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INfORM
International Network for Orofacial Pain and Related Disorders Methodology
A Consortium Focused On Clinical Translation Research

GUIDELINES FOR

DC/TMD Examiner Training and Reliability Assessment

DC/TMD EXAMINER TRAINING AND RELIABILITY COMMITTEE

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CONTENT

Training

The typical training course comprises:

i. Understanding and mastering DC/TMD, Axis I and Axis II assessment and procedures (6 h)
ii. Clinical training with the Reference Standard Examiner or Protocol Supervisor serving as the model, who gives detailed individual feedback during and after the examination (2 h)
iii. Clinical training on other participants while monitored by the Reference Standard Examiner or Protocol Supervisor, who gives detailed individual feedback after the examination (2 h)
iv. Practice in deriving diagnoses from paper cases with the use of the DC/TMD decision tree and diagnosis definitions (2 h)

Participants

Models

The individuals who are being examined.

Examiners

The individuals who perform examinations on the models, and there are two types: ”Clinical examiner” is the individual whose performance is being evaluated and trained and ”Reference standard examiner” is the standard against which each clinical examiner is compared.

Recorder

The individual who takes dictation from the examiner during the procedures and transfers the findings to the recording form.

Reference Standard Examiner

Highly trained and calibrated individual who has demonstrated reliability assessment(s) in the identified language(s) as well as being determined by a Protocol Supervisor to possess the adequate skills and knowledge to function as a Reference Standard Examiner, accredited by and affiliated with a DC/TMD Training and Calibration Center.

Protocol Supervisor

Reference Standard Examiner plus the abilities to manage, lead and conduct a training and calibration course as described below as well as to organize, monitor and supervise a reliability assessment session according to these guidelines. The Protocol Supervisor also observes overall exercise quality and performance quality by each examiner and has to be accredited by and affiliated with a DC/TMD Training and Calibration Center.

Calibration

Models (those with or without the disorders of interest) are generally included for at least part of this stage, and models will typically participate for 2 (or more) hours during which examiners rotate in pairs, with one Reference Standard Examiner or Protocol Supervisor in attendance providing feedback and correction. The Reference Standard Examiner or Protocol Supervisor gives detailed individual feedback after the examination. In addition, feedback from the patients and recorders is forwarded to the examiners after the examination (2 h or more).

Reliability assessment

MODEL RECRUITMENT

Sample size

Number of models to be recruited will depend on number of examiners participating in a given calibration and reliability assessment. The typical design utilizes three clinical examiners and one Reference Standard Examiner, with 16 models, allocated as four models per each of four blocks.

i. A maximum of four examinations is performed on a given model, based on experience that mental fatigue and physiological sensitization for the model become noticeable after four examinations.
ii. Therefore, with three clinical examiners and one Reference Standard Examiner, there are 16 pair-wise comparisons between each clinical examiner and the Reference Standard Examiner; these comparisons require four blocks.

Selection criteria

Inclusion criteria can vary across reliability exercises, depending on which clinical attributes are of interest. For example, the specific requirement for the presence of TMJ noises among part of the model sample is the most common attribute that can influence inclusion criteria.

The typical inclusion criteria for the DC/TMD reliability assessment include, for cases, pain in the facial area of at least five days in the prior 30 days and pain that has persisted for at least 3 (or 6) months; for non-cases, the only inclusion criterion is no facial pain over the prior 3 (or 6) months. This threshold of five for the number of days of pain could be raised, if more severe cases are desired (for example, because more positive findings during the exam are deemed useful, or because the reliability study needs to better map to a chronic pain sample) or it could be lowered, if less severe cases were desired (for example, because the study is evaluating new onset TMD or to make the determination of a case vs control more difficult during the particular exercise).

An additional inclusion criterion is usually age 18 or greater; there is no upper limit on age.

Exclusion criteria for all exercises are insufficient verbal fluency in the host language (e.g., English for a study conducted in that language), and inability to tolerate multiple examinations.

Pregnancy is not an absolute exclusion, but individuals are carefully questioned regarding comfort with sitting for two hours and repeated pain experience during the examination; the latter is more important for cases, in that non-cases typically experience no pain during an examination.

Recruitment ratios

The ratio of cases vs non-cases should range from 1:1 to no more than 2:1; non-cases to cases could also vary up to 2:1. Experienced models vs naïve models should be recruited at approximately 1:1 ratio. An “experienced” model refers to someone with prior participation in a reliability exercise and judged to be a good reporter of the examination procedures; such individuals provide critical feedback regarding examiner performance. A “naïve” model refers to someone who has never participated in one of our TMD examination reliability exercises. Experience vs naïve and cases vs non-cases should be balanced as much as possible – for example, an equal number of naïve and an equal number of experienced cases.

Assignment to blocks

Models should be balanced by case vs non-case status across blocks, to the degree possible within scheduling limitations. There is no requirement for specific assignment of experienced vs naïve models to blocks. Assignment to blocks may be influenced by availability of the model, and hence these are only guidelines.

DESIGN

Block design

The basic reliability exercise will use four blocks with each clinical examiner participating in each block. An alternative design utilizes 4 (or more) blocks, with 4 clinical examiners and 1 reference standard examiner participating in the reliability assessment; in each of the 4 core blocks, one clinical examiner does not participate and instead serves as a recorder, in order to not exceed 4 examinations per block as well as to provide peer evaluation by each of the clinical examiners. This type of design is often preceded and followed by an additional block (total: 6 blocks), during which only the clinical examiners participate, allowing the reference standard examiner to observe each of the clinical examiners before and after the central 4 blocks.

