Construct and content validity of the Dutch translation of the Western Ontario Meniscal Evaluation Tool (WOMET) for evaluating meniscal pathology specific health related quality of life for patients in the Dutch population

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25439

Source
Nationaal Trial Register

Health condition

Lacking a Dutch meniscal specific instrument, the WOMET was translated and validated for the use in a Dutch population.

Sponsors and support

Primary sponsor: sponsor = initiator
Source(s) of monetary or material Support: fund = initiator

Intervention

Outcome measures

Primary outcome

Internal consistency, test-retest reliability, floor and ceiling effects, criterion validity, construct validity, sensitivity and specificity.

Secondary outcome

Smallest detectable change (SDC) and minimal important change (MIC)

Study description

Background summary

A validated instrument for the evaluation of meniscal problems was not yet available for the Dutch population. The Knee Injury and Osteoarthritis Outcome Score (KOOS) and the International Knee Documentation Committee (IKDC) Subjective Knee Evaluation Form had both been validated for patients with meniscal pathology, but neither of them was considered specific enough to evaluate health related quality of life in patients with primarily meniscal pathology. The Western Ontario Meniscal Evaluation Tool (WOMET) is currently the best suitable measurement instrument to measure symptoms most relevant to patients with meniscal pathology. The WOMET had already been validated for use in the Canadian population, but not yet for the Dutch population. The WOMET consists of 16 questions specifically designed to measure health related quality of life in patients with meniscal pathology. A questionnaire cannot directly be applied in every population as it is developed in a specific language for a specific group of people. In order to be applicable in other populations, it needs to be translated, and its measurement properties (reliability, validity and responsiveness have to be assessed for the target population. Lacking a suitable meniscal specific questionnaire, we validated the WOMET questionnaire in the Dutch population.

The WOMET was translated according to a forward-backward translation protocol into Dutch. This version was then presented to a focus group, consisting of seven patients with meniscal pathology, for feedback on the clarity, content and relevance of the questions. The final version was then composed.

Patients who had a symptomatic meniscal lesion, confirmed by MRI-scan were included committing the inclusion criteria. All included patients had to complete three different sets of questionnaires at three different moments: T0 (baseline), T1 (2-4 weeks after T0) and T2 (3 months after treatment). All sets contained the WOMET, KOOS and IKDC questionnaires.

Distribution of participant characteristics and questionnaire scores were checked for normality using the Shapiro Wilk test. Mann-Whitney U-tests were used for comparing

participant characteristics age, gender, general health and activity level between patient and control groups. Discriminative abilities were determined by comparing WOMET total, subscale and individual question scores, and KOOS and IKDC Subjective Knee Evaluation Form total and subscale scores between the patient and control groups using Mann-Whitney U-tests. Pearson's correlation coefficients were calculated to determine correlation between the WOMET, KOOS and IKDC forms total and subscale scores. Floor and ceiling effects of the WOMET were assessed by calculating the percentage of patients and controls with a maximum or minimum score for WOMET total, subscale and individual question scores. When analyzing data for the WOMET, IKDC subjective knee and Current Health Assessment Forms, participant total scores could be calculated if at least 90% of the questions was answered. Non answered questions were completed by filling in the average score of the items that have been answered. For the KOOS subscales, scores could be calculated when at least 50 per cent of the questions per subscale were completed. All analyses were performed using Statistical Package for the Social Sciences (SPSS) and all results were presented in tables.

Study objective

WOMET is has acceptable internal consistency, test-retest reliability, floor and ceiling effects, criterion validity, and construct validity. The WOMET is expected to be responsive to change.

Study design

T0 = baseline

T1 = 2 to 4 weeks after T1

T2 = > months after start treatment

Intervention

Questionsaires. WOMET, KOOS and IKDC questionnaires at three different moments: T0 (baseline), T1 (2-4 weeks after T0) and T2 (>3 months after treatment). The first set of questionnaires (T0) also contained a Tegner Activity Level Form. The second set (T1) had an anchor question about remembrance. The last set contained the anchor question about remembrance and an anchor question about symptoms (T2).

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Eligibility criteria

Inclusion criteria

Patients could be included if they were diagnosed with a symptomatic meniscal tear, confirmed by MRI-scan, and if they were between 18 and 70 years of age.

Controls for this study were eligible to participate if they were aged 18-70 years. They were excluded if they had significant knee problems, or were not able to read or understand the Dutch language.

Exclusion criteria

Patients were excluded if they had ligamental injuries with persistent knee-instability, or chondropathy higher than grade 2 on the Outerbridge scale.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2013
Enrollment:	160
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-11-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4722
NTR-old	NTR4867
Other	: METC 13-058

Study results