
</table>

GS L = Gaze Stability Left; GS R = Gaze Stability Right; GS F = Gaze Stability Flexion; GS E = Gaze Stability Extension; EMT= Eye Movement Test; EMT R= Eye Movement Test Right rotation; EMT L= Eye Movement Test Left Rotation;

### Table 5 Results Cranio Cervical Flexion Test and Cervical Extension Test

<table>
<thead>
<tr>
<th>Variable</th>
<th>Active improvement</th>
<th>Control improvement</th>
<th>Between group differences</th>
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<tr>
<td><strong>Cranio Cerv. Fl. Pressure</strong></td>
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<tr>
<td>CCFT 22 mmHg</td>
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<tr>
<td>CCFT 24 mmHg</td>
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<tr>
<td>CCFT 26-30 mmHg</td>
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<tr>
<td><strong>Cervical Ext. Duration</strong></td>
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<tr>
<td>CE 0-10 sec</td>
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<tr>
<td>CE 11-28 sec</td>
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<tr>
<td>CE 39-119 sec</td>
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<tr>
<td>CE 120 sec</td>
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CCFT= Cranio Cervical Flexion Test; CE= Cervical Extension Test;