Protocol

Clinical feasibility and interpretability of the Dynamic weight-bearing assessment of pain (DAP) in knee osteoarthritis

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1 Introduction

Every year knee osteoarthritis (OA) causes 60,000 Danes to contact the health care system with complaints of pain and functional limitations which affect their everyday lives including work, leisure and social relations[1]. Physiotherapeutic exercise is universally recommended as a primary treatment for knee OA[2,3]. As providers of evidence based treatment physiotherapists also have a responsibility for ensuring the quality of this treatment. An important demand is that treatment should be individualized[4]. This is only possible with adequate monitoring before, during and after the treatment period in order to evaluate the treatment progression and effect[3]. However, the implementation of outcome measures in physiotherapy practice has been claimed not to be satisfactory [5,6]. Also, adequate monitoring requires instruments that meet the quality demands of psychometric properties such as feasibility in clinical practice, validity, reproducibility, sensitivity[7]. Further, information about interpretability is required in order to meaningfully use the instrument for monitoring treatment and evaluating effect. Such an instrument is not readily available [5,8-13].

Patient Reported Outcome Measures (PROMs) are the predominant assessment instruments in the guidelines[2,3], though Performance Measures (PMs) are recommended for evaluation of the ICF component of Body functions and structure[3]. This is in line with research showing that PROMs and PMs yield different results measuring the same construct[14-19]; questionnaires presumably include a more broad life experience[20] whereas performance measures may be more focused on the physical body function[21]. One study found that a performance measure (the Short Physical Performance Battery, SPPB) was associated with age and physiologic factors (e.g. strength and aerobic capacity), whereas a PROM (Late-Life Function and Disability Instrument, LLFDI) was associated with these factors as well as with psychosocial and health factors, in community-dwelling older adults with mobility limitations [22].

As pain in knee OA is often aggravated by weight-bearing movements, a PM with integrated pain evaluation may contribute with valuable information on this interaction, and potential changes after treatment. In fact, some researchers suggest that pain measures in knee OA should always include either performance of pain provoking activities, or questions about pain during these activities[23].

We developed the Dynamic weight-bearing Assessment of Pain (DAP), a performance measure with integrated pain evaluation. The DAP is based on input from both patients and health professionals, ensuring the content validity and clinical relevance of the performance in the test (weight-bearing knee bends)[24]. Acceptable reproducibility of the DAP has been established in a population of people with mild knee OA[25], but other psychometric properties remain to be tested, including feasibility and interpretability in a clinical setting.

1.1 Objectives

There are two objectives to this study;

1) to evaluate the feasibility of the DAP for patients with knee OA in clinical physiotherapy practice
2) to investigate the interpretability of the DAP for patients with knee OA in clinical physiotherapy practice by estimating a cut-off score for a minimum clinically important change.

2 Materials and method

2.1 Material

Physiotherapists treating patients with knee OA are recruited through physiotherapy clinics in Denmark. The inclusion criteria are: providing treatment to patients with knee OA, informed consent to participate. There are no exclusion criteria.

Patients with knee OA receiving physiotherapy are recruited through participating physiotherapists during a period of three months. The inclusion criteria are: receiving treatment for knee OA, informed consent to participate. There are no exclusion criteria.

2.2 Sample size considerations

There are no standards for required sample size in feasibility and interpretability studies. We anticipate including 20 physiotherapists with an expected load of minimum 5 patients each, summing to a minimum of 100 patients.

2.3 Study design

At inclusion the physiotherapists are introduced to the DAP through a written manual, and instructed to rehearse the test before inclusion of patients. For a period of three months the physiotherapists use the DAP to monitor all participating patients who are starting treatment. We anticipate a standard exercise treatment period of six weeks, allowing for two weeks less or more. The treatment can be either individual, in groups or home-based. All assessments are recorded by the participants (physiotherapists or patients).

2.4 Baseline characteristics

The following information is recorded for each patient at baseline:

- content of the PT intervention (described by the treating physiotherapist in free text)
- length (weeks) of the PT intervention (reported by the treating physiotherapist)
- age (patient reported)
- gender
- height (patient reported)
- weight (patient reported)
- symptom duration (years) (patient reported)
- pain besides the knee pain (patient reported)
- baseline knee pain (NRS) (patient reported)
- baseline function (NRS) (patient reported)
- baseline general impact of knee OA (NRS) (patient reported)

2.5 Outcome measures - feasibility

The feasibility of the DAP is evaluated by the physiotherapists and patients at end of treatment.

2.5.1 Questionnaire - physiotherapists

For the physiotherapists a simple questionnaire with five items is applied, concerning the applicability of the DAP in clinical practice. The questionnaire has been developed for use in this study. The items are;

1. "How do you experience the time consumption by using the DAP?"
2. "How do you experience the difficulty by using the DAP?"
3. "How do you experience use of the DAP for monitoring the treatment?"
4. "How do you experience the motivational effect by using the DAP?"
5. "How do you experience use of the DAP as a part of the physiotherapeutic treatment?"

There are four response options; very acceptable, acceptable, unacceptable, very unacceptable. Additional comments are encouraged.

2.5.2 Questionnaire - patients

For the patients a simple questionnaire with one item is applied; "How do you experience the use of DAP as part of the physiotherapeutic treatment?" There are four response options; very acceptable, acceptable, unacceptable, very unacceptable. Additional comments are encouraged.