Length of block

The duration of a block will typically be about 2 h. The typical block utilizes the following structure:

i. Seating models and explaining procedures (5 mins)
ii. Examination period (20 mins) x 4
iii. Rest period between each of examinations 1-3 (10 mins)
iv. Debrief (of models and recorders), dismissal, and compensation (5 mins)

General omission of examination procedures

The Protocol Supervisor may elect for a given reliability assessment that specific procedures be omitted from all examinations.

Modifications of protocol

Models may request that any examination procedure be omitted for any reason. Models may request ice or analgesics during the exercise, typically used during the rest period. Examiners can make the determination to not do a particular procedure if judgment indicates the model is experiencing too much pain. This particular decision is typically made in collaboration with the model and the study monitor can be consulted as well.

Recorders and responsibilities

One recorder will be assigned to each examination room. Recorders will typically remain with the models, thereby providing a constant observer across examinations by each of the examiners. Recorders will prompt examiners as needed for next procedure, and recorders will stop the examination as necessary in order to ensure that all data are being recorded correctly on the examination form.

Examiner responsibilities

Examiners may ask for prompts for next procedure, will dictate findings in manner agreed to by the full exercise team at the outset of the reliability exercise, will review recorded findings on the examination form immediately following the examination in order to insure correctness with what was obtained and dictated, and will provide a case classification. Examiners may consult with the exercise monitor during the exercise.

The Protocol Supervisor will observe each clinical examiner, may provide corrective guidance to examiners after a given examination is completed and recorded, monitors the examination forms for completeness, and makes final qualitative determination regarding performance level of each examiner.

ANALYSIS

Primary dependent variable

Case classification is the primary variable of interest. Upon completion of the study, the case classification should be entered into a database/Excel sheet for immediate analysis. The examination forms must be reviewed, cleaned and copied for later entry into a full dataset for subsequent complete analysis, if needed.

Reliability statistics

The primary statistic for assessing performance (i.e., case classification) is Kappa. The Kappa statistic is augmented by percent agreement for interpretive purposes. ICC is used for dimensional variables (e.g., extent of opening; number of painful muscles).

Comparisons of interest include pair-wise between each clinical examiner and the Reference Standard Examiner and an overall Kappa for all examinations. If a six-block design is used, note that it is unbalanced, and the Kappa program must be able to accomodate missing data.

Training and Calibration Levels

The purposes of the DC/TMD training and calibration levels are to:

1. Promote use of DC/TMD for clinical application in general practice
2. Provide structured training and calibration guidelines for high-level clinical and research applications of DC/TMD
3. Provide structured procedures to ensure diagnostic reliability in languages other than English.

Level 1: Self-instruction

This level should provide a diagnostic reliability that is sufficient for clinical work.

The training comprises:

- Downloading DC/TMD documentation, teaching material and instruction movie(s)

- Reviewing all the material in order to learn the DC/TMD by him/herself

Vilanova et al. showed that self-instruction using documentation and an instruction movie gives similar diagnostic reliability to that of a formal two-day training and calibration course for myalgia, arthralgia, degenerative joint disease, disc displacement with reduction and headache attributed to TMD (Vilanova et al., J Headache Pain, 2015).

To assist self-instruction, a training course, seminar or similar given by an individual who previously is calibrated on at least Level 2 could be considered.

Level 2: Calibration course
Training and calibration course given by an official Reference Standard Examiner or Protocol Supervisor

This level should provide a diagnostic reliability sufficient for clinical work and participation in clinical research. This level comprises training and calibration as described above.

Level 3: Calibration and reliability assessment
Training and calibration course as well as reliability assessment by an official Reference Standard Examiner and a Protocol Supervisor
This level should provide a diagnostic reliability for clinical work and clinical research with individually established levels of agreement with the Reference Standard Examiner that can be published to strengthen the methodological aspects.

This level comprises training, calibration and reliability assessment as described above.

Consortium DC/TMD Training Center requirements

Each Center needs to strictly follow the Consortium Network guidelines for training, calibration and reliability assessment.

Requirements

1. The Center must have at least one affiliated Reference Standard Examiner and one affiliated Protocol Supervisor calibrated regarding DC/TMD in the language to be used.

2. The Protocol Supervisor-to-be has to attend and closely follow an recognized Protocol Supervisor at a training and calibration course as well as during a reliability assessment at an established DC/TMD Training and Calibration Center. To be recognized by the established DC/TMD Training and Calibration Center as a Protocol Supervisor, the Protocol Supervisor-to-be has to demonstrate knowledge and skills sufficient to fulfill the requirements of a Protocol Supervisor (see above). It is up to the established DC/TMD Training and Calibration Center to determine whether the Protocol Supervisor-to-be fulfill these requirements.

5. The DC/TMD Training and Calibration Center must provide self- instruction material (documentation, forms, instructional videos, etc, as needed) in the local language to be published on the Consortium Network website. This material must be free for everyone to access.

6. Representatives from each DC/TMD Training and Calibration Center must be prepared to participate in calibrations between the active Centers.

7. DC/TMD courses given by the Center must be given on a non-profit basis in order to be recognized and authorized by the International RDC/TMD Consortium Network. Fees that cover the costs of conducting training exercises are appropriate.

Consortium DC/TMD Training Centers (Dec 2018)

Center	Affiliation	Affiliated individuals
Malmö, Sweden	Malmö University Orofacial Pain and Jaw Function Malmö, Sweden	Per Alstergren Thomas List Malin Ernberg Julia Lam
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Oulo, Finland	University of Oulo Oulo, Finland	Kirsi Siliplä Tuija Suvinen Tuija Teerijoki-Oksa Ritva Näpänkangas
Umeå, Sweden	Umeå University Clinical Oral Physiology Umeå, Sweden	Catharina Österlund Anna Lövgren Aurelija Ilgunas
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Protocol Supervisors

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