2.6 Analysis - feasibility

All analyses will be carried out using SAS software (V9.3; SAS Institute Inc, Cary, North Carolina, USA). Responses from physiotherapists and patients will be evaluated using descriptive statistics. As there are no defined criteria for acceptable levels for user satisfaction, our cut-offs are based on a guideline for Consensus processes using simple majority, i.e. 51%[26]. We conservatively decided that to conclude that the DAP is feasible in physiotherapy practice, the lower confidence limit of the proportion answer 'acceptable' or 'very acceptable' to the question: "How do you experience use of the DAP as a part of the physiotherapeutic treatment?" should be at least 51% for both physiotherapists and patients, respectively. The remaining questions in the physiotherapy questionnaire and the additional comments are used to evaluate areas for possible adjustment and improvement of the DAP.

2.7 Outcome measures - interpretability

Two outcome measurement instruments will be used to investigate the interpretability; the DAP and TRANS-Q. The DAP is used at baseline and at end of treatment, and at all treatment sessions; no more than once a week however. The TRANS-Q will be applied at end of treatment.

2.7.1 The DAP

The DAP is a simple performance test with an integrated pain score, designed to provide useful information for monitoring treatment progress and evaluating treatment effects in clinical physiotherapy practice. The patient is asked to perform as many standing knee bends as possible within 30 seconds. The knees should reach approximately 80 degrees of flexion and full extension for each knee bend. This is supervised by the rater. There are two scores in the test: 1) number of knee bends during the 30 seconds; 2) pain during knee bends on a Numeric Rating Scale (NRS) from 0 to 10 (0=no pain, 10=worst pain imaginable). The DAP takes about 2 minutes to perform including instructions and

does not require any equipment besides a stopwatch/watch. The number of knee bends are used for motivational purposes while the pain ratings are a measure for pain during a specified weight bearing function.

2.7.2 TRANS-Q

An internal anchor-based approach is used to guide the interpretation of the DAP, by using a transition rating (TRANS-Q) to determine the patient reported change in symptoms[27]. The TRANS-Q is a simple 3-item questionnaire (pain, function and overall), with the question: How do you feel in relation to your pain/function/general well-being now, compared to before you started treatment? The response options are: no change, worse, or better. If patients answer worse or better, they are asked about the degree of change on a seven-point Likert scale: almost the same, hardly any worse/better at all; a little worse/better; somewhat worse/better; moderately worse/better; a good deal worse/better; a great deal worse/better; much worse/better.

2.8 Analysis - interpretability

All analyses will be carried out using SAS software (V9.3; SAS Institute Inc., Cary, North Carolina, USA). Results from the DAP, TRANS-Q and the simple questionnaire are displayed using descriptive statistics. The interpretability of the DAP is evaluated by comparing the DAP scores with TRANS-Q; the distributions of DAP scores (both pain and knee bends) within the three TRANS-Q response categories are used to estimate the cut-off score for clinically relevant change, expressed as Minimal Important Change (MIC). The MIC is determined using an anchor-based method, with scores of TRANS-Q as the external criterion. TRANS-Q scores are trichotomized based on the distribution of data. An example of conservative cut-offs is shown in the table below. The MIC of the DAP pain score is defined as the optimal cut-off point on a Receiver Operating Characteristic (ROC) curve, i.e. the value for which the sum of misclassifications ([1 – sensitivity] + [1 – specificity]) is smallest.[7] The 95% limit cut-off point is calculated as mean change + 1.645 * SDchange of the not importantly changed group.[7]

Response	Trichotomized response
-7. A very great deal worse -6. A great deal worse -5. A good deal worse -4. Moderately worse -3. Somewhat worse -2. A little worse -1. Almost the same, hardly any worse at all	Worsening
0. The same 1. Almost the same, hardly any better at all 2. A little better 3. Somewhat better	No change
4. Moderately better 5. A good deal better 6. A great deal better 7. A very great deal better	Improvement

3 Study sites

The project goes out from the Parker Institute, dept. of Rheumatology, Copenhagen University Hospital Frederiksberg, Denmark. The testing of the DAP for evaluation of feasibility and interpretability takes place at different physiotherapy clinics in Denmark.

4 Ethical considerations

All applied assessment methods are non-invasive, and does not involve any predictable risks. The participants will go through activities which are expected to provoke pain. However, as the pain intensity is not expected to exceed the habitual level of pain during daily activities, the method is not considered to involve any ethical issues. Participants (both patients and physiotherapists) must give informed consent before enrolling in the project. This implies verbal and written information about the objective of the project, and possible risks and advantages during the course of the project, and the right to withdraw from the project at any time without consequences for any further contact with Copenhagen University Hospital Frederiksberg or any of the members in the research team. A copy of the consent is given to the participant. Approval from the health Research Ethics Committee is not necessary as this is neither an intervention study nor a medical device test, and as such is not considered a health research study.

5 Publication of results

The results will be published in an international journal with peer-review, as well as in relevant professional fora. Authorship follows the rules outlined by ICMJE.

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7 Contributions

LK is the principal investigator. LK, MH, EW and HB participated in the design of the study and drafting of the protocol. All authors have given final approval for the protocol.

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9 Competing interests

None.

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